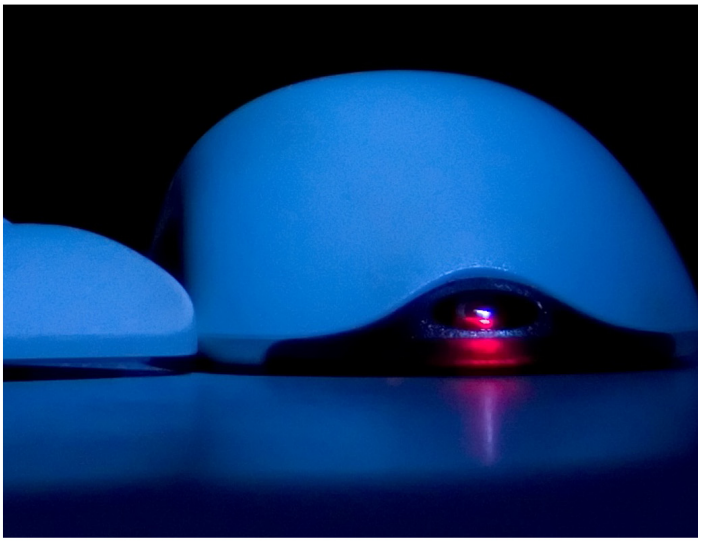
ASPEN

CLIA 116 and CERTIFICATION

11.9.1

Procedures Guide



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Systems Environment

Application Development: Microsoft Visual C++ and C# 2008 (9.0), .NET 3.51 SP1, .NET 4.6.1 or later (ASE-Q only)

Desktop Database (ASE-Q only): SQL Anywhere 11

CMS-supported operating systems and MS Internet Explorer versions are posted on the QTSO website at https://qtso.cms.gov/providers/home-health-agency-hha-providers/reference-manuals in the Minimum System Requirements document under Reference & Manuals.

Oracle Database 12c Enterprise Edition Release 12.1.0.2.0

Oracle Client 12.2.0.1

Optional System Environments

MAPI Compliant E-mail client to support e-mail transfer of survey information

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Introduction

ASPEN Web CLIA runs in a web browser (Internet Explorer) over the CMS intranet. It directly accesses the national CLIA database.

About this Procedures Guide

The *CLIA 116 and Certification Procedures Guide* gives you the information you will need (depending on your user class) to:

- Enter CMS-116 application data in the ASPEN Web CLIA 116 application.
- Create and maintain CLIA lab records, except for subtype 225-NO CLIA NUMBER, using the CLIA 116 web application.
- Create and update certification kits for CLIA labs in ASPEN Central Office (ACO).
- Create new labs of subtype 225 in ACO.
- Access and view CLIA accounting records on ASPEN Web CLIA.

Note: This guide assumes that you are familiar with basic Windows operations and that you have attended CLIA training offered by your agency.

This *CLIA 116 and Certification Procedures Guide* consists of this introduction and the following ten chapters:

- CLIA 116 Procedures: CO, RO, SA

  Provides CMS Central Office (CO), Regional Office (RO), and State Agency (SA) users with task-based procedures for using the CLIA 116 web application.

- CLIA Certification Procedures: CO, RO, SA

  Provides CO, RO, and SA users with task-based procedures for using ACO to create certification kits for CLIA labs.

  Note: Information about creating and maintaining CLIA-related personnel records in ACO is integrated into the *ACO Procedures Guide*. Information and procedures related to the CLIA complaint process and CLIA enforcement case management are included respectively in the *ACTS Procedures Guide* and *AEM Procedures Guide*. These guides are posted on https://qtso.cms.gov/aspenmanguide.html.

- ASPEN Data Transfer: CO, RO, SA

  Provides CO, RO, and SA users with task-based procedures for transferring from/to ACO/ARO and/or ACTS/ACTS RO to/from ASE-Q.

- CLIA 116 Procedures: AO

  Provides Accrediting Organization (AO) users with task-based procedures for using the CLIA 116 web application.

- CLIA 116 Procedures: Exempt

  Provides Exempt state (New York and Washington) users with task-based procedures for using the CLIA 116 web application.

- CLIA 116 Procedures: VA

  Provides Veterans Affairs (VA) users with task-based procedures for using the CLIA 116 web application.

- Browse Accounts

  Provides task-based procedures for using the Browse Accounts module of ASPEN Web CLIA to locate and view CLIA accounting information.

Note: For complete information about the online billing modules of ASPEN Web CLIA, see the *CLIA Accounting Procedures Guide*, which is posted on the QTSO website at https://qtso.cms.gov.

- CLIA Screens

  Contains pictures and brief descriptions of screens in the CLIA 116 web application and in ACO that are relevant to CLIA labs.

- CLIA Fields and Buttons

  Presents descriptions of the fields and buttons in relevant ASPEN Web CLIA and ACO screens.

- Supporting Materials

  Contains supplemental information and reference items.

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On any page, you can click the Increase (+) or Decrease (-) button in the toolbar to adjust the page magnification to your comfort level. Use the bookmarks in the left pane of Adobe Reader to locate and go (click the bookmark) to relevant information in this procedures guide.

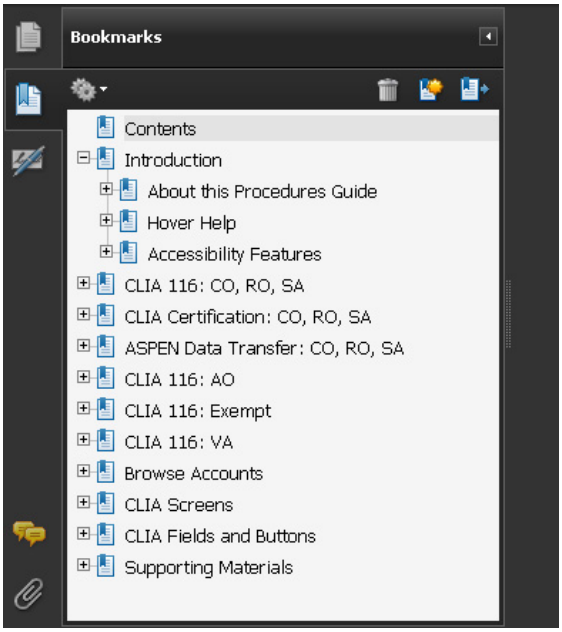

Figure 1: Bookmarks

You can also click the Contents bookmark and then click links in the table of contents to go to relevant topics.

TIP: For best viewing quality in Adobe Reader, go to Edit | Preferences | Page Display (path may vary somewhat depending on version). Select the applicable Smooth Text option.

If you need more information, links to relevant additional material in this document are included. Click a link to directly access the related information.

In the Procedures chapter, there are three types of links (cross-references) to additional material. They are grouped at the end of a procedure or descriptive section.

More ...

Procedure: “View and Enter 116 Specialties” on page 51
Screen: "Specialties tab" on page 307
Procedure: “116 Data Validation” on page 36

- Click the first link to go to the indicated procedure.
- Click the second link to go to a graphic and description of the indicated screen or section of screen.
- Click the third link to go to descriptive information about the indicated topic.

In the Screens chapter (usually), there is another type of link (cross-reference) to additional material:

Fields: "Specialties tab", on page 406

- Click the link to go to the field/column descriptions for the indicated screen or section of screen.

There may also be cross-references in the Fields and Supporting Materials chapters.

View a Printed Copy of this Document

While it is designed to be used easily online, you can print this document if you prefer. If you print this document, use the table of contents to locate the information you need. Links (cross-references) to additional material in this document include page numbers; simply go to the indicated page.

Conventions

This guide uses the following conventions:

Bold In procedures: names of screens, screen sections, windows you open; and buttons, menu options, keys you press.

web Generic reference to the World Wide Web.

ACO Generic reference to ASPEN Central Office (ACO) and ASPEN Regional Office (ARO). When necessary, ARO is explicitly identified.

Facility Properties
Generic reference to the Define New Facility/<FacName> Definition window.

More ...
Introduces a list of “see also” cross-references.

Note: Notes give you important information that may affect how you use a function.

TIP: Tips give you useful hints, suggestions, or alternative approaches.

WARNING! Warnings tell you actions to avoid that may cause harm, or precautions you should take to avoid causing harm.

Accessibility Features

This *CLIA 116 and Certification Procedures Guide*, ASPEN Web, and ACO include a number of 508-compliant accessibility features, which are detailed below.

In this Guide

This procedures guide incorporates the following 508-compliant accessibility features:

- Alternate text (alt text), which screen readers can read, is defined for all graphics. In the Screens chapter, there are links (cross-references) to the field/column descriptions for the indicated screen or section of screen.
- All graphics have captions.
- Information is not conveyed by means of color alone.
- Tables are not used for formatting, so all text is accessible to screen readers.
- Windows keyboard shortcuts are included in the Supporting Materials chapter.
- Reading order is optimized, so content is read correctly by screen readers.

In ASPEN Web

ASPEN Web includes the following 508-compliant accessibility features:

- In the CLIA 116 application, required fields are identified with an asterisk, which screen readers can read.
- All fields on ASPEN Web screens are included in a tabbing sequence, making them keyboard-accessible. You can also tab to *names* of fields/sections that have associated Hover Help. Names of fields/sections that do not have Hover Help are not included in the tabbing sequence.
- Keyboard shortcuts exist for application options, making ASPEN Web keyboard-accessible.
- All error messages are accessible to screen readers.

More …

Supporting Materials: “CLIA 116 Keyboard Shortcuts” on page 574

In ACO

ACO includes the following 508-compliant accessibility features:

- The Accessibility menu option on the System menu lets you specify field color preferences and enable/disable save point notification, i.e., audible confirmation upon saving. October 11, 2016: There is no immediate indication these instructions work. Does that imply this has changed?]

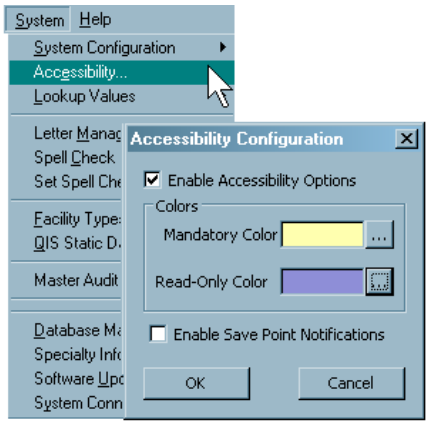

Figure 2: Accessibility option and Accessibility Configuration window

- The main ACO menu includes options corresponding to all toolbar buttons. The menu command IDs are exactly the same as the toolbar command IDs.
- In Tree, List, and Detail views, you can press Tab to move forward through elements, Shift+Tab to move backward. To move from one view to another, press Ctrl+Tab or Ctrl+Shift+Tab.
- All fields on ACO screens are included in a standard Windows tabbing sequence, making them keyboard-accessible.
- Keyboard shortcuts exist for all options, making ACO completely keyboard-accessible.
- You can access Hover Help (Hover Guidance) by pressing Alt-F5 when cursor focus is in a field that has an associated Hover Help icon.
- All error messages are accessible to screen readers.

Hover Help

Hover Help (Hover Guidance) is context-sensitive pop-up Help that provides definitions and descriptions for certain items in the CLIA 116 web application and ACO/ARO.

In the CLIA 116 Web Application

When a field or section name is blue in a CLIA 116 web application window, it indicates Hover Help is available for the field/section.

To view Hover Help for a field/section in the CLIA 116 web application:

1. Simply click the field/section name, or tab to the field/section name and press **Enter**.

   Hover Help for the field/section appears in a pop-up window.

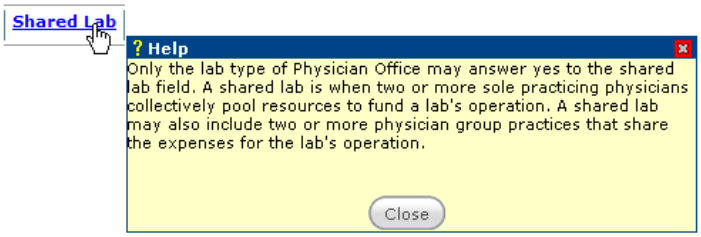

Figure 3: Example of Hover Help in the CLIA 116 web application

2. Click **Close** to dismiss the Help window.

Note: You can tab to *names* of fields/sections that have associated Hover Help, making the Hover Help keyboard-accessible. Names of fields/sections that do not have Hover Help are not included in the tabbing sequence.

In ACO

A gray circle next to a field in ACO indicates Hover Help is available for the field.

To view Hover Help for a field in ACO:

➥ Simply hold the mouse pointer over the Hover Help icon.

Information about the field appears.

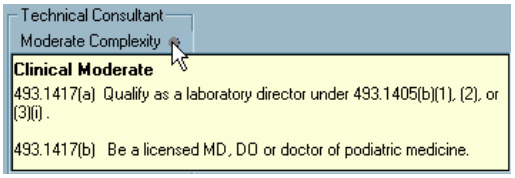

Figure 4: Example of ACO Hover Help

SAs can activate Hover Help (Hover Guidance) on a state-wide basis through the State Customization window in ACO (System menu). ARO users can see Hover Help when they are connected to a state that has activated it.

Acceptable Date Range in ASPEN

ASPEN does not allow dates outside of the range January 1, 1890 to December 31, 2050. You will be notified of an invalid date that is outside this range when it is entered in a field or grid, or on upload to national. A message will indicate the acceptable date range and you cannot save or upload until a valid date is entered.

CLIA 116: CO, RO, SA

The CLIA 116 web application runs in a web browser (Internet Explorer) over the CMS intranet. It directly accesses the national CLIA database.

State users can enter new CMS-116 applications and update records for labs in their own state, and view labs in other states. Regional Office users can update records in their region and view records in other regions. CO users can view and update records for all labs.

CLIA Certificates

Labs can apply for one of four certificate types:

1. Compliance
2. Waiver
3. Accreditation
4. PPM (Provider-Performed Microscopy)

Labs that apply for Waiver or PPM certificates receive the Waiver or PPM certificate when they meet all requirements.

Those labs that apply for Compliance or Accreditation certificates initially receive a Certificate of Registration, certificate type 9-Reg (1) if Compliance and 9-Reg (3) if Accreditation. This allows them to perform testing until eligibility for a Compliance or Accreditation certificate is established by (respectively):

- a survey verifying program compliance
- an AO confirming accreditation

Access the 116 Web Application

CLIA users must have a current national system login in order to open ASPEN Web CLIA and run the 116 application (web app). There are two ways to do this:

- From within ACO

  You can either open ASPEN Web CLIA and then choose to run the 116 application, or go right to the 116 application.

- From a browser, most likely Internet Explorer

SA users generally access the CLIA 116 web app from ACO. RO and CO users may be more inclined to open ASPEN Web CLIA from a browser and access the 116 application from there.

Note: Your ASPEN coordinator defines application access permissions for staff members. If you have difficulty logging in, contact your coordinator. For information and procedures related to creating and maintaining personnel records in ASPEN, including CLIA-specific details, refer to the latest version of the *ACO Procedures Guide*, which is posted on the QTSO website at https://qtso.cms.gov.

Open ASPEN Web CLIA from ACO/ARO

To open ASPEN Web CLIA, you need to have a current national system login.

To open ASPEN Web CLIA from ACO/ARO:

1. Click the **CLIA** button in the ACO/ARO toolbar:

Figure 5: CLIA button in the ACO/ARO toolbar

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
3. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.
4. Select **CLIA**.

   ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

Note: If you know you want to run the CLIA 116 web app, you can open it directly from ACO/ARO and bypass the Select Application window.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299
Procedure: “Open the CLIA 116 Web Application from ACO/ARO” on page 34

Open ASPEN Web CLIA from a Browser

To open ASPEN Web CLIA from your browser, you need to know the URL for the ASPEN Access page and have a current national system login.

To open ASPEN Web CLIA in your browser:

1. Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen
2. Click the **ASPEN Web** link.
3. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
4. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.
5. Select **CLIA**.

   ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

Open the 116 Application from ASPEN Web CLIA

To open the 116 application from ASPEN Web CLIA:

1. Open ASPEN Web CLIA from ACO/ARO or your browser.
2. In the **Select Application** window, click **116 Application**.

   The 116 web app opens to the CLIA 116 Find window.

Note: If you open ASPEN Web CLIA from ACO, then close ACO, ASPEN Web CLIA will shut down too.

More ...

Procedure: “Open ASPEN Web CLIA from ACO/ARO” on page 32
Procedure: “Open ASPEN Web CLIA from a Browser” just above
Screen: "ASPEN Web CLIA - Select Application window" on page 299
Screen: "CLIA 116 Find window" on page 301

Open the CLIA 116 Web Application from ACO/ARO

There are multiple points of access to ASPEN Web CLIA and the CLIA 116 web app in ACO/ARO. You can open the application for general use or open the 116 record for a specific lab.

Open the CLIA 116 Web Application for General Use

When you use this method to access the CLIA 116 web app, it opens to the CLIA 116 Find window. It works well if you want to:

- Locate a lab
- Work on multiple labs
- Add a new lab

To open the CLIA 116 web app to the Find window:

1 Click the **116 Add/Find** button at the top of the **ACO tree**.

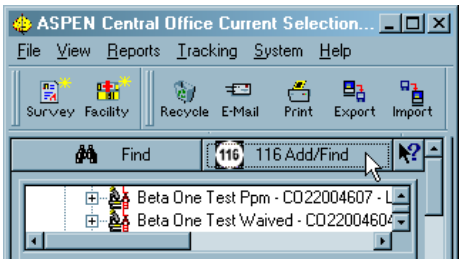

Figure 6: 116 Add/Find button at the top of the ACO tree

Note: The Help button (with question mark) to the right of 116 Add/Find explains the different uses of the ACO Find button (binoculars) and the 116 Add/Find button.

2 In the **Login** window, enter your national **User ID** and **Password** and click **Login**.

3 Click **OK** in the startup warning message to continue.

The CLIA 116 web app opens and displays the CLIA 116 Find window.

Note: If you close ACO, the CLIA 116 web app will shut down too.

More ...

Screen: "Login window" on page 298
Screen: "CLIA 116 Find window" on page 301

Open the CLIA 116 Web Application for a Specific Lab

There are three points of access to the CLIA 116 web app for a specific lab from ACO/ARO.

- Right-click option in the Tree view
- CLIA 116 button in Facility Properties
- CLIA 116 button in a certification kit

When you use any of these methods, the CLIA 116 web app opens and displays the 116 record for the lab in Update mode.

To open a 116 record using the right-click option:

1. Right-click the **lab name** in the **ACO tree**, and select **CLIA 116** from the menu:

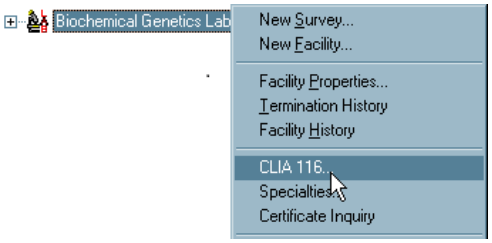

Figure 7: CLIA 116 right-click option

   ASPEN Web CLIA opens.

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
3. Click **OK** in the startup warning message to continue.

   The CLIA 116 web app opens and displays the 116 record for the lab in Update mode.

To open a 116 record from Facility Properties:

1. Click the **CLIA 116** button at the bottom of the Facility Properties window for a CLIA lab:

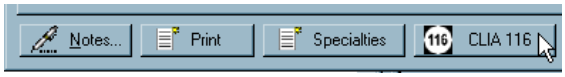

Figure 8: CLIA 116 button on the Facility Properties window

   ASPEN Web CLIA opens.

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
3. Click **OK** in the startup warning message to continue.

   The CLIA 116 web app opens and displays the 116 record for the lab in Update mode.

To open a 116 record from a certification kit:

1. In a certification kit for a CLIA lab, use the **CLIA 116** button on the **Certification & Surveys** tab:

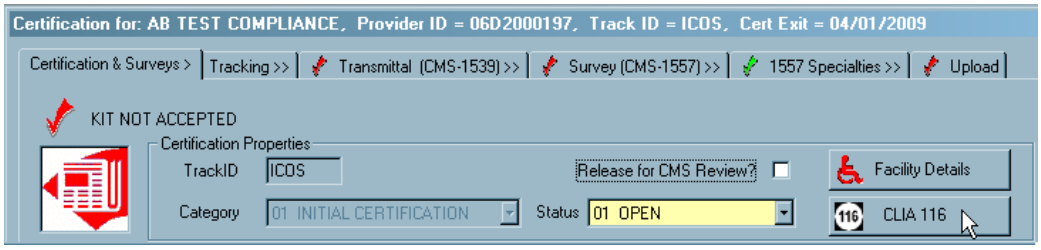

Figure 9: CLIA 116 button on the Certification & Surveys tab

   ASPEN Web CLIA opens.

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.

3. Click **OK** in the startup warning message to continue.

   The CLIA 116 web app opens and displays the 116 record for the lab in Update mode.

Note: If you close ACO, the CLIA 116 web app will shut down too. You will be given the opportunity to save changes.

More ...

Screen: "Login window" on page 298
Screen: "CLIA 116 window" on page 304

116 Data Validation

The CLIA 116 web app validates data and informs you if there are validation errors when you go from one tab to another or save a lab record. Validation errors occur when you do not provide required data, or provide invalid data.

Required Fields

A lab record is not complete until you enter all required information on each tab. Required fields are marked with an asterisk (*).

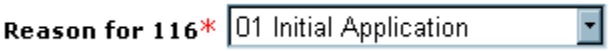

Figure 10: Required field

The CLIA 116 web app checks to see that data is entered in all required fields on a tab when you go to another tab or save a lab record. If required data is missing or invalid, you will receive validation error messages.

Some fields are required only under certain conditions. Those fields may not be marked with an asterisk, but if you try to save a lab record without completing conditionally required fields, you will receive error messages.

Tab Validation

If the CLIA 116 web app finds validation errors when you go to another tab, it lets you know. You can choose OK to override until you save the lab record, or Cancel to go back to the original tab and correct any problems. Field-specific error messages are displayed in red on the tab. There may not be messages for all fields with errors.

Lab Record Validation

A lab's application (CMS-116) must be accepted before it is issued a CLIA number, which is required to generate bills and certificates for the lab. An application is accepted once you complete all required fields on each tab in the CLIA 116 web app, pass all edits, and save the lab record.

Whenever you save a lab record, all data validation edits are applied. If validation errors are found, the system identifies the tabs that have errors. You can either cancel all data entry you have done, or go to the tabs that contain errors and correct them. Field-specific error messages are displayed in red on the applicable tabs. There may not be messages for all fields with errors. You need to correct all errors, explicitly identified or not, and save the record again.

When you save a lab record, an Add or Update transaction record is created and processed overnight. Errors occasionally occur in the nightly processing. In that case, the lab records involved will be read-only until the errors are resolved. If a lab record is read-only, check the top (header) of the record for an upload failure message.

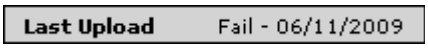

Figure 11: Upload failure message

Adding CLIA Lab Records

To create a record for a lab in the national CLIA database, you enter application data from the CMS-116 form into the CLIA 116 web app. When the lab's application is accepted, a new lab record is generated and downloaded to your state's ACO database during nightly processing.

Note: You can add new lab records at any time. There is no restriction due to batch processing as there is for updating records.

Locate Labs

A comprehensive set of search criteria is available in the CLIA 116 Find window, enabling you to quickly locate existing labs in the national CLIA database. You also *must* use the search function to verify that a lab you are planning to add is not already in the system.

You can specify criteria that make the search as broad or narrow as you need. For example, a broad search specifying a major city and the area code portion of a phone number would return all labs in the city with that area code. Generally, the narrower (more specific) the search, the quicker you will find the lab you want.

ASPEN Web CLIA supports single site and multiple site searches. It searches the entire national database. However, your user type determines which lab records you can add or update. For example, SA users can change data only for labs in their state.

To search for a CLIA lab:

1. Open the CLIA 116 web app.
2. In the **CLIA 116 Find** window, enter any combination of search criteria.

   You can enter all or part of any search element (e.g., all or part of a CLIA #), and use the% (percent) character as a wildcard.

   To enter a lab director's name, you must first enter all or part of Director Last Name to activate the Director First Name field.

   If you do not specify State or Zip, the search will be nationwide.
3. If you do not want to include terminated labs in the search, select **Exclude Terminated Laboratories**.

   The search will return only Active and Pending labs.

4 To run the search, click **Find Now**.

All labs that meet your search criteria are displayed in the CLIA 116 Search Results window.

Note: International labs are discussed in a separate section.

More ...

Procedure: “Access the 116 Web Application” on page 31
Procedure: “Multiple Sites Searches” just below
Procedure: “Partial Text and Wildcard Searches” below
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302
Procedure: “Locate International Labs” on page 60

Multiple Sites Searches

A Multiple Sites Search must include the lab Name or at least one of the Physical Address fields in the search criteria. Search results list all lab sites, including the primary, that match your search criteria.

Until full detail is entered in the CLIA 116 web app for labs with multiple sites, you will be limited in the criteria you can specify for multiple sites searches. To identify labs with multiple sites for which detail has not been entered, you can run the Number of Sites Mismatch report.

➥ To locate all sites for a lab, enter the search criteria including **Name** or at least one **Physical Address** element, select the **Multiple Sites Search** checkbox, and click **Find Now**.

More ...

Procedure: “Locate Labs” on page 38
Procedure: “Partial Text and Wildcard Searches” just below
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302
Supporting Materials: "No. of Sites Mismatch" on page 562

Partial Text and Wildcard Searches

When you search for a lab, you can enter just a part of any search element e.g., part of a lab Name and CLIA #. You can use the percent sign (%) as a wildcard in your partial search text, whether it is alphabetic, numeric, or both.

No wildcard

If you do not include a wildcard, the CLIA 116 web app finds all items that start with the search text.

➥ Type **BU** to find all items that begin with BU, like **Bu**ckley and **Bu**ena; or type **23** to return all items beginning with 23, such as **23**7711.

Wildcard at start

If you place the % character at the start of the search text, the CLIA 116 web app finds all items that include the search text anywhere.

➥ Type **%BU** to find items like **Bu**ckley, **Bu**ena, and Am**bu**lance; or type **%23**, to return items like **23**7711 and 461**23**6.

Wildcard between characters

If you place the % character between two characters in the search text, the CLIA 116 web app finds items that contain the two characters in the order you typed them, but allows other characters to occur between them.

➥ Type **B%U** to find **Bu**ckley, **Bu**ena, and Am**bu**lance, and also **B**ertho**u**d, **B**e**u**lah, and **B**aca Co**u**nty; or type **2%3** to return **23**7711, 461**23**6, and 3**2**987**3**.

Add Lab Records

To add a record for a lab to the national CLIA database, you enter data from the CMS-116 application submitted by the lab. You must first do a search–by lab name at least–to verify that a record for the lab does not already exist in ASPEN Web CLIA. For the lab's application to be accepted, you must enter all required data in the CLIA 116 web app and it must pass validation checks.

To add a CLIA lab to the database:

1. Search the national CLIA database for the lab you want to add, to make sure it is not already in the database.
2. If the lab is not listed in the CLIA 116 Search Results window, click the **Add** button at the bottom.

   A new lab record opens in Add mode with the Demographics tab selected. Some fields may already be populated based on what you entered in the CLIA 116 Find window.

   For a new lab record, the CLIA 116 web app will warn you if it found a duplicate address, phone number, or Federal Tax ID in another lab record. You can choose to continue or cancel.

3 Create the lab record by entering data into the CLIA 116 web app from the hardcopy CLIA application, the CMS-116 form, submitted by the lab and click **Save** when you are done.

If the application is accepted, i.e., there are no data validation errors, a message tells you what the system-generated provider (CLIA) number is for the lab. This is entered as the CLIA # when you return to the CLIA 116 Find window.

An Add transaction for the lab is created and processed overnight, and the new lab record is downloaded to the applicable state database (ACO).

Note: International labs are discussed in a separate section.

More ...

Procedure: "Locate Labs" on page 38
Procedure: "Entering New CMS-116 Applications" (just below)
Procedure: "International Labs" on page 60
Screen: "CLIA 116 window" on page 304
Procedure: "Add International Labs" on page 61

Entering New CMS-116 Applications

The CLIA 116 web app screens closely follow the layout of the printed CLIA application form, the CMS-116. The information you provide in the CLIA 116 web app depends on lab (application) type. The tab structure of the CLIA 116 web app screens allows you to skip areas that may not apply. For example, unless you are adding an Accredited lab, you can skip the Accred Org Info tab. Fields that do not apply do not appear, or are disabled.

Enter Demographics Information

The Demographics tab replicates sections I, II, III and IV of the hardcopy CMS-116. The information captured here includes basic application and identification information for the lab, lab director identity, and the lab's testing schedule.

To enter basic information about a lab:

1 Go to the **Demographics** tab of the lab record.

General Information

2 Select the applicable **Reason for 116**.

Initial Application is the default for new labs.

3 Select the **App Type Requested**.

This is the certificate (application) type requested by the lab. Fields are enabled or disabled according to the selected type. If you change App Type Requested on a new lab record and have already entered data that is invalid for the new type, you will receive an error message. The invalid data must be replaced or removed before you can change the application type.

4 Enter the **State Agency Received Date**.

This is the date the hardcopy CMS-116 was actually received at the SA office.

5 Enter identifying information for the lab: **Name**, contact **Email Address**, **Fed Tax ID**, **Phone** and **Fax** numbers.

Enter only numeric characters for the Federal tax ID, and phone and fax numbers. The system will format the phone and fax numbers as needed.

6 **Class Code** is automatically set to 00 Regular for CO, RO, and SA users.

00 Regular is the class for labs covered by the CLIA program in non-exempt states.

Note: 00 Regular is the default for New York (NY) users, who can create records for exempt labs as well. 05 Exempt is the default tor Washington state (WA) users.

Director Information

7 Enter the lab director's **Last Name**, **First** name, and middle initial (**M.I.**).

The First name and M.I. fields are not enabled until you enter something in the Last Name field.

8 Select the lab director's **Title** and salutation (**Sal**). If you choose 17 Other for Title, enter the applicable position title in the **Other** text field.

Other is enabled only if 17 Other is selected for Title.

WARNING! Do not include duplicate title information in the Last Name and Title fields.

Physical Address

9 Enter the lab's physical address, i.e., the location where tests are performed. Type the **Street** address and **Zip** code.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

Note: Locality, Postal Code, and Country are enabled for international labs only, which are discussed in a separate section.

Mailing Address (if different than physical address)

10 Enter the lab's mailing address: type the **Street** address and **Zip** code and select the **City** if necessary.

State is system-generated based on Zip code.

Note: Locality, Postal Code, and Country are enabled for international labs only, which are discussed in a separate section.

Corporate Address

11 Enter the **Street** address and **Zip** code of the corporate entity that owns the lab; select the **City** if necessary.

Note: Locality, Postal Code, and Country are enabled for international labs only, which are discussed in a separate section.

Form Mailing

12 Choose whether to send bills and certificates to the lab's Physical, Mail, or Corporate address.

Physical is entered by default. The available options depend on which addresses have been entered. When you add a Mailing or Corporate address, a message reminds you to check the Form Mailing settings.

If you remove the Mailing and/or Corporate Address when one or both Form Mailing fields are set to the removed address type(s), the applicable Form Mailing field(s) are cleared. If only the Physical Address remains, Physical is then automatically selected for the cleared field(s). Otherwise, you are reminded to review the Form Mailing values.

Type of Laboratory

13 Select the applicable option. If you choose 29 Other as Type, enter the applicable lab type in the Other text field. Other is enabled only if 29 Other is selected for Type of Laboratory.

Hours of Laboratory Testing

14 Specify the lab's testing schedule: enter **FROM** and **TO** hours for each day the lab is open. If it is always open, click the **24x7** button and the hours are automatically filled in.

More ...

Screen: "Demographics tab" on page 305
Procedure: "Add International Labs" on page 61

Identify Multiple Sites

The Multiple Sites tab replicates section V of the hardcopy CMS-116. A separate record in the CLIA 116 web app is required for each of a lab's locations with the following exceptions:

- Temporary Testing Sites

  The lab moves from testing site to testing site, e.g., mobile units, health screening fairs.

- Non-profit, Federal, State or Local Government Labs

  The lab performs 15 or fewer different tests, including waived. None of the tests are of high complexity.

- Hospital-based Labs

  The labs are all located within a hospital in contiguous buildings on the same campus and under common direction.

If a lab's multiple testing sites or separate locations qualify for the Multiple Sites exception provision, you use the Multiple Sites tab to provide information about them. Multiple sites all have the same CLIA number as the primary lab, which is included in the count of multiple sites.

To enter information about a lab's multiple sites:

1 Go to the **Multiple Sites** tab of the lab record.

General Information

2 Select **Yes** for **Multiple Sites** if the lab has multiple locations and they qualify for a multiple sites exception.

When the Multiple Sites field is initially marked Yes, the primary (current) lab is automatically entered as the first multiple site.

3 For **Number of Sites**, enter the number reported by the lab on the CMS-116.

Active Sites Entered displays a read-only count of active additional sites (Status is Active).

When the Multiple Sites field is initially marked Yes, Number of Sites is set to 2 and Active Sites is set to 1.

Exceptions

4 Indicate whether any Multiple Site exception applies:

Lab with temporary testing sites?

Non-profit, Federal, state or local government lab?

Hospital with several labs at the same address?

Multiple Sites

5 In the **Multiple Sites section**, select **Active** to view only active lab sites, or **All** to view all lab sites including moved and removed labs.

6 **Add**, **Modify**, or **Remove** labs in the Multiple Sites list as needed.

Note: If you change the Multiple Sites field to No after adding multiple sites, all active sites are removed. Moved and removed sites remain in the list.

More ...

Procedure: “Add a Site” (just below)
Procedure: “Update a Site” on page 46
Procedure: “Remove a Site” on page 47
Screen: "Multiple Sites tab" on page 305

Add a Site

To enter detailed information about each of a lab's multiple sites, use the Add button on the Multiple Sites tab.

Note: You cannot add multiple sites records for international labs.

To add a site:

1 In the **Multiple Sites section** of the **Multiple Sites tab**, click **Add**.

-or-

Right-click in the list and select **Add Site**.

The Add button is not enabled if No is selected in the Multiple Sites field. Number of Sites must be at least the number of Active Sites Entered +1 before you can add a site.

2 Enter the **Name**, **Street** address, **Zip** code, and **Phone** number of the additional lab site.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

You cannot enter an **NPI** (National Provider Identifier) for CLIA labs in this release.

3 Select the **Status** of the additional site.

ID is a system-generated sequence number. It indicates the order in which additional sites were added.

4 In the **Tests Performed/Specialties** text box, describe **Tests Performed** at the site and its **Specialties**.

5 Click **Save** to save the information and add the site to the Multiple Sites list.

Note: When a laboratory is terminated, any multiple site locations with a Status of Active will remain Active.

More ...

Screen: "Add/Modify Site window" on page 306

Update a Site

Use the Update button on the Multiple Sites tab to correct information in existing multiple site records.

To update site information:

1 In the **Multiple Sites section** of the **Multiple Sites tab**, select a site and click **Modify**.

-or-

Right-click a site and select **Modify Site**.

2 Make changes as needed.

For the primary site, you can only make changes to Tests Performed/Specialties text. To change basic demographic information about the primary lab site, go to the Demographics tab.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Screen: "Add/Modify Site window" on page 306
Procedure: "Enter Demographics Information" on page 41

Remove a Site

If a lab reports it is no longer testing at a site, you can remove the applicable multiple site record. You cannot remove the primary site.

To remove a site:

➥ In the **Multiple Sites section** of the Multiple Sites tab, select a site and click **Remove**.

-or-

➥ Right-click a site and select **Remove Site**.

The Status of the site changes to Removed. If you are displaying only active sites, the removed site disappears from the Multiple Sites list.

TIP: You can also change Status to Removed through the Update function, or directly on the grid.

---

3 To include removed sites in the **Multiple Sites section**, select the **All** radio button.

Enter Accreditation Information

The Accred Org Info tab replicates section II of the hardcopy CMS-116. It also displays information not on the form, such as AO Confirmed (Y-match) and Remarks.

If a lab chooses to be accredited, it can designate more than one AO for CLIA purposes, i.e., enter more than one X-match, but only one AO can accredit each specialty or subspecialty. The lab will receive a Certificate of Accreditation after the AO surveys the lab and confirms that the lab is in compliance, i.e., enters a Y-match.

Add an AO (X-match)

When you add an Accredited lab (app type 3), you need to select at least one accrediting organization on the Accred Org Info tab before you can save the record. All fields on this tab are disabled for Compliance, Waiver, and PPM labs.

To add an AO:

1 Go to the **Accred Org Info** tab of the lab record.

2 In the **Accrediting Organization Affiliations** section, click **Add**.

A new row is added to the list of AOs.

3 Select the appropriate Accred Org (accrediting organization).

You cannot add an AO here more than once.

More ...

Screen: "Accred Org Info tab" on page 306

Delete an AO

To delete an AO:

1. Go to the **Accred Org Info** tab of the lab record.
2. In the **Accrediting Organization Affiliations** section, select an AO and click **Delete**.

   The AO is marked for removal (crossed out). All fields in the row are immediately disabled and the row is removed when the lab record is saved.

More ...

Screen: "Accred Org Info tab" on page 306

Specialty Information

The Specialties tab both replicates sections VI, VII, and VIII of the CMS-116 form and captures survey specialties data. The 116 specialties are those the lab has included on the CMS-116, which you enter on the Specialties tab of the lab record. The survey specialties are those entered on the 1557 Specialties tab in the ACO certification kit. They reflect what surveyors determined the lab's specialties to be.

View and Enter Specialty Information

What you see on the Specialties tab and what you can enter or update depends on the type of certificate/application as described below. You can at least view (as applicable) a lab's 116 specialties, survey specialties, and survey specialty history.

1-Compliance/9-Reg (1)

The Specialties tab for Certificate of Compliance applications includes the Schedule Codes, Specialty Source, Total Annual test volume, and Sub-specialty sections.

Annual test volumes for All Waived/PPM Tests are optional. If you enter 0 for either test volume, you must also select the No Testing checkbox.

The Sub-specialty section displays 116 specialties, active survey specialties, or survey specialty history depending on the selected Specialty Source. You must enter at least one 116 sub-specialty and associated test volume in the Sub-specialty section (when Specialty Source is 116 Specialties) unless the lab is downgrading its certificate from Compliance to Waiver ornPPM.

2-Waiver

The Specialties tab for Certificate of Waiver applications has the Total Annual test volume and Specialty History sections.

Total annual volume for All Waived Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. The All PPM Tests field is disabled.

Note: It is not currently possible to enter the tests being performed by Waiver labs except as notes.

The Specialty History section displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

3-Accreditation/9-Reg (3)

The Specialties tab for Certificate of Accreditation applications includes the Schedule Codes, Specialty Source, Total Annual test volume and Sub-specialty sections.

Annual test volumes for All Waived/PPM Tests are optional. If you enter 0 for either test volume, you must also select the No Testing checkbox.

The Sub-specialty section displays 116 specialties, active survey specialties, or survey specialty history depending on the selected Specialty Source. You must enter at least one 116 sub-specialty with associated accrediting organization and test volume in the Sub-specialty section (when Specialty Source is 116 Specialties).

4-PPM

The Specialties tab for Certificate of PPM applications has the Total Annual test volume and Specialty History sections.

Total annual volume for All PPM Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008.

Annual volume for All Waived Tests is optional. If you enter 0, you must also select the No Testing checkbox.

Note: It is not currently possible to enter the tests being performed by PPM labs except as notes.

The Specialty History section displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

TIP: You do not have to memorize all these rules. The CLIA 116 web app will not let you save a lab record if required fields are not complete, and the edit messages will tell you what is missing.

To view or enter specialty information for a lab:

1 Go to the **Specialties** tab of the lab record.

Schedule Codes

Schedule codes for Compliance and Accredited laboratories are system-generated and read-only.

This section does not appear for Waiver or PPM labs.

Specialty Source

2 To display 116 specialty data in the Sub-specialty grid, select **116 Specialties**. To display current survey specialty data, select **Survey Specialties**. To display survey specialty history for a Compliance or Accredited lab, select **Specialty History**.

116 Specialties is the default, except for AO users. Last Update Date (of 116 or survey specialties depending on selected source) is system-generated and read-only.

Note: A Specialty History section is automatically displayed below Total Annual test volume for PPM and Waiver labs. If a lab previously held an Accreditation or Compliance certificate, it displays specialty history data; otherwise, it is blank.

Total Annual test volume

3 Enter the number of **All Waived Tests** and **All PPM Tests** performed annually, as applicable.

This section appears for all labs. Whether annual test volumes are required depends on lab type.

Waiver labs - Annual test volume for All Waived Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. All PPM Tests is disabled.

PPM labs - Annual test volume for All PPM Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. All Waived Tests is optional.

Compliance, Accredited labs - Annual test volumes are optional.

When test volume is not required but the field is enabled, you can enter a test volume, or enter 0 and select No Testing if the checkbox is enabled.

Sub-specialties

4 In the Sub-specialty grid, depending on the selected Specialty Source:

- View and enter 116 survey specialties and sub-specialties
- View active survey specialties and sub-specialties
- View survey specialty history for a Compliance or Accredited lab

The Sub-specialty grid does not appear for Waiver or PPM labs because they do not have specialties. However, the Specialty History section is automatically displayed in its place.

More ...

Screen: "Specialties tab" on page 307
Procedure: “View Schedule Codes” on page 55
Fields: "Total Annual test volume", on page 407
Procedure: “View and Enter 116 Specialties” (just below)
Procedure: “View Survey Specialties” on page 52
Procedure: “View Survey Specialty History” on page 54

View and Enter 116 Specialties

Depending on your user class and permissions, you can view and enter 116 specialties for Compliance and Accredited labs in the Sub-specialty grid. 116 specialty information is what a lab includes on the CMS-116 it submits.

To view and enter 116 specialties for a lab:

1 Go to the **Specialties** tab of the lab record.

2 Be sure **Specialty Source** is **116 Specialties**.

For Compliance labs, you will see Test Volume for selected 116 specialty groups.

For Accredited labs, 116 specialty information includes the Accrediting Org for each selected sub-specialty (must be an X-match), and Test Volume for selected specialty groups.

3 Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.

4 For Accredited labs, select the **Accrediting Org** for each sub-specialty.

The options in the drop-down list are the AOs entered on the Accred Org Info, i.e., X-matches.

5 Enter the annual **Test Volume** for each selected specialty group.

This should be the total test volume for the sub-specialties selected in a specialty group.

Total Annual Test Volume is calculated by the system.

More ...

Screen: "Specialties tab" on page 307
Fields: "Total Annual test volume", on page 407

Delete 116 Specialties

When an existing lab with active 116 specialties stops offering a specific specialty, you can delete it.

To delete a 116 specialty:

1 Go to the **Specialties** tab of the lab record.

2 Be sure **Specialty Source** is **116 Specialties**.

3 In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

The deleted specialty is highlighted in red for the rest of the session.

4 Adjust the applicable **Test Volume** as necessary.

If you delete all sub-specialties under a specialty, the Test Volume field is cleared and disabled.

Note: After you save a lab record, data for all deleted specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

View Survey Specialties

You can view survey specialties for Compliance and Accredited labs in the Sub-specialty grid. Survey specialties are entered and updated on the 1557 Specialties tab in ACO certification kits. The survey specialty data shown on the Specialties tab is drawn from a lab's most recent certification kit. It does not include specialty data gathered from a lab prior to performing a status change.

To view survey specialties for a lab:

1 Go to the **Specialties** tab of the lab record.

2 For **Specialty Source**, choose **Survey Specialties**.

For Compliance labs, survey specialty information includes the Effective Date and Expiration Date (only if closed out) for each selected sub-specialty, and Test Volume for selected specialty groups. For Accredited labs, you will see the Accrediting Org for each selected sub-specialty (must be a Y-match), and Test Volume for selected specialty groups.

Note: CO super users can update survey specialties on the Specialties tab for Accredited labs only.

More ...

Screen: "Specialties tab" on page 307

Delete Active Survey Specialties on Accredited Labs

CO Super Users

To delete a survey specialty, you simply deselect it. For Accredited labs, only CO super users can delete active survey specialties on the Specialties tab in the CLIA 116 window. Active survey specialties for Compliance labs are deleted on the 1557 Specialties tab in the applicable certification kit in ACO.

WARNING! Delete a survey specialty only if it was listed in error.

To delete a survey specialty for an Accredited lab:

1 Go to the **Specialties** tab of the lab record.

2 For **Specialty Source**, choose **Survey Specialties**.

3 In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

The deleted specialty is highlighted in red for the rest of the session.

Note: After you save a lab record, data for all deleted specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307
Procedure: “Delete Active Survey Specialties on Compliance Labs” on page 133

Close Out Survey Specialties on Accredited Labs

CO Super Users

Closing out a survey specialty is not the same thing as deleting it. To close out a specialty, you must enter an expiration date for it.

For Accredited labs, only CO super users can close out survey specialties on the Specialties tab in the CLIA 116 window. Survey specialties for Compliance labs are closed out on the 1557 Specialties tab in the applicable certification kit in ACO.

To close out a survey specialty for an Accredited lab:

➥ Enter its **Expiration Date** in the **Sub-specialty grid**.

Note: After you save a lab record, data for all closed out specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307
Procedure: “Close Out Survey Specialties on Compliance Labs” on page 133

View Survey Specialty History

You can view survey specialty history on the Specialties tab for all labs, regardless of certificate type. If the lab has open (active) and closed survey specialties, you will see a complete read-only history of those specialties.

PPM and Waiver labs

The Specialty History section displays a lab’s survey specialty history, if any.

Compliance and Accredited labs

You choose an option to display the survey specialty history for a lab.

Note: In ACO, you can access survey specialty history, including deleted specialties and test volume history, from Tree view or the Facility Properties window.

To view survey specialty history for a PPM or Waiver lab:

1. Go to the **Specialties** tab of the lab record.
2. Look at the **Specialty History** section below Total Annual test volume.

   It displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

To view survey specialty history for a Compliance or Accredited lab:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Specialty History**.

   The survey specialty history for the lab is displayed in an unlabeled section below Total Annual test volume.

More ...

Screen: "Specialties tab" on page 307
Procedure: “View Survey Specialty History in ACO/ARO” on page 134

Delete Closed-out Survey Specialties

CO Super Users

CO super users can delete closed-out survey specialties from a lab's survey specialty history if necessary, e.g., when a specialty was closed out in error.

To delete a closed-out survey specialty:

1. Go to the **Specialty History** section in the lab record.
2. In the history list, select the **Delete** checkbox for the closed-out specialty you want to remove.

   The Delete checkbox is present only for closed-out survey specialties, those with Type Code D.

   WARNING! There is no confirmation message, so be sure you need to delete the closed-out specialty before you save the lab record.

   After you save the lab record, all deleted closed-out survey specialties are removed from the lab's survey specialty history.

More ...

Procedure: "View Survey Specialty History" just above

View Schedule Codes

The Schedule Code Chart displays fees by schedule code for Compliance and Accreditation certificates based on the state where the laboratory is located. It also indicates Waiver and PPM fees.

To view the Schedule Code Chart:

1. Go to the **Specialties** tab of the lab record.
2. In the **Schedule Codes** section, click the **Schedule Code Chart** button.

   The chart is displayed.
3. Click **OK** to close the chart.

More ...

Screen: "Specialties tab" on page 307

Enter Additional Information

On the Additional Info tab, you can enter supplementary information about a lab such as:

- Lab Director Affiliations

  If the director of a laboratory serves as the director for other labs that are separately certified, you can specify those affiliations on the Additional Info tab. An individual can serve as the director for up to five non-Waiver labs–any combination of PPM, Compliance, or Accredited–and an unlimited number of Waiver labs.

- Type of Control

  This is the type of organization that operates the lab.

- Application Signature Date

  This is the date the application was received.

- Cyto PT (Proficiency Testing)

  This section has details about Cyto PT enrollment for Compliance and Accredited labs that are approved for cytology testing (630 specialty code).

To enter additional information about a lab:

1. Go to the **Additional Info** tab of the lab record.

Director Affiliations

2. Enter the **CLIA number** of an affiliated lab (must be active) and click **Insert Affiliated Lab**, or use the **Find** function and select the applicable lab in the search results.

   The lab is added to the list of affiliations.

Note: The Find Affiliated Providers window works just like the CLIA 116 Find window.

Other

3. Select **Type of Control** from the list. If you select **03 Other** or **09 Other Government**, enter the applicable control type in the **Other** text field.
4. Enter the **Application Signature Date**.

   This date is required if the Reason for 116 is Initial Application or Survey.

5. Enter the **Cross Reference Provider Number**, i.e., the CLIA number previously assigned to a lab holding a multiple site certificate.

   This field is required when the termination code for the lab is 13 Multiple to Single Site Certificate.

6 Enter the **CLIA Medicare Number** assigned to the lab.

7 **RO Full Access Users:** If the lab is in the **Federal Jurisdiction** program, select Yes; No or blank if not.

This field is disabled for all other users.

8 Four read-only CASPER Inquiry fields display:

- Date the certification kit was successfully uploaded to CASPER (national reporting system).
- Date the kit passed ASPEN upload edits.
- Determination Approval date entered by the RO.
- Whether the certification kit requires RO review.

Cyto PT Enrollment

This section is relevant only for Compliance and Accredited labs that are approved for cytology testing (630 spec code). The information is set by national batch jobs when they generate Cyto PT letters and is read-only, except CO users can select Enrollment Status once Year is set.

More ...

Screen: "Additional Info tab" on page 308
Procedure: “Locate Labs” on page 38

PT Info

The PT Info tab displays PT Enrollment and PT Score Lists. The read-only lists contain data for the specific lab that is being viewed or updated in the CLIA 116 application.

The PT Enrollment List is sorted by:

Test Year (desc), Analyte #, Program #

The PT Score List is sorted by:

Test Year (desc), Analyte #, Event #, Program #, PT Score Submission Date

To navigate through each list, use First/Previous, Next/Last, or select a specific page to jump to from the page selection drop-down list.

Radio buttons available on the PT Score List display All or Failed / Unsuccessful scores.

More ...

Screen: "PT Info tab" on page 311

Add Notes

The Notes function lets you add notes to a lab record. They can be as brief or extensive as you require. There are separate note panels for State, Regional Office, and Central Office users. You can view note text in all three panels, but enter and edit text only in the panel that is activated depending on your user type.

Note: The Notes function is unavailable until a new lab record is saved and a CLIA # (aka CLIA number, CLIA provider number, CCN, Medicare provider number, provider #/number) has been assigned.

To add notes to the lab record:

1. At the bottom of the lab record, click the **Notes** button.

   The active panel depends on your user type.

2. Enter your note text and click **Save**.

   Notes are saved immediately; you do not have to save the lab record. When note text is first saved, the Notes button label changes to NOTES(*) to indicate there are notes.

More ...

Screen: "Notes window" on page 312
Fields: "Notes", on page 416

Include Attachments

You can add supplemental materials in electronic format to lab records such as relevant document files and digital photos. For example, you can attach scanned copies of the CMS-116 form, or letters and documents from outside agencies.

When you attach a file, a copy of the original is compressed and stored in the national CLIA database. If you move or delete the original, it does not affect the attachment.

Survey and certification records in ACO and complaint/incident records in the ASPEN Complaints/Incidents Tracking System (ACTS) can also have attachments, which are stored in your state database. Attachments to lab records are stored in the national database, and can be viewed only in the CLIA 116 web app.

Add Attachments

The CLIA 116 web app supports attachment of the following file types:.txt,.rtf,.doc,.docx,.html,.pdf,.gif,.jpeg,.jpg,.tif, and.xls.

Note: HIPAA compliance guidelines apply to attachments. Be sure to remove patient names and other identifying information from items you attach to lab records.

To add an attachment to the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, click **Add**.
3. Click **Add** to add a row in the **Attachments** grid.
4. In the **Entry Name** field, type a descriptive name for the attachment.
5. Press the **Tab** key and click **Browse** to the right of the Attach field.
6. Navigate to the folder containing the file you want to attach. Select it, and click **Open**.

   The file name and path are inserted into the Attach field.
7. Press the **Tab** key and the CLIA 116 web app inserts the **File Name** of the attachment and **Date Attached**; the **Attach** field is cleared.
8. Click **Close** to save the attachment information.

More ...

Screen: "Attachments window" on page 312

View Attachments

To view an attached file, there must be an application registered on your system that can open it. For example,.doc files can be opened by MS Word,.bmp is usually associated with Paint,.jpg is usually associated with your web browser.

To view an attachment to the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, click anywhere in the applicable row and click the **View** button, or just click **View** twice.

   The attachment is displayed.
3. To return to the **Attachments** window, close the application displaying the attachment.

More ...

Screen: "Attachments window" on page 312

Remove Attachments

You can remove an attachment altogether or replace it with another.

To remove an attachment from the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, select an attachment and click **Remove**.

To replace one attached file with another:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, select the attachment you want to replace and click **Browse**.
3. Navigate to the folder containing the file you want to attach instead, select it, and click **Open**.

   The file name and path of the replacement are inserted into the Attach field.
4. Press the **Tab** key and the CLIA 116 web app inserts the **File Name** and **Date Attached** of the replacement file.

   The Attach field is cleared and the Entry Name stays the same.

More ...

Screen: "Attachments window" on page 312

International Labs

Locate International Labs

You can search the CLIA database for all international labs or a particular international lab. All search elements are enabled.

To search for international CLIA labs:

1. In the **CLIA 116 Search** window, enter **FN** (for Foreign) as **State**.
2. Also enter all or part of other search elements such as lab **Name** or **Address** to specify search criteria.
3. If you do not want to include terminated international labs in the search, select **Exclude Terminated Laboratories**.

   The search will return only Active and Pending labs.
4. To run the search, click **Find Now**.

   All international labs that meet your search criteria are displayed in the CLIA 116 Search Results window.

More ...

Procedure: “Partial Text and Wildcard Searches” on page 39
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302

Add International Labs

To create a lab record, you enter data from the CMS-116 on the applicable tabs. You must first do a search to verify that a record for the lab does not already exist.

To add an international CLIA lab:

1. Search the CLIA database for the international lab you want to add, to make sure it is not already in the database; for **State**, enter **FN** (Foreign).
2. If the lab is not listed in the CLIA 116 Search Results window, click **Add** at the bottom.

   A new lab record opens in Add mode with the Demographics tab selected. Some fields are already populated based on what you entered in the CLIA 116 Find window. At the very least, State is set to FN and the International Lab checkbox is selected for Physical Address.
3. Complete the lab record using data from the hardcopy CMS-116 submitted by the lab.

   On the Demographics tab:

   - International phone numbers are supported.
   - You can enter Locality, Postal Code, and Country for international addresses (Physical, Mailing, and Corporate). When the International button is selected for any of the addresses, the Zip, Zip extension, City. and State fields are disabled and Locality, Postal Code, and Country are enabled instead.

   Note: State is automatically set to FN for the Physical Address only.
4. Click **Save** when you are done.

   A message tells you what the system-generated provider (CLIA) number is for the lab. This is entered as the CLIA # when you return to the CLIA 116 Find window.

More ...

Procedure: “Locate International Labs” on page 60
Procedure: “Entering New CMS-116 Applications” on page 41
Screen: "CLIA 116 window" on page 304

Updating Lab Records

When changes to a lab record are necessary, you can open the record in Update mode.

Note: Existing lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

Update a Lab Record

If you are an SA user, you can update labs in your state only. You can use Inquiry to view other states' labs. You cannot update Veterans Affairs (VA) labs in your state, but can use Inquiry to view them.

To update the record for a lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.
3. Update the lab record as needed.

   You must always enter Reason for 116 in Update mode.

   You cannot change App Type Requested. Use the Status Change window to change certificate (application) type.

   Only CO super users can change Class Code for any lab. NY and WA users can change Class Code for labs in their state. To prevent the creation of overlapping certificates, a class code change and a status change for a lab cannot be performed on the same day.

   You cannot change Zip code/City/State if there is a Survey Pending Date for the lab.
4. Click **Save** to save your changes. If you do not want to save the changes, click **Cancel**.

More ...

Procedure: "Locate Labs" on page 38
Procedure: "Entering New CMS-116 Applications" on page 41
Screen: "CLIA 116 window" on page 304
Procedure: "Enter Status Changes" on page 67
Procedure: "Change Class Code" on page 242

When a Lab Moves to Another State

For a lab that physically relocates from one state to another, the Operating Status of the lab in the original facility record in ACO is set to CLOSED-MOVED. A new facility record with an ACTIVE status for the lab in its new location is automatically created in ACO. You need to update the lab's physical and mailing address (if applicable) in the CLIA 116 web app.

To update the record for a lab that moves out of state:

1. In the CLIA 116 web app, search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.
3. On the **Demographics** tab, update the lab's **Physical Address** and **Mailing Address** information.

   You cannot change Zip code/City/State if there is a Survey Pending Date for the lab.
4. Update **Corporate Address** and **Form Mailing** options if necessary.
5. Click **Save** to save your changes.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Procedure: "Locate Labs" on page 38
Screen: "Demographics tab" on page 305
Supporting Materials: "Survey Categories/Types" on page 552

Lab Record Inquiry

The Inquiry function accessed from CLIA 116 Search Results provides a read-only view of lab records for informational purposes. You can view any lab in the national CLIA database.

To view a lab record:

1. Search the national CLIA database.
2. In the **CLIA 116 Search Results** list, select a lab and click **Inquiry** at the bottom of the window.

   -or-

   Right-click the lab and select **Inquiry 116**.

   The record for the lab is displayed in read-only Inquiry mode.

More ...

Procedure: “Locate Labs” on page 38
Screen: "CLIA 116 window" on page 304

Certificate and Billing Inquiry

The Cert/Bill Inquiry function, which you can access from the lab record or Status Change window, displays the lab’s certificate and billing history in the CLIA Certificate and Billing Inquiry window. Users with appropriate permissions can request replacement certificates or override adjustment edits for a lab from this window.

CLIA Certificate Status

Pending - The lab has applied for a new certificate type or a continuing certificate. The current certificate expiration date is more than 30 days in the future and the lab has not yet paid fees for the new or continuing certificate. A pending certificate period depends on application type: 12 months prior to expiration of app type 1 renewals, 6 months prior to expiration for app type 2, 3, and 4 renewals. Pending certificate information is not sent to Medicare or Medicaid.

Current - When the lab has paid the required fees and its current certificate is due to expire within 30 days, its pending certificate becomes the current certificate.

History - This is a certificate the lab held in the past.

View Certificate and Billing Information

The Certificate Inquiry section of the CLIA Certificate and Billing Inquiry window displays details about the lab's future (pending), current, and prior (historical) certificates.

The Billing Inquiry section is ordered by certificate date and provides various billing details such as transaction date and description, payment amount, and lockbox date. If no certificate is issued, the line is marked with an asterisk.

To view certificate and billing info for a lab:

➥ Open a lab record in **Update** or **Inquiry** mode and click **Certificate/Billing Inquiry** at the bottom of the window.

-or-

➥ At the bottom of a lab record, click **Status Change**, then click **Cert/Billing** at the bottom of the Status Change window.

More ...

Screen: "CLIA Certificate and Billing Inquiry window" on page 314
Procedure: "Update a Lab Record" on page 62
Procedure: "Lab Record Inquiry" on page 64

Generate Replacement Certificates

SA, RO, and CO users with appropriate permissions can set a field in the CLIA Certificate and Billing Inquiry window to request a replacement certificate for a lab. CMS processes these requests weekly and mails the replacement certificates.

Replacement certificate auditing provides a full history of:

- Requests to issue replacement certificates
- Replacement certificate details: who issued the replacement certificate and when including date, hour, and minute
- AO changes to lab director information that caused replacement certificates to be issued

To request a replacement certificate for a lab:

1. Open the **CLIA Certificate and Billing Inquiry** window.
2. In the middle of the screen, set **Generate Replacement Certificate** to **Yes**.

Note: A replacement certificate cannot be generated if a pending certificate is present.

More ...

Procedure: "View Certificate and Billing Information" on page 65
Screen: "CLIA Certificate and Billing Inquiry window" on page 314

Request Override Adjustment Edits

CO Super Users

CO super users can request override adjustment edits for a lab to resend fees as a result of changes in schedule code.

To request override adjustment edits for a lab:

1. Open the **CLIA Certificate and Billing Inquiry** window.
2. In the middle of the screen, set **Override Adjustment Edits** to **Yes**.

More ...

Procedure: “View Certificate and Billing Information” on page 65
Screen: "CLIA Certificate and Billing Inquiry window" on page 314

CLIA 116 Reports

Print the CMS-116

You can generate the CMS-116 form for a selected lab.

To print the CMS-116 for a lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Print** at the bottom of the window.
3. In the **Report Selection** window, click **CLIA 116 Form**.

   A CMS-116 form for the lab is populated with data from the lab record and generated in PDF format.

More ...

Procedure: “Locate Labs” on page 38
Screen: "CLIA 116 Search Results window" on page 302
Screen: "Report Selection window" on page 303
Supporting Materials: "CMS-116" on page 569

Print CLIA 116 Search Results

You can generate the Search Results list as a report.

WARNING! Surveyors are strongly cautioned NOT to release this information publicly, to use it carefully and only to assist with your routine regulatory and survey-related duties.

To print CLIA 116 search results:

1. Search the national CLIA database.
2. Click **Print** at the bottom of the **CLIA 116 Search Results** window.

3 In the **Report Selection** window, click **CLIA Search Results List**.

The CLIA Search Results List report is generated in PDF format. It lists labs in the order they are displayed in the CLIA 116 Search Results window.

More ...

Procedure: “Locate Labs” on page 38
Screen: "CLIA 116 Search Results window" on page 302
Screen: "Report Selection window" on page 303
Supporting Materials: "CLIA Search Results List" on page 570

Status Changes

A status change occurs when a lab asks to change its certificate type, usually because the lab has changed the type of tests it performs.

The Status Change function is available to the following users:

- SA – when the lab’s physical address is in your state
- RO – when the lab’s physical address is in one of your states
- CO
- Hawaii users can perform status changes for Pacific Territories labs.
- Central Office users can perform status changes for Virgin Islands and international labs.

The Status Change function is unavailable:

- If the lab is terminated.
- If there is a survey pending or in progress in ACO *unless* the survey is part of an initial certification kit and Certificate Type Change Due to Survey was set to Yes in ACO.

Note: To prevent the creation of overlapping certificates, you cannot perform a status change and a class code change for a lab on the same day.

Enter Status Changes

Most status changes share the same basic steps. The CLIA 116 web app follows the rules for various types of status change and will provide informational messages as necessary when processing a status change.

Status changes remain pending until they are processed during the batch program. You can remove a pending status change if necessary.

Within 6 months of Effective Date

If the lab has a current or pending certificate that is within six months of its effective date, you can use a status change to “correct” the certificate type. Corrected certificates retain the original effective date.

If you decide to enter a full status change rather than a correction, the edit checks on the lab record change to those for the new certificate type. If you change certificate type from Waiver to Compliance, you must enter specialties before you can save the record. The CLIA 116 web app will advise you about the date range allowed for the new effective date.

Over 6 months past Effective Date

If the lab's certificate has been in effect for more than six months, any change to the certificate type must be handled as a status change with a new effective date. Depending on the situation, the CLIA 116 web app will either generate the new effective date or let you know the allowable date range. It generally can never be earlier than the current effective date or later than the current expiration date plus one day.

Saving a status change

When you click Save in the Status Change window, you are saving the proposed status change. The CLIA 116 web app generates a warning message that summarizes the details. You have to save the lab record to actually save a status change. The CLIA 116 web application will apply all the edits for the new certificate type. When the lab record is successfully saved, the warning message is retained as an attachment to the record. You can review the message at any time by opening Attachments.

To change the requested application/certificate type:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.
3. As the **Reason for 116** (on the **Demographics** tab), select **02 Change in Certificate Type**.
4. Update **Name** if necessary.
5. On the **Specialties** tab, enter the applicable **Total Annual test volume** as necessary.

   For a status change to application/certificate type 2 Waiver or to 4 PPM, you must enter waived or PPM test volume respectively.
6. At the bottom of the window, click **Status Change**.
7. In the **Status Change section**, answer **Yes** to **Is this a correction?** if you want to "correct" the certificate type.

   The lab must have a current or pending certificate within six months of its Effective Date. If corrections are not allowed, you will receive a message.

8 Select the **New App Type**.

You will receive a message if the lab director has to be qualified for the new application/certificate type.

9 Enter the **New Eff Date** as applicable.

The CLIA 116 web app will either generate the new effective date or tell you the allowable date range.

10 Click **Save**.

If you entered a status change rather than a correction and the new effective date is within six months of the current effective date, a message indicates the lab will be assessed new fees. Click **OK** to continue.

The CLIA 116 web app provides a warning message that summarizes details of the proposed status change including the new application type and effective date, when the current certificate ends, and information about the billing process.

11 Click **OK** in the warning message to save the details of the proposed status change.

WARNING! The status change itself is not saved yet.

12 For a status change to 3 Accreditation, go to the **Accred Org Info** tab and specify an affiliated AO.

13 To save the status change, click **Save** at the bottom of the lab record.

The warning summary is retained as an attachment to the lab record. You can review it at any time from the Attachments window.

More ...

Procedure: “Locate Labs” on page 38
Procedure: “View Attachments” on page 59
Screen: "Demographics tab" on page 305
Screen: "Specialties tab" on page 307
Screen: "Status Change window" on page 315

Row= Notation

A ROW= notation is added whenever there is a status change. This can be useful to the Help Desk if there is an error, so it is a good idea to note it. Each row in the system table represents a particular situation.

In the rare event that ROW=UNKNOWN appears, it means the CLIA 116 web app could not find a row that matches your situation. In this case, the change is not saved and you should contact the Help Desk.

Reverse Pending Status Changes

Status changes remain pending until they are processed during the batch program. You can remove a status change while it is pending, i.e., it is listed as New (see graphic).

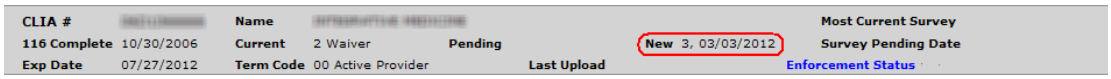

Figure 12: Pending status change

To reverse a pending status change:

1. To remove a status change while it is pending, click **Status Change** at the bottom of the lab record.

   A message tells you a status change is pending and briefly details the specifics of the change.

2. Click **OK** to indicate you want to remove the pending status change.
3. Click **OK** in the confirmation message to remove the pending status change.

Note: If you remove a pending status change to 3 Accreditation, you must also remove the affiliated AO.

Status Change Due to Survey

Certificate Type Change Due to Survey is set to Yes on an initial certification in ACO (in the CLIA section at the bottom of Certification & Surveys tab) in two circumstances:

- During the initial onsite survey, the lab was found to be performing only waived or PPM tests.
- The lab chose to downgrade its registration certificate as a result of survey findings.

After the kit is successfully uploaded, you must enter the status change in the CLIA 116 web app. The timing is important. You *must first* upload the initial cert kit with the certificate type change, then ***wait one day*** before entering the status change in the CLIA 116 web app. If the timing is not correct, you will not be allowed to do the status change.

If a survey is pending or in progress, the Status Change button is disabled. If a lab decides to change its certificate type in the course of a survey, you will not be able to immediately perform a status change. This is because you cannot open the Status Change window until the certification kit containing the survey is successfully uploaded. You need to finish the survey, upload the kit, then change the certificate type in the lab record on the following day.

Note: If no survey will be done, you can delete the certification kit and immediately perform the status change.

Termination and Reactivation

Both terminations and reactivations are entered in the Termination window. As is generally the case in the CLIA 116 web app, the fields that are enabled depend on the situation and your user type and permissions.

Terminate a Lab

The conditions under which you perform terminations vary a good deal. In the case of Accredited labs, for example, the AO conveys to CMS through a Remarks code entered in the CLIA 116 web app that a lab has withdrawn, or was never affiliated. The system then sends a letter to the lab asking them to contact their SA and provide more current information. If the lab's information is not updated by the time its renewal fee is due, the system sends a second letter. If changes are not made, the system will terminate the lab's certificate.

Most terminations share the same basic steps. The CLIA 116 web app follows rules for terminations in various circumstances and activates fields as necessary when processing a termination.

Note: The Termination function is unavailable if there is a survey pending or in progress in ACO *unless* the survey is part of an initial certification kit and Certificate Type Change Due to Survey was set to Yes in ACO.

When a lab has been terminated more than six months and the certificate expiration date has passed, the cleanup program clears certificate information and audits off bills. The assigned termination code can be changed for a cleaned-up lab.

To terminate a lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.
5. In the **Termination** window, select the appropriate **Term Code**.

   Note: SA users cannot select termination codes 80 (Awaiting State Approval), 33 (Accreditation not Confirmed), and 99 (Do Not Reactivate Without Checking with RO). SA and RO users cannot select termination code 08 (Non-Payment of Fees).

   Termination Date is now enabled.

   Note: If you select 13 Multiple to Single Site Certificate, then Cross Reference Provider Number on the Additional Info tab will be required.

6 For **Termination Date**, enter the expiration date for the lab.

7 Click **Save** to save the details of the termination and close the Termination window.

WARNING! The termination is not saved yet.

8 To save the termination, click **Save** at the bottom of the lab record.

When a laboratory is terminated, any multiple site location with a Status of Active will remain Active.

Note: AO information for Accredited labs is removed after 6 months of termination.

More ...

Procedure: “Locate Labs” on page 38
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Supporting Materials: "Termination/Reactivation Scenarios" on page 535

Terminating Labs with Specialties

When you terminate a Compliance or Accredited lab that has specialties, the 116 specialties will be read-only until the termination is processed, at which point they are deleted. Waived/PPM test volume values are set to null.

Survey specialties are closed out and no longer appear on the Specialties tab except in Specialty History. The expiration date for survey specialties is set to the termination date you enter for the certificate. The schedule code and Waived/PPM test volume values are set to null.

You can still view these prior survey specialties:

➥ in the CLIA 116 web app, select the **Specialty History** button on the **Specialties** tab.

-or-

➥ In ACO, right-click the facility in the tree and select **Specialties**.

Note: If you reactivate a lab without a gap, the CLIA 116 web app reopens the lab’s survey specialties and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

Reactivate a Terminated Lab

You can reactivate a lab with or without a gap depending primarily on whether it has been more or less than 6 months since the termination date. The CLIA 116 web app calculates the 6 month cutoff date by adding 6 months to the termination date. If the resulting date is invalid (February 30, for instance), it goes back to the first valid date (February 28).

There are many rules governing the reactivation of terminated labs. The CLIA 116 web app looks at the days since termination, certificate type and status, and activates fields as needed. It also either generates the new effective date for you or advises you of appropriate date ranges.

Whether you reactivate with or without a gap, the Cert & Billing process will run as usual during the batch program. If you expect a fee coupon and/or a certificate as a result of your change, use the Certificate/Billing Inquiry option to check the lab after the Cert & Billing process runs to confirm.

Laboratories applying to the CLIA program for the first time that were terminated with code 80 (Awaiting State Approval) must be reactivated within 6 months of the pending effective date.

For labs terminated more than six months past the certificate expiration date, the cleanup program has already cleared certificate information and audited off bills.

More ...

Procedure: “Reactivate a Lab with a Gap” on page 73
Procedure: “Reactivate a Lab without a Gap” on page 75
Procedure: “View Certificate and Billing Information” on page 65
Procedure: “Reactivate a Terminated (Code 80) Lab” on page 76

Reactivate a Lab with a Gap

If it has been less than six months since the termination date, the lab can be reactivated with a gap, except for Accredited labs with AO confirmation. If it has been more than six months since the termination date, the system forces a gap in the certificate period, regardless of certificate type.

If a gap in the certificate cycle is chosen or forced, you can select either a different certificate (application) type in the Gap App Type field, or the same type the lab held previously. If has been more than six months since the lab was terminated, all other fields are disabled. After you save the Termination window, then save the lab record, the system sets the pending effective date to today’s date.

If it has been less than six months since the lab was terminated, enter the date that will start the new certificate period in the Gap Eff Date field. The current certificate remains terminated, and the termination code appears in certificate history.

If you select a new certificate (application) type, the lab record must pass all edits for that certificate type to be saved successfully. If you change the application type from Waiver to Compliance, at least one specialty and test volume must be selected on the Specialties tab.

To reactivate a lab with a gap in certificate cycles:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.
5. For **Term Code**, select **00 Active Provider**.
6. As appropriate, set **Gap?** to **Yes**.

   This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.
7. As appropriate, enter the **Gap Effective Date**.

   This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date. In that case, the Gap Effective Date should not be later than 6 months from today. The termination code for the pending certificate is set to 00 and the pending effective date is set to this date.
8. As appropriate, select **Gap App Type**.

   This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.
9. Enter information on the **Accred Org Info** and **Specialties** tabs as appropriate.

10 Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

11 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate Labs" on page 38
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Reactivate a Lab without a Gap

If there is no gap in the certificate cycle, the reactivated lab cannot change certificate (application) type. The system re-opens the former certificate and retains the original certificate effective date (*except* for a lab with a current and pending certificate reactivated with a fake gap after more than 6 months).

Note: If you reactivate an Accredited lab with AO confirmation within 6 months, you must reactivate it without a gap.

To reactivate a lab without a gap in certificate cycles:

1 Search the national CLIA database for the lab.

2 In the **CLIA 116 Search Results** list, select the lab.

3 As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.

4 Click **Termination** at the bottom of the window.

5 For **Term Code**, select **00 Active Provider**.

6 As appropriate, set **Gap?** to **No**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate, and there is no gap between the current expiration date and the pending effective date.

7 As appropriate, select **Gap App Type**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate more than 6 months after the current expiration date, and there is no apparent gap between the current expiration date and the pending effective date. This is known as a fake gap.

In that case, select the lab's previous application type. The termination code for the pending certificate is set to 00 and the pending effective date is set to today.

8 As needed, enter information on the **Accred Org Info** and **Specialties** tabs.

For example, when you reactivate a lab without a gap, the CLIA 116 web app reopens the lab's survey specialties that were closed during termination and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

9 Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

10 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate Labs" on page 38
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Reactivate a Terminated (Code 80) Lab

A lab applying to the CLIA program for the first time will sometimes send a completed Laboratory Application (CMS-116) form, along with payment, to the CLIA lockbox address. The CLIA lockbox will cash the check and then send the CMS-116 form to the CLIA billing and issuance contractor for entry into the ASPEN CLIA database and assignment of the CCN. Once the CCN is assigned, the money is applied to the lab and the CLIA 116 Web app will generate termination code 80 (Awaiting State Approval), which indicates that the CMS-116 was entered by an entity other than the State Agency.

The CLIA billing and issuance contractor will then send the completed CMS-116 form to the State Agency with a cover letter that explains the steps needed to complete the processing of the initial application. After verifying the accuracy of the information reported by the laboratory, i.e., checking for duplicates, qualifying lab director, the laboratory must be reactivated by changing the termination code from 80 to 00 (Active). The reactivation must be done in a timely manner (within 6 months of the pending effective date) so that the lab payment can be applied and a new CLIA certificate issued.

Row = Notation

A ROW= notation is added whenever a termination or reactivation is done. This can be useful to the Help Desk if there is an error, so it is a good idea to note it. Each row in the system table represents a particular situation.

In the rare event that ROW=UNKNOWN appears, it means the CLIA 116 web app could not find a row that matches your situation. In this case, the termination or reactivation is not saved and you should contact the Help Desk.

View Audit History

The Audit History window is available from all tabs and gives a complete history of changes made to values of audited fields. The header provides general information about the lab record. The fields in each section vary, but always include:

- Date/time of each change
- ID of user who made the change
- Old and/or current value

To view the audit history for a lab record:

➥ Open a lab record in **Update** or **Inquiry** mode and click **Audit History** at the bottom of the window.

The Audit History window opens. All audited fields are listed. If no changes have been made, the field is blank. If values have changed, they are listed in reverse chronological order with the original value at the bottom and the current value at the top.

More ...

Screen: "Audit History window" on page 313
Procedure: “Update a Lab Record” on page 62
Procedure: “Lab Record Inquiry” on page 64

Audit History - Physical Address example

This example shows the audit history for a lab's physical address.

Physical Address

Date of Change	User ID	Address 1	Address 2	City	State	Zip	Ext	County
Current	N/A	MAIN STREET SUITE 180		COLORADO SPRINGS	CO	80909		200
03/22/2007 19:17	H35V	MAIN STREET SUITE #180						
04/01/2005 18:33	W28K	402 WEST STREET						

Figure 13: Physical Address section

The value of Address 1 under Physical Address has changed twice. The original value was 402 West Street. On 04/01/2005 (April 1, 2005) at 18:33 (6:33 p.m.), a user whose ID was W28K changed it to Main Street Suite #180. On 03/22/2007 (March 22, 2007) at 19:17 (7:17 p.m.), a user whose ID was H35V changed it to Main Street Suite 180 (deleted # before 180), which is the Current value.

Audit History - AO Information examples

In the AO Information section, AOs are sorted numerically by Accreditation Code and data is listed chronologically in descending order, starting with the X-match (first entry of an AO for a laboratory) to provide a full history of changes.

Audit information for all AOs currently sponsoring the laboratory is shown at the top of the AO Information section with the word Current for Date of Change and time and N/A for User ID. Historical information follows.

For any laboratory where the X-match was entered prior to ASPEN 11.3, there will be no audit history for the X-match. All auditing will begin with the first change after the X-match, either Y-match confirmation or remarks code entry.

In the following example, X-match was audited for TJC (01) but not CAP (04), because the X-match was entered before the ASPEN 11.3 release.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01				
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 14: AO Information section

Here is the audit history after a Y-match was entered for TJC.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01	Y	04/17/2018		
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 15: AO Information after Y-match entered

Then a remarks code was entered for TJC.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01	Y	04/17/2018	31	04/17/2018
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:47:12	HELP DESK,HELP DESK	01	Y	04/17/2018	31	04/17/2018
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 16: AO Information after remarks code entered

All AO Information deleted in the cleanup process is audited with the user ID of CLAB in order to accurately track where the removal occurred. Historical information follows in AO code order.

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	04	Y	04/10/2013		
2018-04-18 14:27:50	CLAB	01				
2018-04-17 14:47:12	HELP DESK,HELP DESK	01	Y	04/17/2018	31	04/17/2018
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 17: AO Information after cleanup

Audit History - AO Survey Dates examples

The AO Survey Dates section lists dates of AO surveys in descending chronological order grouped by AO code. Information from audited records includes:

- Date of change - add date for surveys created in ASPEN 11.3 and later, survey date for pre-11.3 surveys
- User who made the change
- AO survey date

All surveys listed on the Accred Org Info tab of the 116 (up to four) are included in the top "current" section; Date of Change is Current and User ID is N/A. The four current surveys are also listed in the "history" section below the current section, but with Date of Change and User ID specified. Any surveys with dates prior to the four current surveys are displayed in the history section below the current surveys.

The example below shows the audit history for a lab with five recorded AO surveys.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date
Current	N/A	04	02/02/2016
Current	N/A	04	04/09/2014
Current	N/A	04	02/06/2013
Current	N/A	04	02/04/2011
02/02/2016 00:00	UACR	04	02/02/2016
04/09/2014 00:00	UACR	04	04/09/2014
02/06/2013 00:00	UACR	04	02/06/2013
02/04/2011 00:00	UACR	04	02/04/2011
02/04/2009 00:00	UACR	04	02/04/2009

Figure 18: AO Survey Dates section

When an AO adds a survey with a date at least one year after the latest current AO survey date, it is added to both the current and history lists. When the fourth oldest AO survey becomes the fifth oldest, it will be removed from the current list, but will remain on the history list. These two points are illustrated below.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date	
Current	N/A	04	04/15/2018	new survey
Current	N/A	04	02/02/2016	
Current	N/A	04	04/09/2014	
Current	N/A	04	02/06/2013	
04/18/2018 15:08	HELP DESK,HELP DESK	04	04/15/2018	new survey
02/02/2016 00:00	UACR	04	02/02/2016	
04/09/2014 00:00	UACR	04	04/09/2014	
02/06/2013 00:00	UACR	04	02/06/2013	
02/04/2011 00:00	UACR	04	02/04/2011	no longer current
02/04/2009 00:00	UACR	04	02/04/2009	

Figure 19: AO Survey Dates - survey added 1 year+ later, 5th oldest survey not current

When an AO changes a survey date within one year of entering the original date, both survey dates are included in the history list as separate entries. The current list will show only the new date.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date	
Current	N/A	04	04/17/2018	new date
Current	N/A	04	02/02/2016	
Current	N/A	04	04/09/2014	
Current	N/A	04	02/06/2013	
04/18/2018 15:59	HELP DESK,HELP DESK	04	04/17/2018	new date
04/18/2018 15:29	HELP DESK,HELP DESK	04	04/15/2018	original date
02/02/2016 00:00	UACR	04	02/02/2016	
04/09/2014 00:00	UACR	04	04/09/2014	
02/06/2013 00:00	UACR	04	02/06/2013	
02/04/2011 00:00	UACR	04	02/04/2011	
02/04/2009 00:00	UACR	04	02/04/2009	

Figure 20: AO Survey Dates - survey date changed within one year

When an AO no longer sponsors the lab, the system deletes all surveys for that AO during cleanup. There will be no current surveys listed for the AO, but the deleted surveys still appear in the history section.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date
04/18/2018 15:59	HELP DESK,HELP DESK	04	04/17/2018
04/18/2018 15:29	HELP DESK,HELP DESK	04	04/15/2018
02/02/2016 00:00	UACR	04	02/02/2016
04/09/2014 00:00	UACR	04	04/09/2014
02/06/2013 00:00	UACR	04	02/06/2013
02/04/2011 00:00	UACR	04	02/04/2011
02/04/2009 00:00	UACR	04	02/04/2009

Figure 21: AO Survey Dates after cleanup

View CWF Files

CO Super Users

When labs receive Medicare denials because of incorrect CLIA certification, CO Super Users need to view system-generated Common Working File (CWF) files in order to verify information sent to Medicare Part B contractors.

To view CWF files:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **CWF Download**.

   This provides access to the appropriate application for viewing CWF files.

More ...

Procedure: “Open ASPEN Web CLIA from ACO/ARO” on page 32
Procedure: “Open ASPEN Web CLIA from a Browser” on page 33
Screen: "ASPEN Web CLIA - Select Application window" on page 299

View MSA Files

CO Super Users

When labs receive Medicare denials because of incorrect CLIA certification, CO Super Users need to view the system-generated Medicaid State Agency (MSA) files in order to verify information sent to Medicaid State Agencies and, if necessary, trigger updates to the CLIA database for insertion in the CWF files.

To view MSA files:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **MSA Download**.

   This provides access to the appropriate application for viewing MSA files.

More ...

Procedure: “Open ASPEN Web CLIA from ACO/ARO” on page 32
Procedure: “Open ASPEN Web CLIA from a Browser” on page 33
Screen: "ASPEN Web CLIA - Select Application window" on page 299

View System Information

The System Information window displays current QIES and ASPEN system information. It indicates any state databases or providers set to read-only due to overnight processing errors, and displays messages posted about system status or processing errors. It also provides access to batch billing job logs (audit files).

To view system information:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **System Information**.

   Current system information and a list of batch billing job logs from the past week are displayed.
3. In the **Batch Jobs** section, enter **From Date** and **To Date** to specify the date range you want and click **Find** to update the list of audit files.
4. in the **View Audit Messages** column, click **View** for the audit file you want to view.

   It opens in a text editor, which you can close when you are done.
5. To print the contents of the System Information window, click the **Print** button.

6 To close the System Information window and return to the Select Application window, click **Done**.

More ...

Procedure: “Open ASPEN Web CLIA from ACO/ARO” on page 32
Procedure: “Open ASPEN Web CLIA from a Browser” on page 33
Screen: "ASPEN Web CLIA - Select Application window" on page 299

CLIA Maintenance

The CLIA Maintenance application in ASPEN Web provides access to the following items for users with appropriate permissions:

- Accreditation Fee Table
- Compliance/Certificate Fee Table
- State Agency List
- PT Program Maintenance
- PT Analyte Maintenance
- PT Program Analyte Maintenance
- PT Enrollment Inquiry
- PT Score Inquiry
- PT File Upload

Access CLIA Maintenance

CLIA users must have a current national system login in order to open ASPEN Web CLIA Maintenance. There are two ways to do this:

- From within ACO
- From a browser, most likely Internet Explorer

SA users will generally access CLIA Maintenance from ACO. RO and CO users may be more inclined to open ASPEN Web CLIA Maintenance from a browser.

Note: Your ASPEN coordinator defines application access permissions for staff members. If you have difficulty logging in, contact your coordinator. For information and procedures related to creating and maintaining personnel records in ASPEN, including CLIA-specific details, refer to the latest version of the *ACO Procedures Guide*, which is posted on the QTSO website at https://qtso.cms.gov.html.

Open CLIA Maintenance from ACO/ARO

To open CLIA Maintenance, you need to have a current national system login.

To open CLIA Maintenance from ACO/ARO:

1. Click the **CLIA** button in the ACO/ARO toolbar:

Figure 22: CLIA button in the ACO/ARO toolbar

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
3. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.
4. Select **CLIA Maintenance System**.

   ASPEN Web CLIA Maintenance opens and the Select Application window appears; available options are specific to your user type.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300

Open CLIA Maintenance from a Browser

To open ASPEN Web CLIA Maintenance in your browser, you need to know the URL for the ASPEN Access page and have a current national system login.

To open ASPEN Web CLIA Maintenance in your browser:

1. Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen
2. Click the **ASPEN Web** link.
3. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
4. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.
5. Select **CLIA Maintenance System**.

   ASPEN Web CLIA Maintenance opens and the Select Application window appears; available options are specific to your user type.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300

View Accreditation Fee Information

CO

Central Office personnel can review accreditation fee information for the latest fee version in the Accreditation Fee Table.

To access the Accreditation Fee Table:

1. Open the **CLIA Maintenance** application.
2. In the ASPEN Web CLIA Maintenance - **Select Application** window, select **Accreditation Fee Table**.

   The Accreditation Fee Table lists all entries in the CLIA State Fee view for the given version number.
3. Use the navigation tools at the top (First, Previous, etc.) to page through the table.
4. To print the entire table, click **Print** at the bottom.
5. Click **Exit** to close the table and return to the Select Application window.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "Accreditation Fee Table" on page 373

View Compliance/Certificate Fee Information

CO

Central Office personnel can open the Compliance/Certificate Fee Table to review compliance and certificate fee information for the latest fee version.

To access the Compliance/Certificate Fee Table:

1. Open the **CLIA Maintenance** application.
2. In the ASPEN Web CLIA Maintenance - **Select Application** window, select **Comp/Cert Fee Table**.

   The Compliance/Certificate Fee Table lists all entries in the CLIA State Fee view for the given version number.
3. Use the navigation tools at the top (First, Previous, etc.) to page through the table.
4. To print the entire table, click **Print** at the bottom.

5 Click **Exit** to close the table and return to the Select Application window.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "Compliance/Certificate Fee Table" on page 374

View and Modify State Agency Information

CO

The State Agency List displays state agency information used on correspondence to labs. CO Super Users can update and add records as necessary.

Open the State Agency List

To display the State Agency List:

1 Open the **CLIA Maintenance** application.

2 In the ASPEN Web CLIA Maintenance - **Select Application** window, select **State Agency Address**.

The State Agency List opens.

3 Use the navigation tools at the top (First, Previous etc.) to page through the table.

4 To print the entire list, click **Print**.

5 Click **Exit** to close the table and return to the Select Application window.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "State Agency List" on page 375

View and Modify Information for a State Agency

To view and modify information for a State Agency:

1 In the State Agency List, select the agency and click **Inquiry** to view agency information.

2 To update agency information, click **Update** and enter the changes.

3 To print the information, click **Print**.

4 Click **Save** to save the changes and return to the State Agency List. Click **Cancel** to exit without making changes or without saving changes you made.

More ...

Procedure: "Open the State Agency List" on page 86
Screen: "State Agency List" on page 375
Screen: "State Agency Address - Update window" on page 375

Add a State Agency

To add address details/an additional address for a State Agency:

1 In the State Agency List, select **Add**.

2 Select **SSA State Code** (required).

Region and State are determined by SSA State Code.

3 Enter information for the new agency.

4 To print the new agency details, click **Print**.

5 Click **Save** to save the new agency record and return to the State Agency List.

6 Click **Cancel** to exit without saving the information you entered.

More ...

Procedure: "Open the State Agency List" on page 86
Screen: "State Agency List" on page 375
Screen: "State Agency Address - Update window" on page 375

PT Programs

When you select the PT Program Maintenance option from the CLIA Maintenance menu, the PT Program List is displayed.

From the PT Program List, CO Super Users and PT Super Users can:

- Add new PT Programs
- Update PT Program information
- Delete PT Program information if there is no associated score, enrollment, or analyte data.

PT Program, SA and RO users can view PT Program information in Inquiry (read-only) mode, and are restricted to viewing only their own programs.

Expired PT Programs are grayed out in the PT Program List.

Open PT Program List

To display the PT Program List:

1. Open the **CLIA Maintenance** application.
2. In ASPEN Web CLIA Maintenance - **Select Application** window, select **PT Program Maintenance**.

   The PT Program List opens.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "PT Program List" on page 376

Add PT Programs

Only CO Super Users and PT Super Users can add PT Programs. When a new PT Program is added, the system assigns a unique, one up ID number. If a PT Program is deleted, that number is skipped. The system will continue to use a one up number and there will be a gap in the numbering for the deleted record. The system supports entry of up to 99 PT Programs.

To add a PT Program:

1. Open the **PT Program List**.
2. Select the **Add** button on the PT Program List screen to open the PT Program - Add window.
3. Select the **Type of Organization** and **Effective Date**.
4. Enter the Physical Address including **Name**, **Street**, **US/International**, **Zip**, and **City**. State is determined by Zip.
5. Enter Contact information.
6. Select **Save** to save the new PT Program record to the PT Program List.

   If a required field is missing, you will receive an error.

More ...

Procedure: “Open PT Program List” on page 88
Screen: "PT Program List" on page 376
Screen: "PT Program Add/Update/Inquiry" on page 377

View/Modify PT Program

Only CO and PT Super Users can modify PT Program information. PT Program, SA and RO users can view the information in Inquiry mode for their own program.

To view/modify a PT Program:

1. Open the **PT Program List**.
2. Select the **Update/Inquiry** button on the PT Program List screen to open the PT Program - Update/Inquiry window.
3. CO and PT Supers Users can update PT Program information as needed.
4. Select **Save** or **Exit**, as applicable, to return to the PT Program List.

   If you select Save and a required field is missing, you will receive an error.

More ...

Procedure: “Open PT Program List” on page 88
Screen: "PT Program List" on page 376
Screen: "PT Program Add/Update/Inquiry" on page 377

PT Analyte

When you select PT Analyte Maintenance from the CLIA Maintenance menu, the PT Analyte List is displayed.

From the PT Analyte List, CO and PT Super Users can:

- Enter new analytes

  The system supports entry of up to 9999 analytes.
- Enter new group analytes
- Associate non-group analytes with a group analyte
- Update analyte information
- Delete an analyte if there is no associated enrollment, PT Program, or score data
- Mark an analyte as deprecated
- Associate an analyte with a specific PT Program for a specific year

- Delete the association of an analyte with a PT Program if there is no enrollment or score data associated with the analyte for a given year
- Copy analytes associated with a given PT Program from a prior year to a new year
- View the number of corrections a given PT Program made to scores in a given test year

PT Program, SA and RO users can view PT Analyte information in Inquiry (read-only) mode for their own programs.

Open PT Analyte List

To display the PT Analyte List:

1. Open the **CLIA Maintenance** application.
2. In ASPEN Web CLIA Maintenance - **Select Application** window, select **PT Analyte Maintenance**.

   The PT Analyte List opens.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "PT Analyte List" on page 378

Add PT Analyte

Only CO and PT Super Users can add a PT Analyte.

To add a PT Analyte:

1. Open the **PT Analyte List**.
2. Select the **Add** button on the PT Analyte List screen to open the PT Analyte - Add window.
3. Enter information in all required fields.
4. Select **Save** to save the new PT Analyte record.

   If a required field is missing, you will receive an error.

More ...

Procedure: “Open PT Analyte List” on page 90
Screen: "PT Analyte List" on page 378
Screen: "PT Analyte Add/Update/Inquiry" on page 378

View/Modify PT Analyte

Only CO and PT Super Users can modify PT Analyte information. PT Program, SA and RO users can view the information in Inquiry mode.

To view/modify a PT Analyte:

1. Open the **PT Analyte List**.
2. Select the **Update/Inquiry** button on the PT Analyte List screen to open the PT Analyte - Update/Inquiry window.
3. CO and PT Super Users can update PT Analytes as needed.
4. If the analyte is no longer valid, check **Deprecated**, and enter **Analyte No Longer Valid After Test Year**.
5. Select **Save** or **Exit**, as applicable, to return to the PT Analyte List.

   If you select Save and a required field is missing, you will receive an error.

More ...

Procedure: “Open PT Analyte List” on page 90
Screen: "PT Analyte List" on page 378
Screen: "PT Analyte Add/Update/Inquiry" on page 378

View and Modify PT Program Analytes

When you select the PT Program Analyte Maintenance option from the CLIA Maintenance menu, the PT Program Analyte Search screen opens. CO and PT Super Users can add and delete program analytes. PT Program, SA and RO users can view a list of program analytes in read-only mode for their own programs. All users can print a hard copy of the list.

To search for a program analyte:

1. Open the **CLIA Maintenance** application.
2. In ASPEN Web CLIA Maintenance - **Select Application** window, select **PT Program Analyte Maintenance**.

   The Program Analyte Search window opens.
3. In the **Search for Approved Program Analytes** screen section, use the drop-down lists to select the **Program #** and **Test Year**.
4. Select **Search**.

   The PT Program Analyte window opens.
5. **New Search** clears all search criteria in both screen sections.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "Program Analyte Search" on page 379
Screen: "PT Program Analyte window" on page 380

Copy PT Program Analytes

From the PT Program Analyte Search window, CO and PT Super Users can open the PT Program Analyte Copy window to copy analytes forward from one test year to another.

To copy PT Program analytes to a new test year:

1. Open the **Program Analyte Search** window.
2. In the **Copy Program Analytes Forward** screen section, select the **Copy From Test Year** from the drop-down list.
3. Enter the **Copy To Test Year.**
4. Select **Search**.

   The PT Program Analyte Copy window opens.
5. Select the checkbox beside the PT Programs whose analytes you want to copy to the new test year.

   If the PT Program already exists in the Copy to Test Year, N/A displays instead of the checkbox.
6. Select the **Process** button to perform the copy.
7. Click **OK** in the confirmation message.

   Operation Successful displays at the top of the Copy From Test Year section.

More ...

Procedure: “To search for a program analyte:” on page 91
Screen: "Program Analyte Search" on page 379
Screen: "PT Program Analyte Copy window" on page 381

Add Analytes to PT Programs

CO and PT Super Users can add and delete analytes from PT Programs.

To add an analyte to a PT Program:

1. Open the **Program Analyte Search** window.
2. In the **Search for Approved Program Analytes** screen section, use the drop-down lists to select the **Program #** and **Test Year**.
3. Select **Search**.

   The PT Program Analyte window opens.
4. Click the **Add** button.

   If there are no analytes to add, a pop-up message displays.

5 Select an analyte from the drop-down list. Continue to add analytes as needed.

6 Click **Save** to save the new analyte records and return to the Program Analyte Search window.

More ...

Procedure: “To search for a program analyte:” on page 91
Screen: "Program Analyte Search" on page 379
Screen: "PT Program Analyte window" on page 380

PT Enrollment and Score Information

Users with the proper security class can view enrollment and score information for the last five years. Details are viewable as read-only, scrollable lists containing data specified by the search screens. An Inquiry button is also available on the PT Enrollment List to view provider address information.

Open PT Enrollment List

To open the PT Enrollment List:

1 Open the **CLIA Maintenance** application.

2 In ASPEN Web CLIA Maintenance - **Select Application** window, select **PT Enrollment Inquiry**.

The PT Enrollment Search window opens.

3 Enter your search criteria.

4 Select the sort order in the Sort By screen section, and click **Find**.

The PT Enrollment List displays with enrollment information that matches the search criteria.

5 Highlight a row and select **Inquiry** to view provider information.

The Inquiry button is not enabled unless a row is selected.

6 Select **Exit** to return to the PT Enrollment List.

7 Select **Main Menu** to exit the PT Enrollment List.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "PT Enrollment Search window" on page 382
Screen: "PT Enrollment List window" on page 383
Screen: "PT Address Inquiry" on page 383

Open PT Score List

To open the PT Score List:

1. Open the **CLIA Maintenance** application.
2. In ASPEN Web CLIA Maintenance - **Select Application** window, select **PT Score Inquiry**.

   The PT Score Search window opens.
3. Enter your search criteria.
4. Select the sort order in the Sort By screen section, and click **Find**.

   The PT Score List displays with score information that matches the search criteria.
5. Select **Main Menu** to exit the PT Score List.

More ...

Procedure: “Open CLIA Maintenance from ACO/ARO” on page 84
Procedure: “Open CLIA Maintenance from a Browser” on page 84
Screen: "ASPEN Web CLIA Maintenance - Select Application window" on page 300
Screen: "PT Score Search window" on page 384
Screen: "PT Score List window" on page 385

Upload PT Files

The PT File Upload option on the CLIA Maintenance menu calls an application that allows qualified PT users to upload data files and download result files. For details, refer to the *CLIA PT Upload User's Guide* from Telligen (formerly Iowa Foundation for Medical Care).

CLIA Certification: CO, RO, SA

This chapter introduces you to the various aspects of processing CLIA certifications in ACO/ARO, including how to create, populate, track, and upload CLIA certification kits and surveys.

CLIA Personnel Records in ACO

For information and procedures related to creating and maintaining personnel records in ACO, including CLIA-specific details, refer to the *ACO Procedures Guide*, which is posted at https://qtso.cms.gov.

CLIA Provider Records in ACO

A record must exist in ACO for a CLIA lab before you can create certification kits, surveys, and complaint/incident intakes (in ACTS) for that lab.

Note: ACO does not include CLIA labs terminated before January 1, 2000, *unless* they have been manually added by your agency *or* they have historical certification kits or surveys that were added to ACO.

CLIA Lab Subtypes

The CLIA lab subtypes supported by ACO are shown below.

· 221 (LAB_CMPL)	Certificate of Compliance
· 222 (LAB_WAIV)	Certificate of Waiver
· 223 (LAB_ACCR)	Certificate of Accreditation
· 224 (LAB_PPMP)	Certificate of PPMP
· 225 (LAB_NOCN)	No CLIA Number (entered in ASPEN)

Figure 23: Lab subtypes

In ACO, CLIA provider information for subtypes 221-224 is automatically entered and updated from the CLIA 116 web app during a nightly extract and load process. You can only add new labs of subtype 225-NO CLIA NUMBER in ACO.

Note: Subtype 220-Pending Certificate Only (all application types) is no longer used, but CLIA provider records of this subtype may still exist in the system.

Open Define New Facility/Facility Properties window

The window specifying facility properties has two possible titles. You use the Define New Facility window to add records for labs of subtype 225 to ACO. When you view or modify an existing provider record for a CLIA lab, the window title is <FacName> Definition where FacName is the name of the lab.

Since the <FacName> Definition window is commonly referred to as Facility Properties (the name of the right-click option used to access it), it is often called the Facility Properties window in this procedures guide.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app. Provider information that you optionally add in ACO will not appear in the national CLIA database.

To open the Define New Facility window:

➥ Click **Facility** on the **ACO Explorer** toolbar, or from the **File** menu, select **New Facility**.

To open the Facility Properties window:

➥ Locate the facility in the **Tree** view, right-click it, and select **Facility Properties**.

Add CLIA Provider Records

A new lab completes a CMS-116 application for a certificate. The data on this form must be entered into the CLIA 116 web app in order for a CLIA number to be assigned to the lab. Once a number is assigned, a provider record will be automatically created in ACO that evening and assigned the correct CLIA subtype: 221 LAB-CMPL, 222 LAB-WAIV, 223 LAB-ACCR, or 224 LAB-PPMP.

The only labs you can directly add via the New Facility function in ACO are of subtype 225 LAB-NO CLIA NUMBER (NOCN). This subtype lets you add labs directly to ACO even if they do not yet have a CLIA number. This makes it possible to enter complaints against labs that are not updated by nightly processing since the CMS-116 has not been completed for them. The CLIA 116 web app does not contain information for these 225 labs.

Note: You *cannot* create certification kits for 225 labs.

As with other provider categories in ACO, you can also add state-licensed labs by creating your own CLIA subtype, such as 22L-Licensed Labs. Subtype 225 is not intended for licensed-only labs.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app. Provider information that you optionally add in ACO will not appear in the national CLIA database.

More ...

Procedure: "Modify CLIA Provider Records" on page 107

Enter Facility Definition Information

The Facility Definition tab in the Define New Facility/Facility Properties window contains basic identification, description, and contact information for a lab.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To enter facility definition information:

1. On the **Facility Definition** tab in the **Define New Facility/Facility Properties** window, as applicable, enter the **Medicaid ID**, **Employer ID**, and **State Key** for the lab.

   The system will generate the **Facility ID**. Do *not* enter a **CMS Certification Number** (CCN aka CLIA #/number, CLIA provider number, Medicare provider number, provider #/number) for a 225 lab as none has been assigned.

2. For a new 225 lab, select **225 Lab-CLIA-No CLIA Number** as the **Type**.
3. Select the **Current Operating Status**, and enter the **Opened** date and **Closed On** date (if applicable) for the lab.
4. You cannot enter an **NPI** (National Provider Identifier) for CLIA labs in this release.
5. In the **TITLE** section, select one or more checkboxes indicating the payor sources.
6. Enter the working **Name** of the lab.
7. Enter the **Legal Name** of the lab.
8. Enter the **Address** of the lab; use **Address 2** for a second address line.
9. Click **Find** to open the **Zip Code Search** window so you can locate and enter the **Zip**, **City**, and **County** for the lab. **State** is automatically entered and is read-only.
10. Enter **Phone** and **Fax** numbers for the lab.
11. If a default value is not entered for **OSCAR State Region**, select the correct value.

12 In the **Contact Information** section, if applicable, enter the name of the **Emerg**. **Contact**, and the emergency contact's **Phone number**, **Extension**, and **E-Mail address**.

13 Enter the name of the **Assessment Contact** if applicable.

14 The **CLIA** section is auto-populated during the nightly update and is read-only for CLIA types 221-224; it is disabled for 225 labs.

15 Select another tab, or click **OK** to save the information and exit.

To add notes to the provider record:

➥ Click **Notes...** at the bottom of the window.

Users with read-only rights to the Facility Properties window can view the notes.

More ...

Procedure: "Open Define New Facility/Facility Properties window" on page 96
Procedure: "Find Address Elements by Zip Code" just below
Screen: "Facility Definition tab" on page 323

Find Address Elements by Zip Code

You can open the Zip Code Search window from the Facility Definition tab and search the ACO provider database for a lab by Zip Code, City, or County. When you select a match from the Search Results list, ACO populates the Zip, City, and County fields on the Facility Definition tab.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To find an address element:

1 On the **Facility Definition** tab, click **Find** in the **Description** section to open the **Zip Code Search** window.

2 In the **Text** field, enter all or part of the address element you want to search for.

If the search text you enter does not appear at the start of the number or name, type an asterisk (*) before the text, e.g., *alw.

3 Select the address element **Type** you want to search in the ACO provider database: **Zip Code**, **City**, or **County**.

You can perform only one type of search at a time.

Note: The search is not restricted to your state, so be sure the item you select applies to your state.

4 Click **Find Now**.

The address elements that match the search criteria appear in the Search Results section.

5 In the **Search Results** list:

➥ Select one of the entries and click **Select**.

-or-

➥ Double-click an entry in the list.

ACO enters the associated Zip, City, and County in the Description section on the Facility Definition tab.

Change 225 Lab Type

If a 225 NOCN lab completes a CMS-116 and then receives a CLIA number when the 116 information is entered and saved in the CLIA 116 web app, a record for the lab is added to ASPEN Web. You need to update its Type on the Facility Definition tab in ACO and enter the CMS Certification Number, i.e., CLIA # from the CLIA 116 web app. The provider record in ACO will then be maintained by the nightly update from the CLIA 116 web app.

Note: You *cannot* change provider type in ACO for labs maintained via the CLIA 116 web app, i.e., CLIA subtypes 221-224.

To change a 225 lab to another lab subtype:

1 Locate the lab in the **Tree** view, right-click it, and select **Facility Properties**.

2 Enter the **CMS Certification Number**, i.e., CLIA #, assigned to the lab in the CLIA 116 web app.

3 Select the appropriate Type (Lab-CLIA 221-224).

Enter Additional Mailing Addresses

Use the Addresses tab to enter additional mailing addresses, or to change the designated primary address for a lab. The Addresses tab lists the address entered on the Facility Definition tab as the physical address of the lab and designates it as primary. Additional addresses are all given an Address Type of 02 Mailing.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To add a mailing address:

1 Click the **Addresses** tab in the **Define New Facility/Facility Properties** window.

2 Click **Add** to open the **Mailing Address** window.

3 Enter the **Care Of** name, the street **Address** and **Address 2** (for a second address line), **City**, and **Zip**.

State defaults to the current state; you can change it if needed.

Addr Type defaults to 02 Mailing. You cannot change it.

4 Click **OK** to save the information and return to the **Addresses** tab.

The additional mailing address is listed there.

5 To designate the address you added as **Primary**, select it and click **Make Primary**.

6 Select another tab, or click **OK** to save the information and exit.

To modify a mailing address:

1 On the **Addresses** tab, select the address you want to modify and click **Modify**.

2 In the **Mailing Address** window, make the necessary changes.

You can only modify the Care Of information for the physical address here; other changes must be made on the Facility Definition tab.

3 Click **OK** to save the information and return to the **Addresses** tab.

To delete a mailing address:

1 On the **Addresses** tab, select the address you want to delete and click **Delete**.

2 Click **Yes** in the confirmation prompt.

If you delete the existing primary address, a message reminds you to select another primary mailing address.

More ...

Screen: "Addresses tab" on page 325
Screen: "Mailing Address window" on page 325

Specify Provider Associations

The Associations tab can optionally be used to assign State Agency units, accreditations, and congressional representatives.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To specify associations for a CLIA lab:

1 In the **Define New Facility/Facility Properties** window, click the **Associations** tab.

2 In the **Agency Associations** section, select the **Management Unit**, **Supervisory/Work Unit**. **LSC/DSI Unit** is not applicable for CLIA labs.

3 In the **External Associations** section, select up to two **Accreditation** organizations for the lab (Accredited lab only).

Accreditation information is optional on this tab. Accreditation details for Accredited labs are entered on the Accred Org Info tab in the CLIA 116 web app.

4 Select the congressional **House District** and **Senate District** representatives for the lab.

5 Select another tab, or click **OK** to save the information and exit.

More ...

Screen: "Associations tab" on page 326

Enter Administration Information

Use the Administration tab to optionally assign administrators and designate primary administrators. You can modify administrator assignment information and remove assigned administrators. You can also add administrator records to ACO. Only administrators in the ACO database can be assigned to labs.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To assign an administrator:

1 In the **Define New Facility/Facility Properties** window, click the **Administration** tab.

2 Search in the **Administration Directory** for the administrator you want to assign: enter all or part of the administrator's last name in the **Name** field and click **Find Now**.

Administrators who match the search criteria are listed.

3 Select the administrator you want to assign to the lab and choose the **Click Here to Assign** button.

-or-

Double-click the applicable administrator.

4 In the **Administrator Information** window that appears, enter the **Started** and **Ended** dates for the administrator, select the appropriate **Administrator Type**, and click **OK**.

The administrator is now listed in the Administrators Linked to this Facility section on the Administration tab.

Note: If the Ended date is prior to today's date, the administrator will be listed in Tree view under the Former Administration node for the lab.

5 To designate an administrator as the primary administrator for the lab, select the administrator and click **Make Primary**.

6 Select another tab, or click **OK** to save the information and exit.

To modify administrator assignment information:

1. In the **Administrators Linked to this Facility** section on the **Administration** tab, select the applicable administrator and click **Modify**.
2. In the **Administrator Information** window, make the necessary modifications and click **OK**.

To delete an assigned administrator:

1. In the **Administrators Linked to this Facility** section on the **Administration** tab, select the applicable administrator.

   WARNING! No confirmation message appears, so be sure you want to remove the selected administrator.

2. Click **Remove** to delete the administrator from the list of **Administrators Linked to this Facility**.

   If you remove the primary administrator, a reminder to select another primary administrator appears.

To add an administrator to ACO:

1. Under the **Administrator Directory Search** section on the **Administration** tab, click **Create Administrator**.
2. In the **Enter Administrator Information** window, provide the requested information.

More ...

Screen: "Administration tab" on page 327
Screen: "Administrator Information window" on page 327
Screen: "Enter Administrator Information" on page 328

Enter Ownership Information

Use the Ownership tab to optionally assign owner companies to labs and designate primary owners. You can modify ownership information and remove assigned owner companies. You can also add owner companies to ACO. Only owner companies in the ACO database can be assigned to labs.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To assign an owner company:

1. In the **Define New Facility/Facility Properties** window, click the **Ownership** tab.
2. Search in the **Owner Directory** for the owner company you want to assign: enter all or part of the company name in the **Name** field and click **Find Now**.

   Owner companies that match the search criteria are listed.

3 Select the owner company you want to assign to the lab and choose the **Click Here to Assign** button.

-or-

Double-click the applicable owner company.

4 In the **Owner Properties** window, enter the requested information and click **OK**.

- Select the owner company's **Financial Category**, **Owner Of** category, and **Ownership Type** from the drop-down lists.

  Note: If the company is Owner of both the Building and Health Care Ops, two separate owner properties records must be created.

- Enter or select the **Start** and **End** dates of ownership.

  Do not enter an End date if this is the primary owner.

- Select the **Management Company** checkbox if applicable.
- Click **OK** to return to the Ownership tab.

The owner company is added to the Owners Linked to this Facility section on the Administration tab.

5 To designate an owner company as the primary owner of the lab, select the owner company and click **Make Primary**.

6 Click **OK** to save the information and exit.

To modify ownership properties:

1 In the **Owners Linked to this Facility** section on the **Ownership** tab, select the applicable owner and click **Modify**.

2 In the **Owner Properties** window, make the necessary modifications and click **OK**.

To delete an assigned owner company:

1 In the **Owners Linked to this Facility** section on the **Ownership** tab, select the applicable owner company.

WARNING! No confirmation message appears, so be sure you want to remove the selected owner.

2 Click **Remove** to delete the owner from the list of **Owners Linked to this Facility**.

If you remove the primary owner company, a reminder to select another primary owner appears.

To add an owner company to ACO:

1. Under the **Owner Directory Search** section on the **Ownership** tab, click **Create Owner**.

   The **Enter Owner Company Information** window opens.

   The company is automatically assigned a system ID number when you click OK. The ID number, which is for the use of site system administrators, appears in the Company System ID field and cannot be changed. To see the number, open the Update Owner Company Information window from the Directory tab.

2. Enter the **Company Name** and the **DBA** (Doing Business As) name for the company.

3. Enter the company's current **Tax ID** number.

   A message will be displayed when you click OK if you do not enter the Tax ID.

4. In the Contact Information section, enter the company's Mailing Address (**Street Address**, **City**, **State**–select from the drop-down list, **Zip**), **Phone** and **Fax** numbers, **E-mail** address, and **URL** (if the company has a web site).

5. If the company is a child (subsidiary) company, select the parent company in the Select Parent Company section. To display the parent companies in the ACO database, click the **Find** button (binoculars) in the Select Parent Company section.

   The Find Owner Company window appears.

   - In the Search Text field, enter the company name or the company tax ID number.

     You can enter part of the name or tax ID number. If the text you enter does not appear at the start of the name or ID, type an asterisk (*) before the text.

   - Select Search By Company Name or Search By Company Tax ID as appropriate.

     You can perform only one type of search at a time.

   - Click **Find Now**.

     The companies that match the search criteria appear in the Search Results section of the window.

   - To choose the company in the Search Results list, highlight the appropriate company and click **Select**.

     -or-

     Double-click the company.

     The Enter Owner Company Information window reappears with the Parent ID and Parent Name fields filled in.

6 Select the **Parent Type**.

7 Click **OK**.

8 To assign the owner company to the facility, click **Yes** to the confirmation prompt.

9 In the **Owner Properties** window that appears, enter the requested information:

- Select the owner company's **Financial Category**, **Owner Of** category, and **Ownership Type** from the drop-down lists.

  Note: If the company is Owner of both the Building and Health Care Ops, two separate owner properties records must be created.

- Enter or select the **Start** and **End** dates of ownership.

  Do not enter an End date if this is the primary owner.

- Select the **Management Company** checkbox if applicable.
- Click **OK** to return to the Ownership tab/Owners window.

  The owner company is now listed in the Owners Linked to this Facility section on the Administration tab.

More ...

Screen: "Ownership tab" on page 329
Screen: "Owner Properties" on page 330
Screen: "Enter Owner Company Information window" on page 330

Enter Licensing Information

The Licensing tab captures basic information about a lab's state-issued license whether the lab is licensure-only or both federally certified and state-licensed.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To enter license information:

1 In the **Define New Facility/Facility Properties** window, click the **Licensing** tab.

2 The **License Number** is entered automatically by ACO from the License Number field on the Facility Definition tab.

3 Select the **License Type**.

4 Enter the **License Issue Date**, **License Effective From** date, and **License Effective To** date.

5 Select the **License Continuing?** box if the answer is **Yes**.

6 Select another tab, or click **OK** to save the information and exit.

More ...

Screen: "Licensing tab" on page 331

Enter Miscellaneous Information

Use the Other tab to enter optional miscellaneous information about a lab such as the geographic location, insurance expiration date, media contact, etc. Inapplicable fields are disabled.

Note: For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app.

To enter miscellaneous information about a lab:

1 In the **Define New Facility/Facility Properties** window, click the **Other** tab.

2 Enter information in applicable fields:

Enabled fields include:

- Latitude and Longitude
- Insurance Expiration
- Surety Bond
- Fiscal Year End
- Special Operating Hours?
- Bankrupt
- Petition Date
- End Date
- Special Focus
- Begin Date
- End Date
- Media Contact
- Chain
- DOJ Contact
- Intermediary/Carrier No.

3 Select another tab, or click **OK** to save the information and exit.

More ...

Screen: "Other tab" on page 332

Modify CLIA Provider Records

The provider information you can modify in ACO for CLIA labs depends on lab type: 221-224 or 225.

221-224

You cannot modify fields that are updated by the nightly extract from the CLIA 116 web app. For example, you cannot modify addresses on either the Facility Definition or Addresses tab. Changes to these fields must be made in the CLIA 116 web app. ACO will then be updated to reflect the changes during the nightly update process.

Other facility property fields can be edited or not according to established rules. The CLIA 116 web app will not reflect changes made in ACO to editable fields.

225

You can modify all fields in provider records for 225 labs *except* fields in the CLIA section on the Facility Definition tab and fields that are read-only for other provider types, e.g., Addr Type on the Mailing Address tab. If a 225 NOCN lab applies for a CLIA number, you need to update CMS Certification Number and Type on the Facility Definition tab.

More ...

Supporting Materials: “CLIA 221-224: Extracted Facility Properties” on page 549
Fields: "Facility Definition tab", on page 440
Procedure: “Change 225 Lab Type” on page 99

When a Lab Moves to Another State

When a lab moves from one state to another, the Operating Status of the lab in the original facility record in ACO is set to CLOSED-MOVED. A new facility record with an ACTIVE status is created for the lab in its new location.

Certification Kits

ACO supports an integrated certification process for CLIA labs. You create kits to enter certification and survey data as well as to track the certification process. As part of the CMS system standardization strategy, CLIA certification data captured at the SA and RO levels by ACO/ARO is uploaded to the national reporting system.

Note: ACO also accommodates state licensure records, but they are not uploaded to the national reporting system.

CLIA Certification Kit Types

The three types of CLIA certification kits in ACO are Initial, Recertification, and Validation. Based on a lab's certificate and application type, ACO automatically calculates L8 (Type of Action), i.e., type of certification kit; creates a kit of the appropriate type; and populates the L8 field on the 1539.

ACO certification kit (L8) is:

Initial when:

- Certificate Type = Pending or Current Registration and Application Type = 1

Recertification when

- Certificate Type = Pending Compliance and Application Type = 1

Validation when

- Certificate Type = Pending or Current Accreditation and Application Type = 3

It is possible to create a certification kit in ACO for a Compliance lab before the lab pays the compliance fee; however, you cannot upload the kit until the fee is paid. This allows you to schedule surveys ahead of time. It also sets the Survey Pending Date, which prevents termination and status changes. You can also create a validation kit in ACO for an Accredited lab regardless of payment status, and you can schedule the validation survey ahead of the visit (once the RO has approved the survey).

A lab may have multiple certificates eligible for a certification kit. For initial and recertification kits, each certificate can support one certification kit. A single Certificate of Accreditation can theoretically support more than one validation kit.

If a lab has changed certificate type over time, it may have certification kits in ACO for previous certificates although its current certificate does not require a certification kit. For example, a PPM lab with a current Microscopy certificate that previously held Compliance and Registration certificates could have recertification and initial certification kits in ACO for those certificates.

Note: Validation kits are listed under the Recertifications node on the Cert/Survey tab.

More ...

To check a lab's certificate history:

Procedure: "View Certificate History" on page 109

To check a lab's certification kits in ACO:

Refer to "View Certification History" in the *ACO Procedures Guide*, which is posted at https://qtso.cms.gov.

Current and Prior Kits

When you create a certification kit, whether initial or recertification, it will be the current kit. There may be two current kits: one that has been uploaded successfully to the national reporting system and a new certification kit that has not been completed. You cannot change the exit dates of the accepted kit's standard surveys.

If you create a certification kit for a laboratory that already has a kit in ACO, and that kit has been uploaded and accepted, the status of the existing kit is changed from Open to Prior. Your new kit becomes the Open kit. You cannot change the exit date(s) of the accepted kit's standard survey(s).

TIP: Current kits are listed as Current on the Alpha and Type tabs and as Open or Closed on the Cert/Survey tab.

When a certification kit is updated to Prior, the status of the kit and all associated surveys is set to Closed. Prior kits cannot be modified, except for revisit dates, CMS-670 data, and CMS-2567 (Statement of Deficiencies) data. You can add followup surveys to Prior kits.

View Certificate History

You can use the Certificate Inquiry option in ACO to check a lab's certificate history. The information is entered from the national database and is read-only.

To view a lab's certificate history:

➥ Expand the **Certificates** node for the lab in the Tree view.

-or-

➥ Right-click the lab in the Tree view and select **Certificate Inquiry**.

The CLIA Certificate Inquiry window displays the lab's certificate history.

More ...

To access certificate history in the CLIA 116 web app:
Procedure: "Certificate and Billing Inquiry" on page 64

Create an Initial Certification Kit

You create an initial certification kit in ACO for a lab applying to become a Compliance lab with:

- a pending or current Registration certificate
- application type 1 (Compliance)
- no existing kit for the certificate

A Compliance lab can have multiple initial certification kits. An initial is created when:

- a Compliance lab first applies to CLIA
- a Compliance lab is re-activated with a gap in certification cycle
- a PPM, Waiver, or Accredited lab applies to become a Compliance lab
- a former Compliance lab that changed certificate type re-applies for a Compliance certificate

To create an initial certification kit for a CLIA lab:

1. Locate the lab in **Tree** view, right-click its name, and select **Create Certification**.

   The Create Certification command is available only in certain circumstances as specified above. For labs meeting those conditions, an initial certification kit will open.

   The Compliance Certificate Effective Date on the Certification & Surveys tab is blank, but is required for upload if Certificate Type Change is set to No, which is the default. It is the date the laboratory was determined to be in compliance with program requirements. Type of Action (L8) on the 1539 is set to 1 Initial.

2. On the **Certification & Surveys** tab of the **Certification** window, enter certification information.
3. Schedule and conduct a survey, and enter citation information.
4. Schedule revisit surveys as needed.
5. Add and monitor certification process details on the **Tracking** tab.
6. View and enter specialty information.
7. Complete **CMS-670** and print **CMS-2567** for each survey.
8. Complete other required forms.
9. Upload the completed kit to the national reporting system.

   The first upload must be manual. After the first successful upload, certification kits created on or after 07/01/2014 are automatically re-uploaded.

   Note: The compliance fee must be paid in full before you can upload the kit.

If Certificate Type Change on the Certification & Surveys tab is set to Yes, you must wait a day after the upload, then change application status in the CLIA 116 web app as appropriate.

Note: If no survey will be done, you can delete the certification kit and immediately perform a status change.

More ...

Procedure: "Enter Certification Information" on page 114
Procedure: "Create Survey Shells" on page 119
Procedure: "Create Citations" on page 123
Procedure: "Create Revisit Survey Shells" on page 160
Procedure: "Track Certification Kits" on page 154
Procedure: "View and Enter Survey Specialty Data" on page 132
Procedure: "CMS-670" on page 138
Procedure: "CMS-2567" on page 139
Procedure: "CMS-1539" on page 136
Procedure: "CMS-1557" on page 137
Procedure: "Upload Certification Kits" on page 143

Create a Recertification Kit

You create a recertification kit for a Compliance lab scheduled to renew its certificate with:

- a pending Compliance certificate
- application type 1
- no existing kit for the certificate

You cannot create a recertification in the absence of a pending Compliance certificate.

Note: If a lab previously held a Compliance certificate but does not currently, all previously uploaded certification kits associated with a Compliance certificate are read-only, even if the lab reapplies for a Compliance certificate.

To create a recertification kit for a Compliance lab:

1. Locate the lab in **Tree** view, right-click its name, and select **Create Certification**.

   The Create Certification command is available only in certain circumstances as specified above. For labs meeting those conditions, a recertification kit will open.

   The Compliance Certificate Effective Date on the Certification & Surveys tab is automatically set to the effective date of the pending Compliance certificate. Type of Action (L8) on the 1539 is set to 2 Recertification.

2. On the **Certification & Surveys** tab of the **Certification** window, enter certification information.
3. Schedule and conduct a survey, and enter citation information.
4. Schedule revisit surveys as needed.
5. Add and monitor certification process details on the **Tracking** tab.
6. Update specialties as needed.
7. Complete **CMS-670** and print **CMS-2567** for each survey.
8. Complete other required forms.

   The compliance fee must be paid in full before you can upload the kit. The first upload must be manual. After the first successful upload, certification kits created on or after 07/01/2014 are automatically re-uploaded.

Note: The compliance fee must be paid in full before the kit can be uploaded.

More ...

Procedure: “Enter Certification Information” on page 114
Procedure: “Create Survey Shells” on page 119
Procedure: “Create Citations” on page 123
Procedure: “Create Revisit Survey Shells” on page 160
Procedure: “Track Certification Kits” on page 154
Procedure: “View and Enter Survey Specialty Data” on page 132
Procedure: “CMS-670” on page 138
Procedure: “CMS-2567” on page 139
Procedure: “CMS-1539” on page 136
Procedure: “CMS-1557” on page 137
Procedure: “Upload Certification Kits” on page 143

Create a Validation Kit

For Accredited labs, ACO/ARO supports the entry, tracking, and upload of validation survey information. Creating a validation kit for an Accredited lab is comparable to creating a recertification for a Compliance lab.

You can create a validation kit for a lab with:

- a pending or current Certificate of Accreditation
- application type 3

To create a validation kit for an Accredited lab:

1. Locate the lab in **Tree** view, right-click its name, and select **Create Certification**.

   The Create Certification command is available only in certain circumstances as specified above. For labs meeting those conditions, a validation kit will open.

   The Compliance Certificate Effective Date on the Certification & Surveys tab is blank and not required for upload. Type of Action (L8) on the 1539 is set to 5 Validation.

   Note: Validation kits are listed as Recertifications under the Certifications node on the Cert/Survey tab.

2. On the **Certification & Surveys** tab of the **Certification** window, enter certification information.
3. Schedule and conduct a survey, and enter citation information.

   Note: You cannot create a validation survey shell until it is approved by the RO, i.e., RO Response = Approved in the CLIA Authorization for State Validation Survey (CMS 2802) section on the Tracking tab.

4. Schedule revisit surveys as needed.
5. Add and monitor certification process details on the **Tracking** tab.
6. View/confirm specialties as needed.
7. Complete **CMS-670** and print **CMS-2567** for each survey.
8. Complete other required forms.

   Note: When you receive RO approval for a validation survey, you can print CMS-2802A from the Select Form(s) to print window.

9 Upload the completed kit to the national reporting system.

You cannot upload a validation kit until RO approval is received and a Y-match is present. The first upload must be manual. After the first successful upload, validation kits created on or after 07/01/2014 are automatically re-uploaded.

Note: You can access validation kits that have not been uploaded to update or upload the information even if the associated certificate is no longer current.

More ...

Procedure: "Enter Certification Information" on page 114
Procedure: "Create Survey Shells" on page 119
Procedure: "Create Citations" on page 123
Procedure: "Create Revisit Survey Shells" on page 160
Procedure: "Track Certification Kits" on page 154
Procedure: "View and Enter Survey Specialty Data" on page 132
Procedure: "CMS-670" on page 138
Procedure: "CMS-2567" on page 139
Procedure: "CMS-1539" on page 136
Procedure: "CMS-1557" on page 137
Procedure: "CMS-2802A" on page 139
Procedure: "Upload Certification Kits" on page 143
Procedure: "CLIA Authorization for State Validation Survey (CMS 2802)" on page 153

Enter Certification Information

You enter basic information about a certification on the Certification & Surveys tab of the certification kit.

To enter certification information:

1 Open the certification kit: locate the kit in **Tree** view, right-click it, and select **Certification Kit**.

If the kit has not been uploaded and the certificate associated with the kit no longer exists, a message tells you the kit should be deleted and a new kit created.

2 Scroll to the **Certification Properties** section at the top of the **Certification & Surveys** tab.

TrackID and **Category** are supplied by ACO. Surveys created in the certification kit will have Event IDs whose first four characters match the certification TrackID.

3 Select the certification **Status**.

Open is selected by default.

4. Select the **Release for CMS Review?** checkbox if appropriate, and click **Yes** in the confirmation message.

   You can manually select this option to send an action item to the RO requesting a review before uploading a kit.

5. Click the **Facility Details** button to access the **Facility Properties for Certification** window. Click **Done** to return to the **Certification & Surveys** tab.

   Information is carried in from the lab's provider record in ACO. The only field you can modify is Legal Name and only if you have the appropriate button-level security and the certification kit is Current. Otherwise, the information is read-only.

6. Click the **CLIA 116** button to start the CLIA 116 web app and open the 116 form (lab record) for the current lab.

7. Assign **Responsible Parties**:

   ➥ Click **Edit** to open the Responsible Parties window.

   ➥ Click the **Add S.A.** or **Add R.O.** button to select the SA/RO member.

   ➥ Type the first few letters of the last name or select the name from the drop-down list.

   ➥ Select the **Primary** checkbox to designate the primary responsible party.

   You can designate both SA and RO responsible parties. There must always be at least one responsible party. Assignments made here are carried over to Responsible Parties on the Tracking tab.

8. The IJ question (COPs out of compliance - is there an IJ?) above the Citation List grid does not apply to CLIA labs.

9. Go to the **Special Fields** section; you may have to scroll down to see it.

   - The **Control Fields** and **Related Identifiers** areas provide read-only information.
   - You can enter notes or instructions in the **RO/SA Message** area:

     ➥ Enter message date and text in the **RO Date**/**RO Text** or **SA Date**/**SA Text** fields as appropriate.

10 Complete the **CLIA** section as applicable.

Compliance Certificate Effective Date is required for new initial certifications. It is the date the laboratory was determined to be in compliance with program requirements. It is automatically set for recertifications, and disabled for validations.

Certificate Type Change Due to Survey is enabled and required only for initial certification kits.

➥ Choose **Yes** if a lab has chosen to downgrade its certificate type due to initial survey findings, or if you arrive at the site and the lab is performing only waived or PPM tests.

➥ Otherwise, choose **No**.

When this field is set to No, which is the default, the Compliance Certificate Effective Date is required. If Yes, the Effective Date should stay blank.

Certification Kit Created On is automatically entered and read-only.

Note: If Certificate Type Change is set to Yes, you must wait a day after the kit is uploaded, then change application status in the CLIA 116 web app as appropriate. However, you can delete the certification kit and immediately perform the status change if no survey will be done.

11 Click **AO Detail** at the bottom of the **Certification** window to view AO survey information for the lab.

This button is provided only for Accredited labs. The information is read-only.

TIP: You can also click AO Detail in the Facility Properties for Certification window (see step 5) to open the AO Details window.

12 Click **Done** to save the information and close the **Certification** window.

If you have not created a survey (new certification kit only), a message asks if you want to.

13 Click **Yes** if you want to create a survey, **No** if not.

When you close the Certification window for a new kit, an Initial, Recertification, or Validation node, as appropriate, will appear below the lab in Tree view.

Figure 24: Initial certification kit node

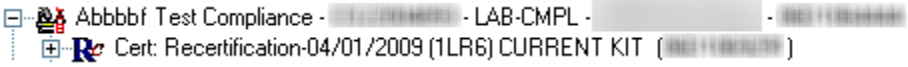

Figure 25: Recertification kit node

Figure 26: Validation survey/certification kit node

More ...

Screen: "Certification Properties and Responsible Parties" on page 333
Screen: "Special Fields" on page 335
Procedure: “Flagged Kits” on page 156
Procedure: “Change Status Due to Survey” on page 158

Close a Certification Kit

When no further action on a certification kit is needed, you can mark it as closed.

To close a certification kit:

1. Go to the **Certification Properties** section at the top of the **Certification & Surveys** tab.
2. For **Status**, select **Closed**.

If a Lab Moves to Another State

When a laboratory moves out of state, all certification kits that were created for it in the first state remain in that state’s database and are read-only. All new certification kits must be created by the state where the laboratory is now active. If you search for the lab by CCN in ARO, it will show all states where the lab has existed and indicate the current location.

Surveys

In ACO, surveys are components of certification kits. Once a certification kit has been created, a new survey can be set up at any time during the associated 2-year certificate cycle, even before the survey visit.

WARNING! Do not use old certification kits, i.e., those created during a previous certificate cycle, for any current survey type: Initial, Recertification, or Validation.

For a Compliance lab, it is possible to create a survey shell in ACO before the lab pays the compliance fee; however, the kit cannot be uploaded until the fee is paid. This allows you to schedule surveys ahead of time. It also sets the Survey Pending Date in CLIA, which prevents termination and status changes.

Note: You cannot create a validation survey shell until it is approved by the RO, i.e., RO Response = Approved in the CLIA Authorization for State Validation Survey (CMS 2802) section on the Tracking tab.

Surveys have a status of either Open or Closed. You can change information or add new information to an open survey. You can view, but not make changes, to closed surveys. Revisits require special processing.

More ...

Procedure: “Revisits” on page 160

Centralize Survey Definition and Scheduling

An important step SAs can take to facilitate ASPEN data transfer is to have scheduling supervisors create all survey shells (events) in ACO (or ACTS). Then they can distribute (export) the centrally-defined visits to field staff as necessary.

This approach has several advantages:

- Removes the task of survey definition from the surveyor.
- Ensures accuracy, since provider and surveyor information comes directly from the state database.
- Ensures that knowledgeable staff are defining surveys within a secure ACO/ACTS environment.
- Eliminates creation of multiple survey events for one visit on several laptops.

- Simplifies merging between ASE-Q users.
- Minimizes support overhead for merging field results back into ACO/ACTS.

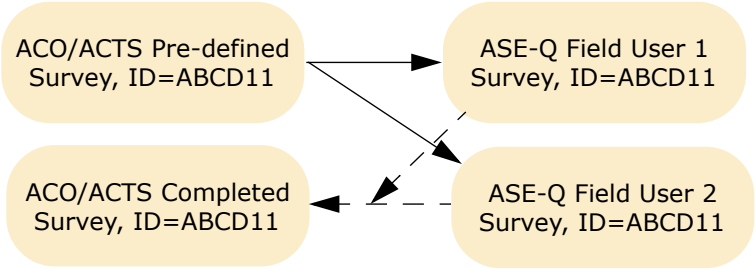

Figure 27: Centralized survey event definition

More ...

"ASPEN Data Transfer: CO, RO, SA" on page 175

Create Survey Shells

The scheduling supervisor can set up a survey shell in ACO (or ACTS), then export it to ASPEN Survey Explorer-Quality (ASE-Q) on team members' laptops.

To create a survey shell:

1. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
2. Click the **New** button under the Surveys grid.

   You will receive a message if you are creating a survey for a Compliance lab that has not paid the compliance fee. You can create the survey but the kit cannot be uploaded until the lab pays the fee.

   Note: You cannot create a validation survey shell until it is approved by the RO, i.e., RO Response = Approved in the CLIA Authorization for State Validation Survey (CMS 2802) section on the Tracking tab.

3. Click **OK** in the **Initial Survey Type** window to open the **Create Health Survey** window.

   Health Survey is the only survey type option for CLIA labs.

   You will receive a message if you try to create a survey for a closed lab. You can choose to continue or not.

4 Enter basic survey information.

Start and Exit (X3)

Exit date must be the same as or later than the Start date.

Status

Open is selected by default.

IQCP

Select to indicate the lab is following the IQCP process at the time of the survey.

Shell Only

Selected by default for new surveys and revisits. Shell surveys are not added automatically to ASPEN Enforcement Manager (AEM) cases.

Category

Survey category (type) is Health by default.

Regulation(s)

Select the regulation sets that apply to the survey.

Team Roster

Assign surveyors to the survey team.

Type of Survey

Select one or more.

Extent(s)

Select one or more.

SOD Tracking

Enter dates pertaining to the Statement of Deficiencies (SOD) when available, specify Revisit Status, and select 2567/B Entry Complete when applicable.

5 Click **OK** and click **Yes** in the message to enter citation details now, or click **No** and enter them later.

No is the default.

➥ To enter citations later, select the survey in the **Survey List** section on the **Certification & Surveys** tab and click **Citations Mgr**.

More ...

Screen: "Create Health Survey/Survey Properties window" on page 353
Procedure: “IQCP” on page 125
Procedure: “Assign Regulation Sets” on page 121
Procedure: “Assign Survey Team Members” on page 121
Procedure: “Record Deficiencies” on page 123

Assign Regulation Sets

You must assign at least one applicable regulation set to a survey when you create the shell.

To assign regulation sets to a survey:

1. In the **Create Health Survey**/**Survey Properties** window, select one or more Regulation(s) that apply to the survey.

   The most current Federal regulation set is listed by default for CLIA labs. CLIA surveys currently use Federal regulation set D-7.01.

   You cannot select more than one Federal set with the same regulation ID.

   Only state regulation sets are listed for licensure-only labs.

2. To see all applicable Federal and state regulation sets, click **Show All**; click **Filter** to see the "filtered" list again.

   Regulation sets already selected are included in the filtered list.

Assign Survey Team Members

You normally make survey team assignments when you create a survey shell. The IDs and names of surveyors on the survey team are listed in the Team Roster pane of the Create Health Survey/Survey Properties window. As needed, you can modify the team roster, change the active surveyor, and designate a team leader.

You use different windows in ACO and ARO to assign survey team members.

ACO - To make survey team assignments:

1. In the **Create Health Survey**/**Survey Properties** window, click **Update** to add or remove survey team members.

2. In the **Staff Availability List** window, select the surveyors you want on the team by clicking the applicable checkboxes.

   By default, the list of staff members is filtered by the Work Unit setting in the current My Selections set.

   The list of staff members is also filtered by the Facility Type setting in the current My Selections set in ACO and by Allowed Facility Types in the Enter/Update Surveyor window, so that only active surveyors who are eligible to work on surveys of the currently displayed facility types are included:

   - *if* you have AST installed
   - *and if* "Use facility types of active selection" is selected on the Scheduling tab of My Preferences in AST. It is deselected by default, so you must select it and then click Save Settings.

If these conditions are not met, the list of staff members in the Staff Availability List window is not filtered at all by facility type.

Note: A message appears if you select a staff member whose General Staff Type is 02 Clerical/Support (in the Enter/Update Surveyor Information window). You can choose whether to go ahead and add that staff member or not.

3 To remove a surveyor from the team, simply clear the applicable checkbox and click **Yes** in the confirmation prompt.

Be sure you really want to remove the surveyor and all associated citations.

4 Click **OK** in the **Staff Availability List** window to return to the **Create Health Survey**/**Survey Properties** window.

Surveyors you added are listed as team members in the Team Roster pane. Any surveyors you removed are no longer listed and all citations they wrote no longer appear in the Citations section of the Citation Manager.

ARO - To add a survey team member:

1 In the **Create Health Survey**/**Survey Properties** window, click **Update** to add surveyors.

2 In the **Add Team Member** window, enter the new team member's **Federal Surveyor ID** if you know it, then go to 4.

3 If you do not know the surveyor's Federal Surveyor ID, click **Find...** to search the database.

➥ Enter **Search Text** and click **Find Now**.

➥ In the **Search Results** list, select the surveyor you want and click **Select**.

-or-

➥ Double-click the surveyor.

4 In the **Add Team Member** window, **Save and Continue** to add another surveyor to the team, or **Save & Exit** to return to the **Create Health Survey**/**Survey Properties** window.

When you return to the Create Health Survey/Survey Properties window, the surveyors you added are listed as team members in the Team Roster pane.

ARO - To remove a survey team member:

1 Click the **Alpha**, **Type**, or **Cert/Survey** tab and locate the survey you want.

2 Right-click the survey and select **Team Roster**.

3 Click **Yes** in the confirmation prompt if you really want to remove the surveyor and all citations written by the surveyor.

The surveyor is no longer listed as a team member in the Team Roster window and all citations written by the surveyor are removed from the Citations section of the Citation Manager.

4 Click **Done**.

More ...

Screen: "Staff Availability List window" on page 359
Screen: "Citation Manager window" on page 355

Record Deficiencies

Once a survey shell is created, survey team members will record deficiencies found during the survey in the ACO Citation Manager. You can enter citation text, designate IQCP tags, and assign specialties.

Create Citations

When you add a tag to the Citations section of the Citation Manager, you can enter basic details about the cited tag as well as citation text.

To add a citation:

1 Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.

2 Select the applicable survey, then click **Citations Mgr**.

To add citations, you must be a member of the survey team. Supervisors can view and edit citations.

3 In the **Regulations** section of the **Citation Manager** window, select the tag you want to cite and drag it to the **Citations** section.

Condition-level tags are displayed in green and marked (Condition) in both the Regulations and Citations sections.

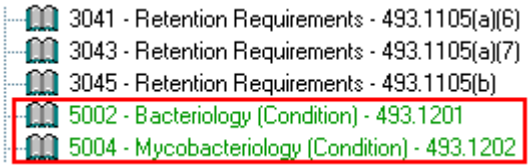

Figure 28: Condition-level tags

4 In the **Citation Properties** window that opens, enter citation information.

Fields that do not apply are disabled or do not appear.

- Select the **IQCP** checkbox, if appropriate.
- For a combined survey, make sure each selected **Citation Category** applies to the tag.

  All categories are selected by default, so you must deselect any that do not apply.
- Assign applicable specialties to the tag.

5 Click **OK** and enter citation text in the **Citation** word processor.

Although you can enter and format an unlimited amount of text in the word processor, there is a limit of 128K of citation text per tag (approximately 80 printed pages) that can print on the CMS-2567 and related forms.

6 Click **OK** to save the text and return to the **Citation Manager** window.

7 Repeat steps 3 to 6 for each citation.

8 Attach supplemental materials in electronic format, if any, to the survey.

9 View repeat deficiencies, if any.

10 Click **Done** to exit the **Citation Manager** window.

Citations are shown in the Citation List section of the Certification window.

TIP: You can edit some fields directly on the Citation List grid. All fields are read-only, however, for comment tags 0000 and 9999 and for tags that are complaint-related only, i.e., Complaint is the only selected Citation Category in Citation Properties.

More ...

Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356
Procedure: “EQC” on page 128
Procedure: “IQCP” on page 125
Procedure: “Assign Tag-level Survey Specialties” on page 125
Procedure: “Add Survey Attachments” on page 129
Procedure: “EQC” on page 128
Screen: "Citation List" on page 334

Assign Tag-level Survey Specialties

When you cite associated specialty (ASSP) tags, you need to specify associated survey specialties.

To assign survey specialties to a tag:

1. Open the **Citation Manager**.
2. In the **Regulations** section, select an ASSP tag and drag it to the **Citations** section.

   -or-

   If you have already added an ASSP tag, but have not assigned specialties, right-click it in the **Citations** section and select **Citation Properties**.
3. In the **Citation Properties**/**Update Citation Properties** window, click the **Specialties** button.

   Note: The Specialties button is enabled only for tags that require specialty information.
4. Select the applicable **Survey Specialties/Sub-specialties** (tests) to associate with the citation.

   Only specialties applicable to the selected D-tag are listed.
5. For each selected test, specify its **Test Complexity**.

More ...

Screen: "Citation Manager window" on page 355

IQCP

CMS developed the Individualized Quality Control Plan (IQCP) as an alternative to the Equivalent Quality Control (EQC) process. IQCP was fully implemented beginning January 1, 2016. IQCP allows laboratories the flexibility to design QC policies and procedures based on the unique characteristics of their operational methods and non-waived test systems.

Labs have two options for CLIA compliance:

- Follow CLIA QC regulations as written.

  -or-

- Implement an acceptable IQCP.

The following survey categories are eligible for IQCP:

- Recertification
- Initial
- Complaint
- FMS

PT Desk review and Cytology surveys are not eligible for IQCP. If they are combined with one of the above categories, you can mark the survey as IQCP, but IQCP information on national will only be associated with the IQCP-eligible categories for the survey.

Mark Surveys as IQCP

In order to mark tags on a survey as IQCP, you must first indicate the lab will be following the IQCP process for the survey.

To mark a survey as IQCP:

➥ In the **Create Health Survey**/**Survey Properties** window, select the **IQCP** checkbox.

Mark Tags as IQCP

When you cite an IQCP-eligible tag in Citation Manager on a survey marked as IQCP, the IQCP checkbox appears on the Citation Properties window. Tags marked as IQCP are included on the CMS-2567 (though they are not distinguished as IQCP) and are uploaded.

To mark a tag as IQCP:

1. Open the **Citation Manager**.
2. In the **Regulations** section, select a tag that is IQCP-eligible and drag it to the **Citations** section.

   -or-

   If you have already added an IQCP-eligible tag, but have not marked it as IQCP, right-click it in the **Citations** section and select **Citation Properties**.

3 In the **Citation Properties**/**Update Citation Properties** window, select the **IQCP** checkbox.

It appears only for eligible tags on surveys marked as IQCP. A 'P' is appended to IQCP tags in the Citations section of the Citation Manager.

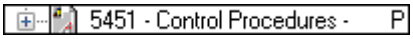

Figure 29: IQCP tag

If you cite an eligible tag, but do not mark it as IQCP, the P does not appear.

More ...

Procedure: "IQCP" on page 125
Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356

IQCP Letters

During the IQCP Education and Transition Period (01/01/14-01/01/16), the following two templates for laboratory director letters will be available:

- QC01 CLIA IQCP LETTER ATTACHMENT 2
- QC02 CLIA IQCP LETTER ATTACHMENT 3

Both letters provide an overview of CLIA QC policies and IQCP.

The letter generated from the QC01 template is sent to a lab director when a survey finds that the lab does not meet certain CLIA QC regulations and an IQCP is not yet in place. The letter template includes the QC Exclusion macro, which automatically fills in all the tags that were cited as QC exclusion.

Note: QC01 replaces the QCEX letter template, which is no longer available for selection when you generate a survey letter. However, the history of QCEX letters generated prior to ASPEN 10.1.5.8 will be maintained.

The QC02 letter is sent to the director of a lab that has an IQCP in place, but it does not meet all IQCP requirements. The QC02 letter template includes the IQCP Conditions macro, which automatically fills in the conditions (i.e., requirements) selected when the letter is generated. Any or all of the following IQCP requirements can be selected:

- RA must address all 5 components
- RA must cover the 3 phases of testing
- RA must include in-house data
- QCP must be approved, signed, & dated by LD
- QA must include review of IQCP

Based on the selected requirements, one or more corresponding bullet items are added to the letter.

More ...

Screen: "Letter word processor" on page 368

For detailed information about letter macros, refer to *ASPEN Letter Macros*, which is posted on https://qtso.cms.gov.

IQCP Attachment Reports

The number of times the QC01 and QC02 letters are sent is stored in the database along with the QC Exclusion tags (in QC01 letters) and the IQCP requirements selected (in QC02 letters). At specified intervals, the Attachment 2 and Attachment 3 reports are run for each state.

The Attachment 2 report lists the number of Attachment 2 (QC01) letters sent and the number of times eligible D-tags were cited as QC Exclusion. The Attachment 3 report indicates the number of Attachment 3 (QC02) letters sent and shows how many times each IQCP requirement was selected and included in a letter. These numbers from the state reports are entered into a spreadsheet, which provides totals by region and nationwide.

EQC

CMS developed IQCP as an alternative to the Equivalent Quality Control (EQC) process. IQCP was fully implemented beginning January 1, 2016. There may be tags added prior to that date that were marked as EQC. The following rules apply to QC exclusion tags:

- You cannot enter tag-level POC dates. The POC Detail section in Citation Properties is disabled.
- QC exclusion tags do not carry forward from the previous survey to a revisit.
- QC exclusion tags are not printed on the CMS-2567.
- QC exclusion tags are not uploaded.

More ...

Screen: "Citation Properties window" on page 356
Procedure: “IQCP” on page 125

View Repeat Deficiencies

For CLIA labs, the Citation Manager provides access to a list of repeat deficiencies from previous surveys that used the same regulation set as the current survey. You can view citation text to determine if a tag is cited on the current survey for the same reason it was cited previously. You can also view regulation text and interpretive guidelines for each previously cited tag.

To view repeat deficiencies:

1. In the **Citation Manager** window, click the **Repeat Deficiencies** button at the bottom of the window to open the **Repeat Deficiencies** window.

   It lists tags cited in the current survey that were previously cited in any survey, complaint, or certification conducted for the lab since January 12, 2004 using the same regulation set.

2. To view citation evidence text, regulation text, or the interpretative guidelines for a tag, select the tag and click the **Citation Text**, **Regulation**, or **Interpretive Guide** button (respectively) at the bottom of the window.

   You can copy citation, regulation, or interpretive guideline text and paste it into citations on the current survey.

3. Click **Close** to return to the **Citation Manager**.

More ...

Screen: "Citation Manager window" on page 355

Add Survey Attachments

You can add supplemental materials in electronic format, such as relevant document files and digital photos, to individual surveys. All attachments associated with a lab are listed on the Alpha and Type tabs in Tree view under the lab's Attachments node.

To add an attachment to a survey:

1. In the **Citation Manager** window, click the **Attach** button.
2. In the **Survey Attachment Documents** window, enter a **Description** of the attachment and click **Attach/View**.
3. In the **Open** window, navigate to the folder containing the file you want to attach and select it, then click **Open**.

   A message asks if you want to preview or edit the attachment.

4 Click **Yes** or **No** as appropriate.

If Yes, the attachment is displayed. To return to ACO, close the application displaying the attachment. The File Name of the attachment is added in the Survey Attachment Documents window.

If No, the File Name of the attachment is immediately added in the Survey Attachment Documents window.

5 Click **Close** in the **Survey Attachment Documents** window.

More ...

Screen: "Citation Manager window" on page 355

Delete a Survey

You can permanently delete a survey from the Recycle node if you know that you no longer need it.

Note: Deleting a survey is permanent. You cannot restore a survey after you delete it.

To permanently delete a survey:

1 Right-click the survey in the **Recycle** node and select **Delete**.

2 Click **Yes** in the confirmation message.

The survey is permanently deleted.

-or-

1 Click the **Recycle** node to display recycled surveys in **List** view (right pane).

2 Select one or more surveys.

3 Right-click and select **Delete**.

4 Click **Yes** in the confirmation message.

The survey(s) are permanently deleted.

TIP: If you have moved several (not all) surveys associated with a laboratory to the Recycle node and want to permanently delete them, you can right-click each survey and delete, right-click the provider and delete all associated recycled surveys, or display and delete all recycled surveys in List view; the provider is not deleted.

Lab Personnel and Specialties

SAs use CMS-1557, the Survey Report Form (CLIA) to report information about lab personnel and specialty/test volume to CMS and to determine compliance with individual CLIA standards. The Survey (CMS-1557) and 1557 Specialties tabs of ACO's Certification window respectively replicate the Personnel and SPECIALTIES/SUBSPECIALTIES portions of the CMS-1557 form.

Specify Personnel Qualifications

The Survey (CMS-1557) tab of the Certification window corresponds to the Personnel section of the paper CMS-1557. You use it to enter the number of lab employees qualified for each applicable regulatory section.

Additional general information on this tab includes:

- Survey Status categories
- Simultaneous Survey indicator
- Medicare numbers of associated providers

To enter general information and qualifications of lab personnel:

1. Click the **Survey (CMS-1557)** tab in the **Certification** window.

   This tab does not appear for certification kits with a Prior status.
2. **State License Number** is entered by the system; read-only.
3. For **Simultaneous Survey**, select **Yes** or **No**.

   Enabled only for validation kits.
4. **Survey Status** is entered by the system; read-only.
5. Enter up to six **Medicare Provider Number(s)** of associated providers.
6. In the **Personnel** section, enter the number of qualified staff members in each applicable regulatory area.

   Hover Help (Hover Guidance) provides the regulatory definition for each position.

Note: The Survey (CMS-1557) tab does not appear for certification kits with a Prior status.

More ...

Screen: "Survey (CMS-1557)" on page 343

View and Enter Survey Specialty Data

The 1557 Specialties tab of the Certification window in certification kits with Current status corresponds to the SPECIALTIES/SUBSPECIALTIES section of the paper CMS-1557. Key 1557 Specialties functions include:

- For Compliance labs, update test volumes and respond to Immuno/Blood product questions. Delete or close out survey specialties as necessary.
- For Accredited labs, confirm specialty data and indicate any discrepancies found.
- For both Compliance and Accredited labs, the system calculates and displays total test volume and schedule code values.

Note: This tab does not appear in certification kits for PPM, Waiver, or closed labs or in kits with a Prior status. Also, it is disabled when Certificate Type Change Due to Survey is set to Yes. If survey specialty data has already been entered, a message appears and the fields are cleared.

Whether survey specialty data is required and manually or automatically entered depends on certification kit type.

- **Initial Certification**

  Survey specialty information is required for initial certifications. Most initial certifications display current 116 specialty data. This needs to be updated to correspond to survey findings.

  If a lab is being re-activated with a gap, the initial certification does not show 116 specialties because all specialty data in CLIA has been closed out. You must enter new specialty information that reflects survey findings.

- **Recertification**

  Recertifications display current 1557 (survey) specialty data. You can update this information for Compliance labs to correspond to survey findings.

- **Validation**

  AOs enter and maintain survey specialty data in the CLIA 116 web app. Specialty data is read-only in ACO for validation kits. You can indicate if you found any discrepancies in the data reported by the AO.

TIP: Specialty history is stored at the facility level for CLIA labs. You can view it in the Survey Specialty Information window.

To enter/confirm survey specialties for a lab:

1. Click the **1557 Specialties** tab in the **Certification** window.
2. **Compliance** kits - Select applicable sub-specialties and enter the **Effective Date** (required) for each.

   Validation kits - Confirm dates entered by the AO.

3. **Compliance** kits - For each applicable specialty, enter **Test Volume** (required).

   Validation kits - Confirm test volume entered by the AO.
4. Are **Immunohematology Tests Performed** - select **Yes** or **No**.
5. Are **Blood Products Collected** - select **Yes** or **No**.
6. **Total Annual Test Volume**, **Certificate Schedule**, and **Compliance Schedule** are automatically entered.
7. **Validation** kits - Select the appropriate **Discrepancy Found** option.

More ...

Procedure: “View Survey Specialty History in ACO/ARO” on page 134
Screen: "1557 Specialties" on page 344

Delete Active Survey Specialties on Compliance Labs

To delete a survey specialty, you simply deselect it. In ACO, you can delete active survey specialties for Compliance labs. ACO audits deleted specialties. For Accredited labs, active survey specialties are deleted and closed out by CO super users only on the Specialties tab in the CLIA 116 web app.

To delete a survey specialty on a Compliance lab:

➥ Simply clear the checkbox for it on the **1557 Specialties** tab and choose **Yes** in the confirmation message.

WARNING! Delete a survey specialty only if it was listed in error.

Close Out Survey Specialties on Compliance Labs

Deleting a specialty is not the same thing as closing it out. To close out a specialty, you must enter an expiration date for it.

In ACO, you can delete active survey specialties for Compliance labs. ACO audits deleted specialties. For Accredited labs, active survey specialties are deleted and closed out by CO super users only on the Specialties tab in the CLIA 116 web app.

To close out a survey specialty:

➥ Enter its **Expiration Date** on the **1557 Specialties** tab.

The 1557 Specialties tab displays only active specialties. When you save after deleting or closing out a specialty, it will no longer appear on the 1557 Specialties tab. You can optionally view closed and deleted specialties on the Survey Specialty Information window.

More ...

Procedure: “Delete Active Survey Specialties on Accredited Labs” on page 53
Procedure: “View Survey Specialty History in ACO/ARO” below

1557 Specialty Edits

The edits applied to specialty data entered on the 1557 Specialties tab in ACO are the same as in the CLIA 116 web app. Below is an example of a user message generated by a 1557 edit in ACO.

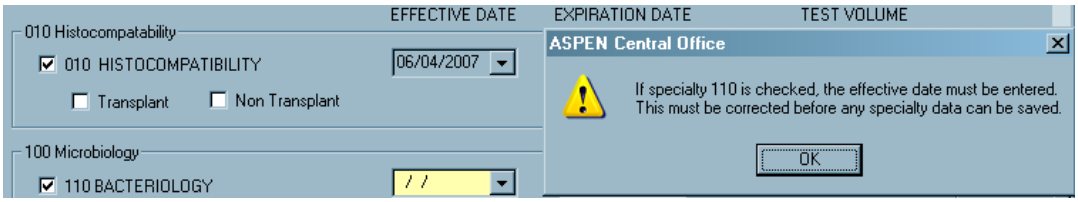

Figure 30: Specialty data entry error message

View Survey Specialty History in ACO/ARO

ACO provides a specialty inquiry window, Survey Specialty Information, which you can access from Tree view or the Facility Properties window. This window presents a read-only history of survey specialties for any lab with open (active) and closed specialties. It also lists deleted specialties that ACO is auditing and provides a history of test volume values.

ARO - RO and CO users can change the expiration date for one or more recently closed survey specialties.

The Survey Specialty Information window is available for any lab, regardless of certificate type. It is populated with survey specialty information that is gathered from the CLIA 116 web app and surveys, and stored at the facility level. If there are no specialties recorded for a lab, that is noted.

To open the Survey Specialty Information window:

1. Right-click a lab in the **Tree** view and select **Specialties**.

   -or-

   Open the **Facility Properties** window for the lab and click the **Specialties** button at the bottom of the window.

2. Select **Active Specialties Only** to view currently active specialties or **All Specialties** to view both active and closed specialties.

   The Survey Specialty Information window displays the following read-only specialty information for the lab.

   - **Expiration date to CWF/MSA** (Common Working File/Medicaid State Agency) is the lab's current certificate expiration date plus six months. This date is sent to CWF and MSA files as the specialty expiration date.

     Note: Do not provide this date to the laboratories, as it leads them to believe they have an extra six months on their current certificate.

   - **Total Test Volume** is shown as applicable.

- The **Specialty History** section lists survey specialties for any lab with open (active) and closed specialties. Active specialties are listed by default, with a default sort order by specialty code (Spec column). To display both active and closed specialties, select **All Specialties**.
- The **Delete Log** displays deleted specialties that are being audited by ACO.
- The **Test Volume History** section lists specialty test volume values.

RO, CO - To change the Closed Date of one or more specialties:

1. Open the **Survey Specialty Information** window for a lab.
2. Be sure to select **All Specialties** in order to display closed specialties.
3. Select one or more specialties with a Closed Date you want to change and click **Change Close Date**. To multi-select, Shift+click consecutive specialties or Ctrl+click non-consecutive specialties.

   If any of the selected specialties fail any edits, you will receive messages and the Closed Date will not be changed for those specialties.
4. In the **Change Closed Date** window, enter the **new Closed Date** and click **OK**.

   The new expiration date for the specialty is entered if it meets the following conditions:

   - It is no more than 6 months in the future.
   - It is before or the same as the expiration date of the CLIA certificate.
   - It is after the specialty's effective date.
   - It is before the effective date for the next specialty of the given type.
5. Click **Print** at the bottom of the screen to print the displayed specialty data.

   Note: USER ID may be truncated in the report.

Forms

ACO certification kit screens are designed to correspond as closely as possible to the CMS forms and instructions used in the field. The forms that must be completed (with certain exceptions) for CLIA certification kits are:

- CMS-1539
- CMS-1557
- CMS-2802A - validation kits only
- CMS-2567
- CMS-670

The first three are stored with the certification kit, the next two with the survey.

CMS-1539

The Transmittal (CMS-1539) tab of the Certification window replicates the CMS-1539 Certification and Transmittal form. The SA enters provider and program participation information in Part I, while the RO or SSA enters administrative information in Part II. Enabled fields vary depending on the mode (ACO or ARO).

Multiple CMS-1539s can exist in cases of followup surveys that occur before scheduled submissions or when there is a change in correction dates. CMS-1539 C&T information can be updated prior to each submission to the national reporting system.

To enter CMS-1539 data:

1. Click the **Transmittal (CMS-1539)** tab in the **Certification** window.

   Note: This tab does not appear for certification kits with a Prior status.

2. **SA** - Enter provider and program participation information in Part I.

   Fields that do not apply to the current lab either are disabled or are not displayed.

   - Effective Date: Change of Ownership (L9) - disabled for initial certification kits that have not been accepted by the national reporting system.
   - Type of Action (L8) - enabled only for recertification kits that have not been accepted by the national reporting system. If there are no prior kits, L8 is set to Initial and cannot be changed.

     Note: Must be 5 Validation for labs with a Certificate of Accreditation.

   - Fiscal Year Ending Date (L35) - use the format MM/DD, e.g., 02/04. ACO provides the "/".
   - Certified As (L12) - Indicate whether the lab is certified as A - In Compliance or B - Not in Compliance.
   - State Remarks - use field 30 at the bottom of the window.

     If the remarks are brief, they will appear in field 16 on the form; if they are long, they will be in field 30.

   - Surveyor Sign Date (L19) and State Agency Approval date (L20) - enter or select these dates.

3. **RO or SA -** Enter administrative information in Part II.

   - Eligible to Participate (L21) - Yes or No.
   - Original Date of Participation (L24) - the CLIA Application Received date populates this field and is read-only.
   - Termination Code (L30) - for CLIA labs, entered through the CLIA 116 web app in the Termination window.

- Expiration Date (L28) - for CLIA labs, must be entered through the CLIA 116 web app in the Termination window when Term (Termination) Code is anything but 00 Active Provider.
- Intermediary/Carrier No. - Number and name of provider's Medicare Administrative Contractor (MAC).
- RO Receipt Date (L32) - enabled in ARO. Required depending on circumstances. If this field is required but blank when the kit is uploaded, ACO enters the date.
- RO Analyst - enter initials.
- Determination Approval date (L33) - Required if L12 = B or condition-level deficiencies exist. An action item is automatically triggered when an upload of a CLIA certification kit requiring L33 is attempted. The format is: FORWARD TO RO - CERTIFICATION FOR: <LAB NAME>. It is sent to all CLIA RO Responsible Parties, if any are assigned to the certification on the Tracking tab; otherwise, it is broadcast to all CLIA RO users.
- Remarks - if the remarks are brief, they will appear in field 16 on the form; if they are long, they will be in field 30.

4 Click **Print** at the bottom of the window to print the **CMS-1539** form.

To generate the CMS-1539 for a certification:

➥ Select the survey in the Survey List section on the Certification & Surveys tab and click the Survey Forms button. In the Select Form(s) to print window, choose **CMS 1539** and click **OK**.

Note: The data must be entered in the certification kit. Do not use the 1539 Entry button.

The 1539 is generated.

More ...

Screen: "CMS-1539 - Part I" on page 341
Screen: "CMS-1539 - Part II" on page 342

CMS-1557

This form combines data from the Survey (CMS-1557) and 1557 Specialties tabs. It will not print if data validation checks fail.

To print the CMS 1557, aka the Survey Report Form (CLIA):

➥ Click **Print** at the bottom of the window.

CMS-670

Initial certification and recertification surveys are sometimes conducted in combination with other surveys. ACO provides a single window where you can enter all survey hours broken down by survey type (here, Category Description). Only those hours attributed to the certification survey will be uploaded with the certification kit.

If state licensure surveys: State Licensure, Initial Licensure, Re-Licensure, and Licensure Complaint are combined with a Federal initial certification or recertification survey (or complaint/incident investigation/survey), the corresponding Licensure rows in the CMS-670 grid are disabled due to existing CMS-670 guidelines. Licensure rows are, however, enabled for state licensure surveys of federally certified providers that are not combined with a Federal initial certification or recertification survey (or complaint/incident investigation/survey).

To enter CMS-670 data:

1. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
2. Select a survey and click **Update 670** to open the **CMS 670 Workload Detail** window.

   It lists all surveyors on the roster, with rows for each survey type (here, Category Description). Survey dates and types are brought forward from the Survey Properties window.
3. Select the **Lead** checkbox to indicate the survey team leader.
4. Select or de-select **On Team** as appropriate for survey team members.

   The On Team checkbox is selected by default for all team members and all survey types (Category Descriptions).
5. Enter hours for each staff member and survey type (Category Description), as appropriate.
6. Click **Office Hours...** to enter supervisory and clerical hours for each survey type (Survey Category); click **OK** when you are done.

   You will receive overridable messages if you do not enter all required office hours.
7. Click **Print** at the bottom of the **CMS 670 Workload Detail** window to print the **CMS-670** form.

8 Click **Close** to close the **CMS 670 Workload Detail** window.

You will receive overridable messages if you have not entered all required hours.

Note: The 670 Summary report is available from the Reports menu (Survey History Reports|670 Summary (670S). It summarizes 670 workload hours recorded for selected facility types within a specified date range.

More ...

Screen: "Survey List" on page 334
Screen: "CMS 670 Workload Detail window" on page 360

CMS-2567

There are several versions of the CMS-2567 form: 2567, 2567A, 2567B, and 2567L. The CMS-2567 form is the Statement of Deficiencies sent to the lab detailing the deficiencies found on the survey of the facility. The CMS-2567A lists minor deficiencies for which a POC is not required, but brings them to the lab's attention. The CMS-2567L lists deficiencies to be corrected and is publicly posted. The CMS-2567B lists deficiencies found on a revisit.

You can print CMS-2567 from the Select Form(s) to print window. IQCP tags are printed on the CMS-2567. Tags marked as QC exclusion prior to 01/01/16 are not included. Citations moved to another tag or removed due to IDR/Independent IDR will not be printed on CMS-2567s or certain other survey forms.

Note: The CMS 2567 Sent To Facility report is available on the Reports menu; select Scheduling and Tracking Reports | Tracking Reports | CMS 2567 Sent to Facilities. For each listed survey, the report shows how many days elapsed between the survey exit date and the date that the CMS-2567 was sent. If desired, you can include surveys for which no CMS-2567 has been sent.

CMS-2802A

The RO Approval fields in the CLIA Authorization for State Validation Survey (CMS-2802) section of the Tracking tab supply data for the CMS-2802A. After the RO has authorized a validation survey, i.e., RO Response = Approved, you can print CMS-2802A from the Select Form(s) to print window by selecting the CMS 2802 (Validation) checkbox.

Print Survey Forms

You can generate and print survey-related CMS forms from various places in ACO including Tree view, certification kits, and the Citation Manager.

To display and print survey forms:

1. In the **Tree** view, locate and right-click the appropriate survey, and select **Print Forms**.

   -or-

   In a certification kit, select the survey in the **Survey List** on the **Certification & Surveys** tab and click **Survey Forms**.

   -or-

   Open the **Citation Manager** for the survey and click **Forms...**.

   -or-

   At the bottom of the **Certification** window, click **Print**.

2. In the **Select Form(s) to print** window, select the forms you want to print.

   You can select one or more forms.

   - If you select the CMS-2567 report, which encompasses CMS-2567L/A, you can specify the components you want to include. The CMS-2567B is for revisits with corrected deficiencies. If state tags are cited, they print separately on the CMS-2567 State Form or, for corrected state deficiencies, on the State CMS-2567B Revisit Report.

     Note: Citations moved to another tag or removed due to IDR/Independent IDR will not be printed on CMS-2567s or the Quick Report (draft CMS-2567).

   - You can enter data for the 670 using the proper Entry button. To enter CMS-1539 data, you must go to the Transmittal (CMS-1539) tab in the certification kit.

3. Click **OK**.

   Each form you selected is displayed in a report preview window.

4. To print or export a form, click the **Print Report** or **Export Report** button on the preview window's toolbar. Provide requested information, then click **OK**.

5. Click the **X** in the upper-right corner to close each preview window.

More ...

Screen: "Citation Manager window" on page 355
Screen: "Select Form(s) to Print window" on page 358

Reports

Print Quick Reports

You can generate a number of reports through right-click menus that you access from nodes and items in ACO Explorer. These quick reports present information about the selected entity.

To generate and print a quick report:

1. In the **Tree** or **List** view, right-click an item such as a lab, certification kit, lab administrator, or lab owner.
2. Select **Quick Report** (or Quick Reports), then the report you want to print.
3. Click **OK**.

   A report preview window displays each report.
4. To print or export the report, click **Print** or **Export** on the preview window's toolbar. Provide requested information, then click **OK**.
5. Click the X in the upper-right corner to close each preview window.

Print Reports (Reports Menu)

You can generate various reports through the Reports menu including a number that are CLIA-specific. These reports combine and present information from multiple labs.

Note: You can also print batched letters from the Reports menu.

To generate and print a report:

1. From the **Reports** menu, select **CLIA Reports** (or other option) and then select the report you want to print.
2. In the **CLIA/Choose Report Options** or **Find** window that appears, specify report options.
3. Click **OK**.

   The report is generated and displayed in a preview window.
4. To print or export the report, click **Print** or **Export** on the preview window's toolbar. Provide requested information, then click **OK**.
5. Click the **X** in the upper-right corner to close each preview window.

More ...

Supporting Materials: "CLIA Reports" on page 559

Insert Backup Text

When an ASPEN word processor/text editor is open for entering or editing text, ACO takes a “snapshot” of its contents every two minutes if at least 500 characters have been entered. The snapshot is saved as a .txt file. These backup files are stored in the ackupDir folder in the ACO Data directory.

Note: If you paste text passages containing more than 500 characters, but do not leave the word processor open for at least two minutes, the text is not backed up.

If you lose a quantity of work due to:

- hardware failure

  -or-

- inadvertent deletion of text,

you can restore the text from within the word processor.

To insert backup text:

1. If necessary, open the applicable word processor.
2. Place the cursor where you want to insert the backup text.
3. Select **Insert Backup File** from the **File** menu.

   ACO displays the contents of the WPBackupDir folder in the Select Backup File window.
4. Locate the applicable backup file.

   For example, a citation text backup filename consists of the following elements:

   <Survey EventID><ASPEN Reg Set ID><Tag><StaffID>.txt
5. Double-click the file to insert the text into the word processor.

   Note: ACO overwrites existing backup files every two minutes only if more than 500 new characters have been entered in the word processor. This prevents the backup from being overwritten by the contents of an empty word processor while you are locating and inserting the file.

Upload Certification Kits

When all information has been provided and forms completed (all checkmarks are green, indicators on Cert & Surveys tab set to “Facility and CMS 670 Edits Passed” and “CMS 670 Complete”) for a CLIA certification kit, it is ready for upload to the national reporting system. The first upload of a kit–whether initial, recertification, or validation–must be initiated manually. After the first successful upload, certification kits created on or after 07/01/2014 are automatically re-uploaded, although an upload can also be triggered manually. Any kit created before 07/01/2014 *must* be manually uploaded.

Note: You can upload validation kits that have not previously been uploaded even after a new renewal certificate has been issued.

Manual Upload

Manual upload is required:

- the first time a CLIA certification kit is uploaded
- for certification kits created before 07/01/2014

After the first successful manual upload, CLIA certification kits created on or after 07/01/2014 are automatically re-uploaded when they qualify. Subsequent update uploads are also automatic. You can still manually trigger uploads if desired; it may be useful as a diagnostic tool if auto-uploads are failing. Manually uploaded kits must pass the same page, kit, and national edit checks as for automatic upload.

Note: Although manual uploads can be initiated at any time, upload processing to national does not occur on Saturday and Sunday.

To manually initiate an upload:

1. Click the **Upload** tab in the **Certification** window.

   Previous upload transactions for the certification kit are listed in the Prior Certification Kit Uploads section.

2. On the **Upload** tab, click the **Prevalidate and Upload** button and click **Yes** in response to the confirmation prompt.

   ACO prevalidates the certification kit. If all required information is supplied and valid, ACO transmits the kit. The status of the transaction is 00 - Pending.

   If an upload attempt fails, the Upload Transaction Errors section on the Upload tab will provide details about the errors that occurred during either the prevalidation or the upload. You must correct the errors and then upload the kit again.

When the upload attempt succeeds and the transaction status is Pending, i.e., the kit is pending upload to the national reporting system during the overnight process, the kit is read-only. If you must make changes to the kit with Pending status, you can delete the Pending transaction, then upload the kit again after updating it. Otherwise, you must wait until the overnight jobs process the Pending upload.

When the certification kit is accepted by the national reporting system, the status changes to 10 - Successful, and the kit will be updateable. After the kit is accepted, you cannot:

- Change the survey exit date.
- Delete the kit.

Automatic Upload

ASPEN's automatic upload engine continually monitors for changes to CLIA recertification kits created on or after 07/01/2014. Uploads occur automatically when the data appears ready for upload.

Note: Although automatic uploads can be initiated at any time, upload processing to national does not occur on Saturday and Sunday.

Qualification Phase

In the qualification phase, data is reviewed for completeness and to ensure the applicable business rules are met. When a recertification kit is created or updated, directly or through related functions such as Citation Manager or survey import, the qualification checks are applied each time the kit is saved to determine if it is ready for upload processing.

Transaction Queue

As soon as a recertification kit successfully passes qualification, the auto-upload process queues it for upload. Approximately every 10 minutes, the system checks to see if any kits are queued and, if so, it processes the appropriate upload transaction (Add, Update, etc.) to the national reporting system.

Auto-upload Processing

Data qualification, transaction queuing, and upload processing occur in the background. You will not be aware of these processes and can work uninterrupted.

Automatic upload transactions must pass national edit checks. In the event an auto-upload transaction fails one or more edits, responsible parties assigned to the kit receive both an e-mail and action item notification of the reasons for failure.

Many updates to a kit may be made throughout the day. These daily changes become available to the national reporting system during the overnight load process.

Restrictions on Uploads

The following restrictions apply to CLIA kit uploads:

- Prevalidate and Upload is disabled daily (including weekends) between 10PM ET and 4AM ET. You cannot upload CLIA certification kits during this time to ensure that changes to accounting data do not occur while the Nightly Adjustment File is created.
- If Certificate Type Change is set to Yes on the Certification & Surveys tab of an initial kit, you must wait a day after the upload, then change application status in the CLIA 116 web app as appropriate.

  Note: If no survey will be done, you can delete the certification kit and immediately perform a status change.

- Compliance labs must have paid the compliance fee in full; if not, the upload fails. Compliance fee payment status is indicated on the Upload tab.
- CLIA certification kits flagged for RO review (SF08 is set to 1) cannot be uploaded until they are reviewed. A count of condition-level tags is sent to national. If the number of condition-level tags changes, the count is updated on national. If a flagged kit with condition-level tags is deleted prior to upload, all data for the kit is removed from national.
- You cannot upload validation kits until RO Response = Approved on the Tracking tab and there is a Y-match.

- Specialty data
  - Compliance kits must include specialty data. Non-accredited specialties are included in uploads.
  - Validation kits do not upload specialty data.
  - Kits with Addition of Specialties surveys must include specialty data.
  - If Certificate Type Change Due to Survey (at the bottom of the Certification & Surveys tab) = Yes, the certification kit does not include specialty data.
- For CLIA kits with an upload transaction status of 00 - Pending, the entire certification kit is read-only until the kit is successfully uploaded. You also cannot import data from ASE-Q or change survey data in ACO or ACTS that would affect the certification kit until it is successfully uploaded.

Payment Status

You cannot upload a certification kit for a Compliance lab until it has paid the compliance fee in full. If you create a survey shell associated with a certification kit for a Compliance lab that has not paid the compliance fee, you will receive a warning, but can go ahead and create the survey shell. You can also enter citations and complete forms prior to receipt of the compliance fee.

Compliance fee payment status is indicated on the Upload tab for initial and recertification kits. A red checkmark indicates the lab has not paid the compliance fee; a green checkmark indicates it has paid. Accredited labs do not pay a compliance fee, so the standard upload icon appears for validation kits on the Upload tab.

The body of the Upload tab in initial and recertification kits also shows the payment status for the lab.

Figure 31: Compliance fee paid

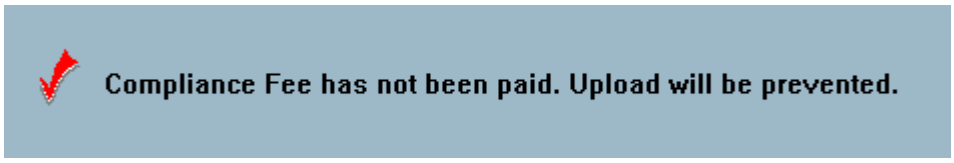

Figure 32: Compliance fee not paid

You can initiate upload of a certification kit for a lab that has not paid the compliance fee. Pre-validation and post-validation edits are applied to ensure that the kit passes all data and business rule edits. However, the upload will always fail with a -1 status due to the payment not being received.

If there are other upload errors, you can correct the data prior to the receipt of payment. When payment is received, you will be able to successfully upload the kit. You can track certification kits that are waiting to be uploaded after payment is received.

More ...

Procedure: "Track Upload Transactions" on page 155

Historical Certificate Data

With any upload transaction from the CLIA 116 web app including provider data, ASPEN uploads all historical certificates. The following historical certificate data is uploaded:

- Effective Date of the certificate
- Expiration Date of the certificate
- Application type code (1, 3, 2, 4)
- Certificate type code (1, 9, 3, 2, 4)
- Lab's Class (classification) Code (00, 05, 10)
- Lab's Term (termination) Code
- Mailed Date, i.e., date certificate was mailed to lab

Overnight Process

During the day, data is entered into both the CLIA 116 web app and ACO. During the nightly processing, data in the national reporting system is updated with changes made in the CLIA 116 web app as well as the survey/certification kit information uploaded from ACO.

Certification kits entered in ACO are uploaded to the national reporting system during the nightly processing. Any certification kit with a status of 00 (Pending upload) is sent to the national reporting system, which will send back a transaction status of 10 (Success) or 15 (Failure) for each certification kit that is loaded. Failures occur when kits do not pass national upload edits; the edit messages will be displayed in ACO. You must correct the errors and upload again.

More ...

Procedure: "National Upload Edits" on page 148

Edits

There are several layers of edits applied as you enter data into certification kits in ACO and upload them to the national reporting system. They ensure that data in the kits is complete and correct.

Screen-Level Edits

As you enter data into a certification kit in ACO, edits are applied each time you leave a window or tab. ACO issues warning messages for data fields that do not pass their edits.

In most cases, you can bypass these edits by answering Yes or Yes to All to the edit warning messages. On the 1557 Specialties tab, however, there are several edits you cannot bypass; you must correct the data before continuing. When all the information on the Transmittal (CMS-1539), Survey (CMS-1557), or 1557 Specialties tab passes the tab edits and no edit has been bypassed, the checkmark on the tab changes from red to green.

Pre-Validation Edits

When you select the Pre-Validate and Upload button on the Upload tab of a certification kit, pre-validation edits are applied. This edit layer ensures that all the page/tab level edits have been applied (i.e., all the checkmarks are green) and that the data entered for the certification kit is complete.

Post-Validation Edits

Once a certification kit passes the pre-validation edits, post-validation edits are applied. This edit layer ensures that all the data entered for the certification kit passes the business rules defined for CLIA.

If any post-validation edits fail, the upload transaction will be set to -1 and the edit messages are displayed so you can correct the data. You must then re-upload the certification kit.

National Upload Edits

Once a certification kit passes all the post-validation edits, its status is set to Pending Upload. During nightly processing, the certification kit is sent to the national reporting system where edits are applied to ensure the data is complete and meets CLIA business rules. In most cases these edits are duplicates of post-validation edits and data errors will be caught on upload rather than during overnight processing.

If all national upload edits pass, the status of the upload in ACO will be set to 10 - Successful. If any national upload edits fail, the status of the upload in ACO will be set to 15 - Failed and you will be able to see the edit message in ACO. You must correct the errors and upload the certification again.

More ...

Procedure: “Upload Errors” on page 149

Upload Status

When a certification kit passes all prevalidation and upload edits, its status will be one of the following, depending on where it is in the overnight upload process.

00 - Pending

Certification kit passed ACO edits and upload transaction will be processed during the next overnight cycle. The certification kit will be read-only while there is a pending transaction.

05 - In Process

Overnight cycle has begun. Upload transaction was pending (00) and has been sent to the national reporting system; waiting for response. Users will not see the 05 status value as it exists only during the nightly job cycle.

10 - Successful

Certification kit was successfully loaded to the national reporting system.

Upload Errors

If invalid or missing data is detected, the upload transaction is terminated. Edit messages are displayed and you must correct or enter data before uploading again. There are two types of upload failures:

-1 - Failure

Transaction failed ACO edits and was not uploaded. Data needs to be corrected and re-uploaded. The transactions must be manually re-uploaded once the data is corrected.

15 - Failure

Transaction failed national upload edits and was not loaded. Correct data in ACO and upload again. The transactions must be manually re-uploaded once the data is corrected.

In the following cases, kits can be uploaded after you are warned of missing data:

- If a kit includes a combined survey with a complaint/incident component, you can upload the kit even if workload hours for the complaint/incident portion have not been entered on the CMS-670 form. You will receive a warning message.
- For revisit surveys, you will receive a warning if the system finds no deficiencies. A warning message indicates that the offending revisits will not be uploaded. You can stop or continue the upload process.

To resolve an upload error:

1. For unsuccessful transactions, click the transaction on the **Upload** tab.

   The Upload Transaction Errors section appears and lists the problems.
2. Use this information to resolve the listed issues.
3. If necessary, cut and paste the error information to send to support personnel.

Flag Indicator (SF08)

The first upload (Add) transaction for a certification kit (successful or not) sets the Flag Indicator status (SF08) in the Special Fields section at the bottom of the Certification & Surveys tab. The Release for CMS Review? checkbox at the top of the Certification & Surveys tab is also selected, if it has not already been manually selected by the State Agency.

An icon next to the checkbox indicates if the kit is flagged for RO extended review or not SF08 is recalculated with each attempted Add transaction until one is successful; the status is then frozen.

More ...

Procedure: "Flag a Kit for Review by the RO" on page 156

Late Certification Kits

A certification kit is considered late if it has not been successfully uploaded within a specified number of days from the certification exit date, i.e., Date of Survey (L34). Two upload monitoring emails are automatically generated and provide notification of late cert kits:

- Late Certification Kit Upload Review

  Lists certification kits that have never been uploaded and are late.
- Late Certification Kit Uploads

  Lists certification kits that have not been accepted after a given number of days and kits that were previously accepted but can no longer be uploaded due to failed validation.

More ...

Supporting Materials: "Upload Monitoring Emails" on page 550

View Failed and Overdue Uploads

From the Tracking menu, you can generate lists with details about failed and overdue uploads of:

- Certification kits
- Special surveys

By default, both lists are filtered according to your active My Selections set.

View Failed and Overdue Certification Kit Uploads

The Failed and Overdue Certification Kit Uploads window lists all certification kits in need of an upload or completion. You can open the Certification window for a selected certification kit and make needed changes.

To view failed and overdue certification kit uploads:

1. From the **Tracking** menu, select **Failed and Overdue Certification Kit Uploads**.

   The Failed and Overdue Certification Kit Uploads window lists failed (orange) and overdue (yellow) cert kit uploads, and incomplete (green) kits that require additional data before an upload can occur. Status is explicitly indicated in the Upload Status column.

   The following information is displayed:

   - Track ID
   - Provider Number
   - Created Date of certification kit
   - Age (in Days) of kt
   - Facility Name
   - Last Upload Date
   - Upload Status: Failed, Overdue, or Incomplete

   TIP: You can change the sort order of the list by clicking any column heading.

2. Adjust **Filter Options** at the top as needed; click **Refresh List** to update the display.
3. To view explanations of errors associated with a failed upload in the **Upload Transaction Errors** section, click in the applicable row.
4. Select a certification kit (row) and click the **Certification Kit** button to open the corresponding Certification screen.

5 Click **Print** to print the displayed list as a report.

6 In the report preview window, click the **Export** icon to generate the list in the format of choice.

More ...

Screen: "Failed and Overdue Certification Kit Uploads window" on page 351

View Failed and Overdue Special Survey Uploads

The Failed and Overdue Special Survey (SRVY) Uploads window lists all special surveys in need of an upload or completion. You can open the Survey Properties window for a selected survey and make needed changes.

To view failed and overdue special survey uploads:

1 From the **Tracking** menu, select **Failed and Overdue Special Survey Uploads**.

The Failed and Overdue Special Survey (SRVY) Uploads window lists failed (orange) and overdue (yellow) special surveys uploads, and incomplete (green) surveys that require additional data before an upload can occur. Status is explicitly indicated in the Upload Status column.

The following information is displayed:

- Event ID
- Provider Number
- Exit Date of survey
- Age (in Days) of survey
- Facility Name
- Last Upload Date
- Upload Status: Failed, Overdue, or Incomplete

TIP: You can change the sort order of the list by clicking any column heading.

2 Adjust **Filter Options** at the top as needed; click **Refresh List** to update the display.

3 To view explanations of errors associated with a failed upload in the **Upload Transaction Errors** section, click in the applicable row.

4 Select a survey (row) and click the **Survey Properties** button to open the corresponding Survey Properties window.

5 Click **Print** to print the displayed list as a report.

6 In the report preview window, click the **Export** icon to generate the list in the format of choice.

More ...

Screen: "Failed and Overdue Special Survey Uploads window" on page 361

Tracking

The Tracking tab provides a central point for monitoring all aspects of the certification process, both fieldwork and internal office procedures.

Certification Summary

Displays Certification date (L34) and status, and Health survey exit date.

CLIA Authorization for State Validation Survey (CMS 2802)

The RO Approval fields in this section facilitate communication between the states and RO when the states perform validation surveys on CLIA Accredited labs. It supplies data for the CMS-2802A form.

When you select the Request for RO Approval checkbox, ACO sends an RO APPROVAL REQUEST - VALIDATION action item to the RO Responsible Party. If no RO Responsible Party is specified, the message goes to all CLIA RO users in the region.

The RO then accesses this section to approve or deny the validation survey and record the date. When the RO completes the information, ARO sends an RO RESPONSE - VALIDATION action item to the SA Responsible Party.

After the RO has authorized a validation survey, i.e., RO Response = Approved, you can print the CMS-2802A from the Select Form(s) to print window by selecting the CMS 2802 (Validation) checkbox, and create the survey shell.

Responsible Parties

You can designate responsible parties for the certification, both SA and RO. There must always be at least one responsible party. Assignments made here are carried over to Responsible Parties on the Certification & Surveys tab.

Activities/Action Items

On this tab you can assign activities to staff members. Action items are automatically sent to the assigned personnel.

More …

For a comprehensive list of action item messages, refer to the *AST Procedures Guide*, which is posted on https://qtso.cms.gov.

Processing Steps

The Processing Steps subtab provides detailed information about individual tasks in the certification process. In many cases, steps are created and dates are entered automatically as information is entered in ASPEN. You can add and modify items manually as needed.

2567/POC/IDR

This subtab includes/accesses a summary of dates and details for all Statements of Deficiencies (SODs) and Plans of Correction (POCs) connected with the certification.

Enforcement

This subtab provides a summary of enforcement actions associated with the certification.

Notices

From this subtab, you can print letters and view the letter history for the certification.

CHOW

This section is not applicable in CLIA certification kits.

Track Certification Kits

The Certification Kits window lists certification kits with details about each including kit and upload status. You can filter the listed kits by provider type, status, and date. From the list, you can open individual kits.

To view a list of certification kits:

1. From the **Tracking** menu, select **Certifications** to open the **Certification Kits** window.

   Initial certifications appear in red and recertifications appear in blue. In the ODIE column, a blank space indicates that no attempt has been made to upload the kit, a yellow envelope indicates at least one attempt has been made to upload, and a green checkmark indicates that the kit has been successfully uploaded.

   TIP: A certification kit is not listed in the Certification Kits window until it includes a survey.

2 Use the **Provider Type**, **Status**, and **Dates** filters to tailor the list of certification kits.

➥ Select the desired **Provider Type**(**s**) and **Status**.

➥ Enter the start and end **Dates** of the date range you want.

This is a range of certification exit dates, i.e., L34 - the exit date of the Health standard survey.

3 After setting the filters, click **Set** to refresh the list of certification kits.

4 To see only the most recently modified kits, select **Show Kits Modified Since Last Upload**.

The list of certification kits automatically refreshes.

5 **RO -** Select the **RO Quick List** checkbox to display initial and unaccepted flagged certification kits.

The list of certification kits automatically refreshes.

6 Click **Print Tracking Report** to view/print information about the listed certification kits in report form.

The Sort Order window appears. You can sort the report by Facility Name, Provider ID, or Survey Date, in ascending or descending order.

7 Select a certification and click **View Highlighted Certification** to open the corresponding kit.

-or-

Simply double-click a certification in the list.

8 Click **Print List** to view/print the information in the **Certification Kits** window in the order the kits are listed.

More ...

Screen: "Certification Kits window" on page 348

Track Upload Transactions

You can view a selected list of upload transactions for a specified time period with details about each transaction.

To view upload transactions:

1 From the **Tracking** menu, select **Transactions**.

2 In the **Please Specify Transactions to List** window:

➥ Enter the **Start Date** and **End Date** of the desired transaction date range.

The transaction dates are system-generated when transactions occur.

➥ To filter by provider type, select the **Facility Types** checkbox to open the **Filter Select Dialog**. Select the provider types you want.

You are limited to specifying a subset of facility types in your active selection set. If you do not select any, you will receive a message, the Facility Types checkbox will be cleared, and all facility types–not just those in your selection set–will be included.

➥ Choose which of seven groups of transactions to display.

3 Click **OK** to open the **Transactions** window.

All transactions matching your specified criteria are displayed. The list of transactions is also filtered according to your active My Selections settings.

Initial certifications are red; recertifications are blue. The Action column shows the action assigned by ASPEN for processing each upload transaction. You can sort this list by any of the column headings.

4 Use **Start Date**, **End Date**, **Selection Criteria**, **Sort Order**, and **Facility Type Filter** at the top of the **Transactions** window to redefine filtering criteria and sort order as desired; click **Refresh List** to update the display.

5 To view the text of error messages (if any) associated with a transaction, select the transaction to open the **Upload Transaction Errors** section.

6 Select a transaction and click **View Related Certification Kit** or double-click a transaction to display the related certification kit.

7 Click **Print** to print the displayed transaction list as a report.

8 In the report preview window, click **Export** (red arrow with envelope) to generate the transaction list in the format of choice.

More ...

Screen: "Please Specify Transactions window" on page 349
Screen: "Transactions window" on page 350

Flagged Kits

Flag a Kit for Review by the RO

When an upload is attempted, ACO automatically flags a certification kit for RO review, i.e., sets SF08 to 1 - Flagged, in the following circumstances:

- One or more uncorrected condition-level citations exist.

  All condition-level tags are green and labeled as (Condition) in Citation Manager. A count of condition-level tags is sent to national to indicate existing COPs whether or not an upload is successful.

- L12 on the 1539 is B - Not in Compliance.

The SA can also manually request a review before attempting an upload by selecting the Release for CMS Review option on the Certification & Surveys tab.

Whether the kit is flagged for review automatically or manually, the FORWARD TO RO - CERTIFICATION FOR: <FACILITY NAME> action item is triggered and sent to the CLIA RO Responsible Parties assigned to the certification on the Tracking tab. If no RO Responsible Party is assigned, it is broadcast to all CLIA RO users in the appropriate region.

If the number of condition-level tags is changed on a flagged kit pending RO review, national is updated accordingly. If a flagged kit includes condition-level tags and is deleted prior to upload, all data for the kit is removed from national.

You cannot upload certification kits flagged for RO review until the RO has entered RO Receipt Date (L32) and Determination Approval date (L33) on the 1539.

SA - To flag a kit for review by the RO:

➥ Manually select the **Release for CMS Review** checkbox at the top of the **Certification & Surveys** tab.

-or-

➥ Upload a certification kit where **L33** is required to automatically set **SF08** to **Flagged**.

If ACO flagged the kit automatically during an upload attempt, the flag icon appears next to Release for CMS Review and the certification kit will be listed in the Transactions window.

Whether the kit was flagged automatically or manually, the FORWARD TO RO - CERTIFICATION FOR: <FACILITY NAME> <CCN> action item is triggered and sent to the appropriate CLIA RO personnel.

Review Initial and Flagged Certifications

RO - To review an initial or flagged kit:

1. Double-click the kit in the **Certification Kits** or **Transactions** window to open it.

   -or-

   Double-click the FORWARD TO RO - CERTIFICATION FOR action item to open the flagged kit.
2. Review the **CMS-2567**s of the surveys associated with the certification.
3. Enter/review data entry hours in the **CMS-670**.
4. Click the **Transmittal (CMS-1539)** tab and enter required information.
5. Review lab personnel and specialty information and update as necessary.
6. Click the **Upload** tab to view prior uploads.

7 Select an unsuccessful transaction (red light icon) to display associated error messages.

Note: If the transaction failed because of missing data that must be entered by the Regional Office, then the RO needs to complete the certification kit and upload it to the national reporting system.

8 Fill in the **RO Receipt Date (L32)** and **Determination Approval (L33)** date.

ACO automatically closes the FORWARD TO RO action item when the RO enters L33. A kit that passes all edit checks can be uploaded/re-uploaded. When the upload is successful, the Flag Indicator status (SF08) is frozen.

The first upload must be manual. After the first successful upload, certification kits created on or after 07/01/2014 are automatically re-uploaded.

To manually upload the kit, the RO must save and exit the kit after entering L32 and L33, reopen it, then upload. Alternatively, have the SA upload the kit. Otherwise, L33 is blanked out and the upload fails. This is because the system assumes the SA is uploading the kit and the SA cannot enter L33, so the system removes the value.

More ...

Procedure: “CMS-2567” on page 139
Procedure: “CMS-670” on page 138
Procedure: “CMS-1539” on page 136
Procedure: “Specify Personnel Qualifications” on page 131
Procedure: “View and Enter Survey Specialty Data” on page 132
Procedure: “Upload Certification Kits” on page 143

Change Status Due to Survey

On an initial certification, you set Certificate Type Change Due to Survey (in the CLIA section at the bottom of Certification & Surveys tab) to Yes in two circumstances:

- During the onsite survey, you find the lab is performing only waived or PPM tests.
- The lab chooses to downgrade its certificate as a result of survey findings.

Consequences

When Certificate Type Change Due to Survey = Yes:

- The CMS-2567 is optional.
- The 1557 Specialties tab is disabled.
- If specialty data already exists on the 1557 Specialties tab, a confirmation message tells you that the data will be removed.
- You will probably need to enter a status change in the CLIA 116 web app, for example, 1 Compliance to 2 Waiver.

Timing of Status Change

After an initial kit with a certificate (application) type change due to survey is successfully uploaded, you can enter the status change in the CLIA 116 web app. The timing is important. You *must first* upload the initial cert kit with the certificate type change to the national reporting system, then *wait one day* before entering the status change in the web app. A successful upload clears out the Survey Pending Date in the web app, which may disable the status change function. The proper sequence and timing is shown below.

Day	ACO	CLIA Web App
1	Create survey shell.	Survey Pending Date is set to survey exit date (X3). You cannot enter a status change.
2	Complete certification kit and upload it successfully to the national reporting system. Status = 00 - Pending Upload	N/A
3	Status = 10 - Successful	Survey Pending Date is blanked out. You can enter a status change.

Note: If no survey will be done, you can delete the certification kit and immediately perform the status change.

More ...

Supporting Materials: “Status Values for Upload Transactions” on page 558

Revisits

Create Revisit Survey Shells

Revisits can be scheduled as necessary until all deficiencies are corrected. If changes are made to the standard (initial) survey or the preceding revisit, you must manually update the current revisit as appropriate.

After each revisit linked to a certification kit is completed, the kit is automatically re-uploaded if created on or after 07/01/2014. Otherwise, you should manually upload the kit again.

If the standard or preceding revisit is a combined certification/complaint survey, but survey citations are linked only to the certification or complaint, the revisit will not be created as a combined survey. It will be a certification or complaint survey as appropriate.

To create a revisit survey shell:

1. In the **ACO tree**, locate and expand the lab.
2. Right-click the applicable certification kit, and select **Certification Kit**.
3. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
4. Click the **Create Revisit** button.

   TIP: You can also right-click the survey in **Tree view** and select **Create Followup Survey**.

5. In the **Create Followup** window - as needed - change default dates, update the **Team Roster**, and select **Carry Text Forward**.

   You cannot create multiple followups with the same exit date for the same survey. You *can* add followup surveys to Prior kits.

   A message appears if you select a staff member to add to the Team Roster whose General Staff Type is 02 Clerical/Support (in the Enter/Update Surveyor Information window). You can choose whether to go ahead and add that staff member or not.

6. Click **OK** to create the revisit.

   The new revisit survey is added to the tree. Revisits are identified on the Alpha, Type, and Cert/Survey tabs by an asterisk preceding the event ID. The last digit of the event ID is greater than 1 (2 for the first revisit, 3 for the second, and so on).

You can enter Corrected dates directly in the Citation List section once a revisit is defined.

If you create a revisit for a standard survey or revisit linked to an intake in ACTS, it will be automatically linked to that intake.

Note: If changes are made to the standard survey or the preceding revisit, you must manually update the current revisit as appropriate.

More ...

Screen: "Survey List" on page 334
Screen: "Create Followup window" on page 360

Enter Tag-level POC Dates

For each revisit, you can provide tag-level POC dates in the POC Detail section of the Citation Properties window.

Note: If the QC Exclusion checkbox was selected for a tag prior to 01/01/16, the POC Detail section is disabled.

To enter tag-level POC dates:

1. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
2. Select the applicable survey, then click **Citations Mgr**.
3. In the **Citations** section, right-click a tag and select **Citation Properties** to open the **Update Citation Properties** window.
4. In the **POC Received from Facility** field, enter the date POC for the current tag was received from the provider.
5. In the **Facility POC Complete** field, which corresponds to field X5 on the CMS-2567, enter the date the provider completed the POC.
6. To apply the POC dates for the current tag to all other tags cited in the survey, click **Set All Tags to These POC Dates**.
7. In the **SA POC Accepted** field, enter or select the date the State Survey Agency accepted the POC.

More ...

Screen: "Survey List" on page 334
Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356

Enter Survey-level POC Information

For each revisit, you can enter survey-level POC dates and notes in the POC Tracking window. This is a convenient means for recording and tracking revisions to POCs.

To enter survey-level POC information:

1. In the **Survey List** section of the **Certification & Surveys** tab, click **POC** in the **Track** column of the survey for which you want to enter POC information.

   You must provide a 2567 Issued date before you can open the POC Tracking window.

2. In the **POC Tracking** window, enter relevant survey-level **POC** dates and add **POC Notes** as needed.
3. Click **Letter** if you want to generate POC-related letters, then click **New...** in the **Notices History** window.

More ...

Screen: "Survey List" on page 334
Screen: "POC Tracking window" on page 347

Enter Correction Dates

ACO considers a deficiency to be corrected when a correction date has been entered for the tag in the Citation Manager or in the Citation List grid. It is the date the deficiency was found to be corrected during a revisit. If multiple surveyors have cited a tag and one surveyor enters a correction date, that date is automatically entered for the other surveyors' cites.

You can enter correction dates only for revisit surveys and the correction date cannot be before the survey on which the tag was first cited or after the latest revisit in which the tag is cited. A red checkmark appears to the left of a citation in the Citations list if a correction date has been entered.

The Correction Dates option in the Citation Manager window lets you specify the correction date for one or more citations associated with a survey, whereas you can enter the correction date only for a selected citation in the Citation Properties window or Citation List grid.

Note: If the Completed date (X5) is the same as the Exit date (X3) of the survey, this indicates the correction was made during the survey. In this case, there is no need for a corrected date.

To enter correction dates in the Citation Manager:

1. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
2. Select the applicable survey, then click **Citations Mgr**.

3 In the **Citations** section of the Citation Manager window, right-click a tag and select **Correction Dates**.

4 Choose the desired option:

- To enter the correction date on the selected citation only, click **Selected Citation**.
- To enter the correction date on all citations of tags from the same regulation set as the selected citation, click **Selected Reg Set**.
- To change the correction date on all the citations associated with the survey, click **All Citations**.

5 In the **Correction Date** window, enter the **Citation Correction Date** and click **OK**.

The correction date for the selected or multiple citations is updated accordingly.

-or-

1 In the **Citations** section, right-click a tag and select **Citation Properties**.

2 In the **Update Citation Properties** window, enter the **Correction Date**.

This field appears only for followup surveys.

To enter correction dates in the Citation List grid:

➥ In the **Citation List** section of the **Certification & Surveys** tab, enter the correction date for individual tags in the **Corrected** column.

More ...

Screen: "Survey List" on page 334
Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356
Screen: "Citation List" on page 334

ASSP Merge on Upload

ACO stores the cited tags, start and exit dates of surveys, and ASSP data for each visit. When data is uploaded, some of the data must be combined in order to fit the data rules on the national reporting system.

When a survey is re-uploaded after a revisit, all tags cited on the original survey and on the revisits will be uploaded. Associated specialty data entered for a tag will be combined based on the ASSP information added for each visit.

Here is an example:

1 For each visit, open the **Citation Manager**.

2 Right-click an ASSP tag in the **Citations** section, 5781 for this example, and select **Citation Properties**.

3 In the **Update Citation Properties** window, click the **Specialties** button. Let us assume this is what you see for visits 1 and 2:

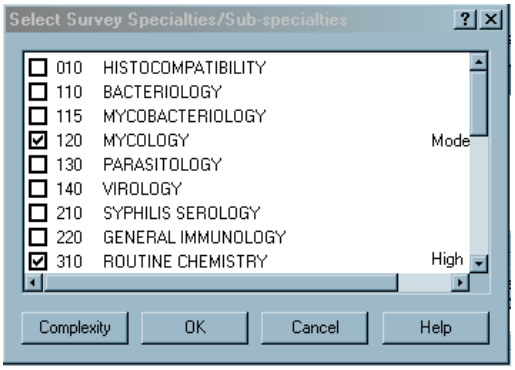

Figure 33: Visit #1 - Tag 5781

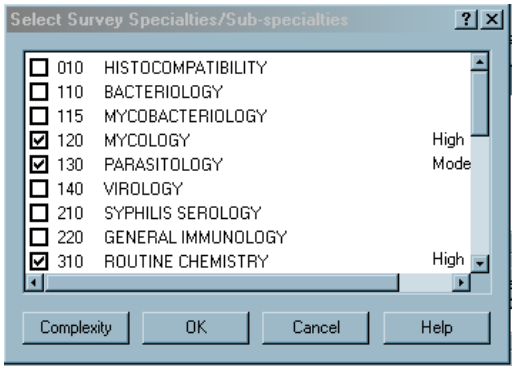

Figure 34: Visit #2 - Tag 5781

On upload, the ASSP values for Tag 5781 from the two visits will be combined.

The values uploaded to the national reporting system will be:

- 120 Both (High and Moderate complexities are combined to Both)
- 130 Moderate
- 310 High

More ...

Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356

Offsite Surveys

Followups are often performed offsite. When a revisit survey shell is created, the survey extent is automatically set to Routine/Std Survey. For an offsite survey, you need to change the extent and enter the applicable 670 workload hours.

Change Survey Extent

You can readily modify the survey shell to indicate the revisit will be an offsite survey by changing the extent.

To change survey extent:

1. Scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.
2. Select the applicable survey, then click **Update**.
3. In the **Extent(s)** section of the **Survey Properties** window, clear the checkbox for **Routine/Std Survey**.
4. Select **Offsite/Paper** instead.

More ...

Screen: "Survey List" on page 334
Screen: "Create Health Survey/Survey Properties window" on page 353

Enter 670 Offsite Hours

The rules for entering 670 workload data for offsite surveys are not the same as for standard surveys:

- ACO does not populate the Arrival and Depart fields and prevents you from entering these dates.
- You *must* enter Pre-Survey Hours and/or Off Site hours.
- Do *not* enter On-Site and Travel hours (E - H).

More ...

Screen: "CMS 670 Workload Detail window" on page 360

Special Case Surveys

PT Desk Reviews

All SAs are required to conduct Proficiency Testing (PT) desk reviews for their Compliance laboratories at least every 30-45 days to determine their compliance with CLIA PT requirements. In ACO, PT Desk reviews are entered as offsite revisits.

To enter a PT Desk review:

1. In the most recent certification kit for the lab within the last two years, scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.

2 Click the **Create Revisit** button to create a revisit survey.

If the selected survey already has revisits assigned, select the latest revisit before selecting Create Revisit.

Note: No tags should carry forward to the revisit since they all should have already been corrected.

3 In the **Extent(s)** section of the **Survey Properties** window, clear the checkbox for **Routine/Std Survey** and select **Offsite/Paper** instead.

4 Open the **Citation Manager** and cite tag **D2016 - Successful Participation**.

5 Open the **CMS 670 Workload** window and enter **Pre-Survey Hours** and/or **Off Site** hours. Do *not* enter On-Site and Travel hours.

6 Also enter clerical and supervisory hours in the **Form 670 Input** window.

7 Upload the certification kit.

More ...

Screen: "Survey List" on page 334
Procedure: “Create Revisit Survey Shells” on page 160
Screen: "Create Health Survey/Survey Properties window" on page 353
Screen: "Citation Manager window" on page 355
Screen: "Citation Properties window" on page 356
Screen: "CMS 670 Workload Detail window" on page 360
Procedure: “Upload Certification Kits” on page 143

Addition of Specialty Surveys

Addition of Specialty surveys may be entered as revisits. The revisit can be left as the default standard/routine survey or changed to an offsite survey. The SA determines whether the revisit should be onsite or offsite depending on the added specialty and equipment in place at the lab.

To enter an Addition of Specialty survey:

1 In the most recent certification kit for the lab within the last two years, scroll to the **Survey List** section on the **Certification & Surveys** tab of the **Certification** window.

2 Click the **Create Revisit** button to create a revisit survey.

If the selected survey already has revisits assigned, select the latest revisit before selecting Create Revisit.

Note: No tags should carry forward to the revisit since they all should have already been corrected.

3 In the **Survey Properties** window, select **S-Add of Specialties** for Type of Survey.

4 Select survey extent:

- For an **offsite** Addition of Specialty survey, select **F-Offsite/Paper** as the Extent for the survey.
- For an **onsite** Addition of Specialty survey, select **A-Routine/Std Survey** or **D-Other Survey** as the Extent.

5 Enter 670 hours:

- For an **offsite** survey, enter **Pre-Survey Hours** and/or **Off Site** hours. Do *not* enter On-Site and Travel hours.
- For an **onsite** survey, enter applicable 670 hours.

The kit is automatically re-uploaded if created on or after 07/01/2014. Otherwise, you should manually upload the kit again.

More ...

Screen: "Survey List" on page 334
Procedure: "Create Revisit Survey Shells" on page 160
Screen: "Create Health Survey/Survey Properties window" on page 353
Screen: "CMS 670 Workload Detail window" on page 360
Procedure: "Upload Certification Kits" on page 143

Manage Federal Monitoring System Events

RO/CO

The functionality of the national Federal Monitoring System (FMS) is fully supported in ASPEN. RO/CO users access and manage FMS records in ARO from the FMS Tracking screen, which is opened through the Tracking menu.

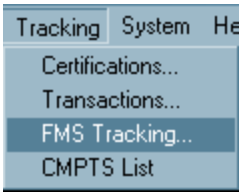

Figure 35: FMS Tracking option on Tracking menu

New and updated FMS records are uploaded to national on a nightly basis.

View FMS Events

RO/CO

The FMS Tracking option in ARO provides RO/CO users a central point for monitoring all aspects of FMS events. From here you can access and manage FMS records. By default, the list of FMS events is filtered according to your active selection set. You can set additional filtering criteria.

To view and filter FMS events:

1. From the **Tracking** menu, select **FMS Tracking** to open the **FMS Tracking** window.

   The Provider Type filter reflects the facility types in your active selection set. You can change this if desired, and set additional filters–one, several, or all of: FMS Exit Date range, Revisits Only, FMS Type, State, CCN (CMS Certification Number).
2. To filter by a range of FMS survey exit dates, enter the starting **FMS Exit Date** and the **to** (ending date) of the desired range.
3. To display only FMS revisit events, select the Revisits Only? checkbox.
4. To filter by event type, select the desired **FMS Type**.
5. To view FMS events for a particular **State**, select it from the drop-down list.
6. To view FMS events for a particular provider, enter its **CCN**.
7. Click **Apply Filter Settings**.

   The list of FMS events is refreshed according to the filters you specified.

More ...

Screen: "FMS Tracking window - ARO" on page 362

Create and Update FMS Records

RO/CO

You can create an FMS record, and view or modify information about a selected FMS record through the FMS Add/Update screen. From the FMS Tracking window, you can directly delete an FMS event.

To create an FMS record:

1. In the **FMS Tracking** window, click **Add**.
2. Enter the **CCN** in the **FMS Provider Selection** window that appears, or click **Find** to locate the provider and insert the number.
3. Click **OK** in the **FMS Provider Selection** window and **Yes** in the **Confirm Provider** window.
4. In the **FMS Add/Update** screen, enter applicable information.
5. Provider information is entered from Facility Properties and is read-only.
6. Select the **Type** and **Extent of Federal** (FMS) **Survey**.
7. The **In Casper** and **Upload Pending** indicators are automatically selected as appropriate.
8. Use the **Federal Survey** and **State Agency Survey** sections to create and/or link Federal or state surveys to the FMS event.
9. Select **Yes** or **No** and enter dates as appropriate for the items in the next section.

10 If applicable, select tags in the **Conditions/Standards** section that you intend to check for compliance on the survey.

The Conditions/Standards section is enabled only if Extent of Federal Survey = 4 Partial without LSC and a Federal survey is linked to the FMS record. This section lists the condition and standard level tags in the Federal regulation set assigned to the linked survey. The regulation set is listed under Associated Regulations.

11 Click **OK** to save the information and close the **FMS Add/Update** window.

To modify an FMS record:

1 In the **FMS Tracking** window, select the record you want to modify and click **Modify**.

2 In the **FMS Add/Update** screen, make your changes and click **OK**.

To delete an FMS record:

1 In the **FMS Tracking** window, select the record you want to delete and click **Delete**.

2 Click **Yes** in the confirmation prompt.

More ...

Screen: "FMS Tracking window - ARO" on page 362
Screen: "FMS Add/Update window - ARO" on page 363
Procedure: “Create and Link FMS Surveys” on page 171

Print FMS Reports

RO/CO

From the FMS Tracking window, you can generate three reports:

- FMS Tracking Report
  Prints the information in the FMS Tracking window in report form.
- All FMS transactions
  Prints details about all cases in the FMS Tracking window that are pending upload, or have been uploaded–successfully or not.
- All Failed FMS transactions without success
  Prints details about all cases in the FMS Tracking window whose latest upload transaction failed.

You can specify filtering criteria to customize the reports for your needs.

To generate FMS reports:

1 In the **FMS Tracking** window, select the report you want to print from the **FMS Reports** drop-down list.

2 In the **Filters** section, specify filtering criteria for the report.

If you enter a CCN, all other filter specifications are ignored. The report will include all FMS cases for the given provider.

3 Click the **Report** button to apply the filters and update the list of FMS cases that meet the criteria.

If you select FMS Tracking Report, it prints directly and includes all listed cases. The report is sorted by the column selected in the FMS Tracking window.

If you choose either "All FMS transactions" or "All Failed FMS transactions", a report review window (with the report name as title) opens and displays the specified filtering criteria (read-only) from FMS Tracking.

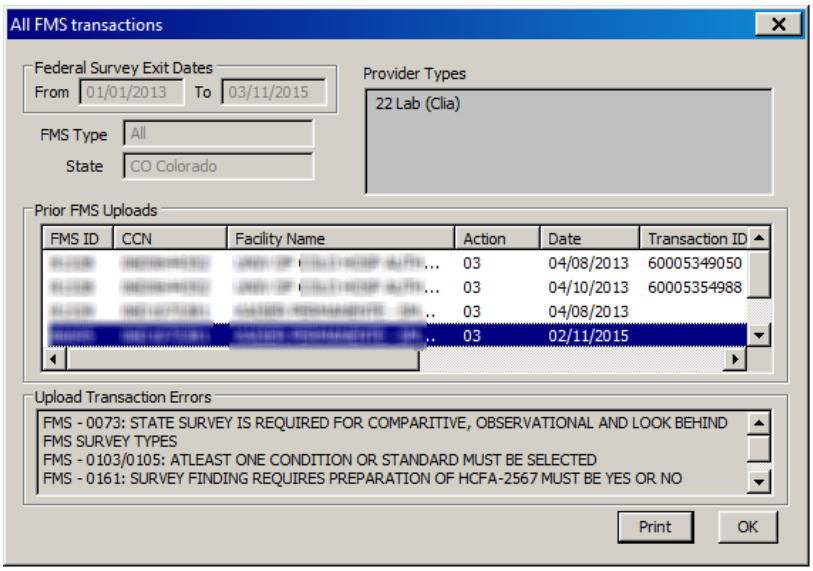

Figure 36: FMS report review window

If you selected Revisits Only in FMS Tracking, "for Revisits Only" appears under the State field. If you entered a CCN, filter settings (top part of screen) are blanked out; the CCN appears in the window title.

Prior FMS Uploads lists upload transactions for the cases listed in FMS Tracking. These are the items that will be included in the report.

4 Select a transaction in Prior FMS Uploads to view associated messages (not necessarily errors) in the Upload Transaction Errors panel.

5 To change filtering criteria, select **OK** to return to FMS Tracking.

6 To generate the "All FMS transactions" or "All Failed FMS transactions" report, click **Print** in the report review window.

The two FMS transactions reports are sorted by: CCN, then FMS ID (case number), then transaction date (descending).

More ...

Procedure: "View FMS Events" on page 167
Screen: "FMS Tracking window - ARO" on page 362

Create and Link FMS Surveys

RO/CO

Only RO/CO users can create, modify, and delete standard (initial) Federal Monitoring surveys. FMS surveys cannot be combined with other survey types except D-Follow-up/Revisit.

Note: SA, RO, and CO (ACO and ARO) users can create, modify, and delete FMS revisit surveys.

There are three possible ways to create and link a standard Federal survey to an FMS event:

- Create and link a survey from within an FMS record.
- Create the FMS survey directly in ARO (or import it from ASE-Q) and link it to an FMS record.
- Change Type of Survey for an existing survey to C-Federal Monitoring and link it to an FMS record.

FMS surveys are included in Tree view under the provider's FMS Surveys node, which lists only surveys of type C-Federal Monitoring. The Surveys node lists all surveys other than FMS. If an FMS survey has been successfully uploaded, that is indicated.

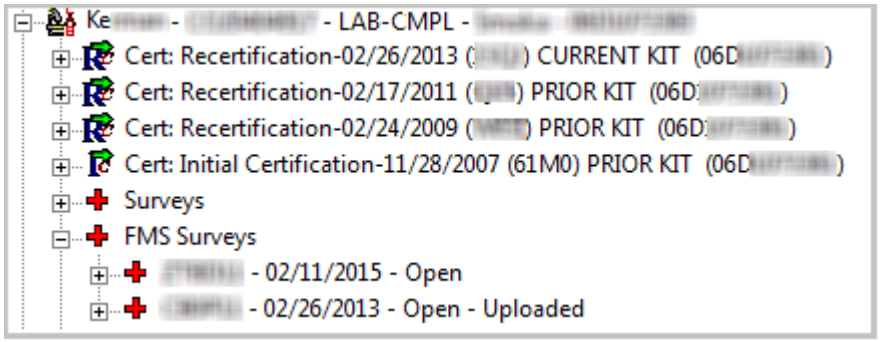

Figure 37: FMS Surveys node in Tree view

Note: SA users have read-only access to standard surveys listed under the FMS Surveys node. SA, RO, and CO users have full access to FMS revisits.

To create and link a standard survey from an FMS event:

1. In the **FMS Tracking** window, select the record you want to add a survey to and click **Modify**.
2. In the **FMS Add/Update** screen, click **Select** to the right of the **Health** indicator in the **Federal Survey** section.

   The Select button for Heath will be enabled once you specify Extent of Federal Survey.

3 In the **Select FMS Health Survey** window, click **Create**.

4 In the **Create Health Survey** window, enter basic survey information.

C-Federal Monitoring is selected by default as Type of Survey. You will not be able to remove this category after the survey is saved.

For Extent(s), A-Routine/Std Survey is selected by default. If Type of Federal Survey in the FMS Add/Update window is F Federal Jurisdictional, then J-Federal Jurisdictional is also selected by default as an extent.

5 Click **OK** to save the new survey.

The survey is automatically linked to the FMS event and listed in the Federal Survey section in the FMS Add/Update window.

To create a standard FMS survey directly:

1 In the **Tree** view, right-click the **Surveys** or **FMS Surveys** node.

2 Select **New Survey**.

3 In the **Create Health Survey** window, enter basic survey information.

4 Choose a Federal regulation set and for **Type of Survey**, select **C-Federal Monitoring**.

To link an existing standard FMS survey:

1 In the **FMS Tracking** window, select the record you want to link a survey to and click **Modify**.

2 In the **FMS Add/Update** screen, click **Select** to the right of the **Health** indicator to open the **Select FMS Health Survey** window.

The Select button for Heath will be enabled once you specify Extent of Federal Survey.

Surveys of type C-Federal Monitoring already defined for the provider (if any) are listed in the Select FMS Health Survey window.

3 Highlight the survey you want to link and click **OK**.

The survey is linked to the FMS event and listed in the Federal Survey section in the FMS Add/Update window.

To link a related standard state survey:

1 In the **FMS Add/Update** screen, click **Select** in the **State Agency Survey** section.

The Select button is enabled if Type of Survey = Comparative, Observational, or Look Behind.

2 In the **Select Related State Survey** window, highlight the survey you want to link and click **OK**.

The survey is linked to the FMS event and listed in the State Agency Survey section in the FMS Add/Update window.

State surveys are not listed until you link a Federal Health survey. Complaint-only surveys are included in the list only if the FMS case is Observational. The list is restricted to surveys with exit dates no more than one year prior to or 60 days following the exit date of the linked Federal survey.

Note: You cannot create a state survey from the Select Related State Survey window. The Create button is disabled.

To remove a linked FMS or related state survey:

1 In the **FMS Add/Update** screen, click the applicable **Select** button to open the **Select FMS Health Survey** or **Select Related State Survey** window.

2 Click **Remove** to unlink the highlighted (linked) survey from the FMS record.

3 Click **OK**.

The survey is no longer listed in the Federal Survey or State Agency Survey section (as applicable) in the FMS Add/Update window.

More ...

Screen: "FMS Tracking window - ARO" on page 362
Screen: "FMS Add/Update window - ARO" on page 363
Procedure: “Create Survey Shells” on page 119 (start with step 4)
Procedure: “Create Revisit Survey Shells” on page 160

Upload FMS Events

When all information has been entered for an FMS event–including survey data, citations, and 670 workload data–it should be uploaded. You must manually initiate the first upload of an FMS record. Subsequent uploads are automatic, if the first upload was successful.

After the initial successful upload of an FMS event, you cannot delete linked surveys, Federal or state. You also cannot modify the following fields:

- Type of Federal Survey
- Extent of Federal Survey
- Start and Exit dates of Federal survey

Changes you make to other fields in the FMS record after the initial successful upload are sent implicitly (automatically) to national. No action is required on your part.

To upload an FMS record:

1. In the **FMS Tracking** window, select the record you want to upload and click **Modify**.
2. At the bottom of the **FMS Add/Update** screen, click **Upload**.

   Previous upload transactions for the FMS event are listed in the Prior FMS Uploads section of the FMS Transactions screen.
3. Click **Prevalidate and Upload** to start the upload process.

   ACO prevalidates the FMS record. If it encounters problems, you will receive a message. The transaction is added to the Prior FMS Uploads section with a status of -1- Failed.

   If all required information is supplied and valid, ACO transmits the FMS record and a message indicates the success of the transaction. The transaction is added to the Prior FMS Uploads section with a status of 0 - Pending. When the FMS record is accepted by national, the status changes to 10 - Successful.
4. If the upload transaction failed, select it in the **Prior FMS Uploads** section to list problems in the **Upload Transaction Errors** section.
5. Make the necessary corrections and attempt the upload again.
6. To see if an FMS record has been uploaded successfully, open the **FMS Transactions** screen for the record and check **Status** in the **Prior FMS Uploads** section.

   -or-

   Check under the **FMS Surveys** node for the provider in **Tree** view to see if linked survey(s) are marked as **Uploaded**.

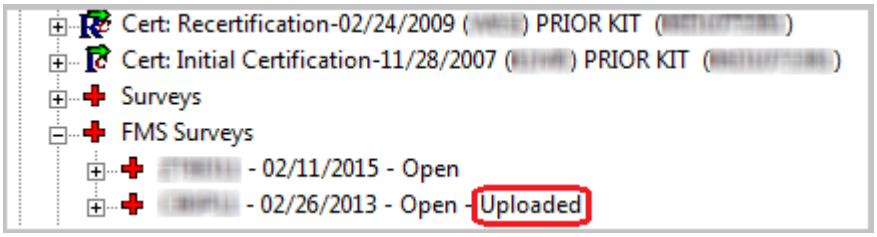

Figure 38: FMS Surveys node

More ...

Screen: "FMS Tracking window - ARO" on page 362
Screen: "FMS Add/Update window - ARO" on page 363

ASPEN Data Transfer: CO, RO, SA

ASPEN's data exchange functionality lets you seamlessly transfer ASPEN data from ACO/ARO and/or ACTS/ACTS RO to ASE-Q, and import it back into ACO/ARO and/or ACTS/ACTS RO from ASE-Q when surveys are completed. When you transfer a survey from ACO/ARO and/or ACTS/ACTS RO, associated provider information and any linked complaint/incident information is automatically sent along with the survey.

All exported data is encrypted to protect any confidential information. The data is compressed and copied to a transfer file with a .ZIP extension. ASPENTX.ZIP is the default transfer filename.

Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

The destination location of a transfer file can be any of the following:

- USB drive
- Hard drive
- Email

To import (copy) data from an ASPEN transfer file, you must be an authorized user running an ASPEN application.

Note: Although you can export linked intake information from ACO/ARO, you cannot view it in ACO/ARO.

Regulation sets associated with surveys do not transfer with the surveys. You can export and import regulation sets separately.

ACO Data Exchange

Export Data from ACO

From ACO/ARO, you can export one or more surveys with associated provider and intake information in an encrypted format to a transfer location. When there are discrepancies between source and destination, one or more Merge windows may open to let you resolve the differences. Surveyors can import the contents of the export transfer file into ASE-Q.

To export a survey:

1. Locate and select the survey in the **Tree** or **List** view, and drag it to the **Export** button in the toolbar.

   TIP: To export more than one survey, you can multi-select surveys in List view (Shift+click consecutive surveys or Ctrl+click non-consecutive surveys). To export all surveys for a provider, drag that provider to the Export button. You can also export multiple surveys from Tree view one at a time; each additional survey is appended to the transfer file.

2. In the **Export** window, indicate your transfer location.

   ➥ Select **ASPEN Transfer Location** and then select the applicable location from the drop-down list (defaults are usually the roots of the C and A drives).

   -or-

   ➥ Select **Other Location**. Enter the transfer location path, or click **Find** (binoculars) to navigate to and select the location.

   ASPENTX.ZIP is the default export transfer filename. You can assign another name if you wish. Renaming to provide meaningful descriptive information, such as event ID, is recommended.

   Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

3. Click **OK** in the **Export** window.

4 In the **Survey Export** window, select the surveys you want to send to the transfer destination.

The title bar indicates the Source of the listed survey(s) and the export Destination. If just one survey is listed, it is selected by default. If multiple surveys are listed, no survey is selected by default.

➥ Use **Select All** or **Select None** to select or deselect all surveys in the list.

➥ To use source values for all fields, click **Always Use Source** to toggle it to Yes.

TIP: Set to Yes only if you are certain the destination does not have more current survey information.

When set to No (the default), you will be prompted to resolve conflicts between the export source and destination.

5 Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

Include Attachments is selected by default.

6 Click **Continue with Export**.

If there are differences between source and destination content, one or more Merge windows may appear.

7 Resolve source/destination differences and continue the transfer.

The survey(s), any survey-level attachments (unless you deselected Include Attachments), and linked intake(s) are compressed, encrypted, and stored in the transfer file. The Finalize Transfer window appears for each exported survey. It displays a log of changes made during the export.

8 Click **Apply** to complete the export process, or **Cancel** to reverse the transfer.

When the export is complete, surveyors can import the survey(s) and intake(s) into ASE-Q.

More ...

Screen: "Export window" on page 364
Screen: "Survey Export window" on page 364
Procedure: “Data Merge” on page 194
Procedure: “Import Data into ASE-Q” on page 181

Email Data from ACO

From ACO/ARO, you can email one or more surveys with associated provider and intake information to one or more recipients. ACO creates a transfer file containing the survey(s) as an attachment to an email. Surveyors can import the contents of the transfer file into ASE-Q.

TIP: Your agency's email system must be configured to support the MAPI email interchange protocol. Most email systems are pre-configured with this feature.

To email a survey:

1. Locate and select the survey in the **Tree** or **List** view, and drag it to the **E-mail** button in the toolbar.

   A blank email message is created and the survey(s) and any linked complaint/incident intake(s) are compressed and transferred to ASPENTx.zip, which is included as an attachment to the email.

   Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

2. In the **Message** window, specify recipients and message text.
3. When recipients receive the message, they should save the transfer file to the location of choice, then import its contents into ASE-Q.

   The survey(s) and intake(s) in the transfer file will be decompressed during the import. As with any standard data transfer process, one or more Merge windows may appear if there are differences between source and destination content.

Import Data into ACO

You can import surveys into ACO/ARO from transfer locations as needed. When a survey has been completed in the field, you will want to import the survey findings from ASE-Q into ACO (or ACTS). If there are discrepancies between source and destination, one or more Merge windows may open to let you resolve the differences. Survey attachments, such as digital photos and other electronic documents, are automatically imported.

Note: Survey teams using more than one laptop should merge the final findings onto a single laptop or transfer file before exporting to ACO.

With ASPEN 10.1.7, an allowed import version indicator is included with source data. If the application (destination) version is older than the source's allowed import version, or the source data’s version is newer than the destination version, the import is stopped. If the source version is older than the destination version, you will receive a warning.

To import a survey:

1. On the **ACO toolbar**, click **Import.**
2. In the **Import** window, select **Surveys** as the Import Type.
3. Indicate the location of the transfer file:

   ➥ Select **ASPEN Transfer Location** and then select the applicable location from the drop-down list.

   -or-

   ➥ Select **Zip or mdb file**. Enter the transfer location path, or click **Find** (binoculars) to navigate to and select the location.

   ASPENTX.ZIP is the default transfer filename. The name may have been changed on export to be more descriptive.

   Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

4. Click **OK**.

   ASE-Q searches for the export transfer location or file. When it is located, the Survey Import window appears. It lists the surveys contained in the transfer location or file.

5. In the **Survey Import** window, select the surveys you want to import.

   The title bar indicates the Source of the listed surveys and the import Destination. If just one survey is listed, it is selected by default. If multiple surveys are listed, no survey is selected by default.

   - Use **Select All** or **Select None** to select or deselect all surveys in the list.
   - To use source values for all fields, click **Always Use Source** to toggle it to Yes.

     When set to No (the default), you will be prompted to resolve conflicts between the source and destination.

6. Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

   Include Attachments is selected by default.

7. Click **Continue with Import**.

   If there are differences between source and destination content, one or more Merge windows may appear.

   All survey-level attachments are imported unless you deselected Include Attachments.

8 Resolve source/destination differences and continue the transfer.

The surveys and associated information are imported from the export transfer location or file and decompressed. The Finalize Transfer window appears for each imported survey. It displays a log of changes made during the import.

9 Click **Apply** to complete the import process, or Cancel to reverse the transfer.

More ...

Procedure: “Data Merge” on page 194
Screen: "Import window - ACO/ARO" on page 365

Export ASE-Q Sybase Database Patch

ASPEN includes a mechanism for deploying database changes to ASE-Q. Changes to the Sybase database are posted to the state Oracle server (ACO), then you can use standard transfer functions to apply the update to ASE-Q without going through a software release process.

To export a database patch from ACO (Oracle):

1 From the File menu in ACO, select Export Database Patch.

2 In the Export window, indicate your transfer location.

➥ Select ASPEN Transfer Location and then select the applicable location from the drop-down list (defaults are usually the root of the C and A drives).

-or-

➥ Select Other Location. Enter the transfer location path, or click Find to navigate to and select the location.

ASPENTX.ZIP is the default export transfer filename. You can assign a more descriptive name if you wish.

Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

3 Click **OK** in the **Export** window.

The ASE-Q database patch is copied to the transfer file. Messages indicate progress of the transfer.

ASE-Q users can now import and apply the database patch.

More ...

Screen: "Export window" on page 364

Refer to “Import ASE-Q Sybase Database Patch” in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

ASE-Q Data Exchange

ASE-Q provides the framework to let you easily transfer a variety of ASPEN data including:

- Surveys
- Complaint/incident intakes
- ASE-Q user accounts
- Regulation sets

ASE-Q supports the following methods for importing and exporting ASPEN data:

- Transfer files
- Direct-connect ACO/ACTS to ASE-Q
- Wireless ASE-Q to ASE-Q
- Wired ASE-Q to ASE-Q

You can use the method most suitable for your office procedures, hardware setup, and the task at hand. All data is encrypted as it is transferred to protect personal and confidential information.

For surveys, the recommended practice is to create the provider record in ACO, create a survey shell with dates and team members specified, and export it. Field surveyors then import the survey into ASE-Q. When the survey is completed, the survey and citations are exported or emailed back to ACO (or ACTS).

Note: The procedures in this section cover basic ASPEN import/export steps. Your state's encryption procedures may necessitate additional steps.

Import Data into ASE-Q

When you import a survey and linked complaint/incident intakes (if any), the provider and surveyor records are added or updated in the ASE-Q Sybase database. If there are discrepancies between source and destination, one or more Merge windows may open to let you resolve the differences. Survey attachments, such as digital photos and other electronic documents, are automatically imported.

With ASPEN 10.1.7, an allowed import version indicator is included with source data. If the application (destination) version is older than the source's allowed import version, or the source data's version is newer than the destination version, the import is stopped. If the source version is older than the destination version, you will receive a warning.

To import data:

1. If you are importing data from a transfer file on a USB drive, insert it into your USB port.
2. On the **ASE-Q toolbar**, click the **Import** button.
3. In the **Import** window, select **Surveys**.
4. Use the appropriate **Import From** option to indicate the location of the transfer file.
   - **ASPEN Transfer Location**–Select the applicable location.

     Note: ASE-Q detects and lists any removable drives (such as USB drives) plugged in at the time of transfer.

     -or-
   - **Other Zip File Location**–Enter the path to the transfer file, or click **Find** (binoculars) to navigate to and select the location.

   Note: The **Locate ASE Database** option is for ASE-Q to ASE-Q network transfers (wired or wireless).

5. Click **OK**.

   ASE-Q searches for the export transfer file. When the file is located, the Survey Import window appears. It lists the surveys contained in the transfer file.
6. In the **Survey Import** window, select the surveys you want to import.

   The title bar indicates the Source of the listed surveys and the import Destination. If just one survey is listed, it is selected by default. If multiple surveys are listed, no survey is selected by default.

   ➥ Use **Select All** or **Select None** to select or deselect all surveys in the list.

   ➥ To use source values for all fields, click **Always Use Source** to toggle it to Yes.

   When set to No (the default), you will be prompted to resolve conflicts between the export source and destination.

   Note: Many fields have predefined merge rules that may override the Always Use Source setting.

7 Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

Include Attachments is selected by default.

8 Click **Continue with Import**.

If there are differences between source and destination content, one or more Merge windows may appear.

9 Resolve source/destination differences and continue the transfer.

If the survey(s) and associated provider record(s) do not already reside in ASE-Q, they are imported from the export transfer file and decompressed. The Finalize Transfer window appears for each imported survey. It displays a log of changes made during the import.

10 Click **Apply** to complete the import process, or **Cancel** to reverse the transfer.

The imported survey(s) and provider(s) are now included on tabs in the Tree view. Any linked intakes are listed under the applicable surveys. All attachments to the survey(s) are imported unless you deselected Include Attachments.

More ...

Screen: "Import window - ASE-Q" on page 365
Procedure: “Direct Transfer: ASE-Q to ASE-Q” on page 191
Procedure: “Data Merge” on page 194

Export Data from ASE-Q

When a survey is complete, you will typically export the survey and citations from ASE-Q for import into ACO (or ACTS). You can export a single survey and linked intake(s) from ASE-Q, or export a provider in order to transfer all associated surveys and linked intakes, but not the provider information.

When there are discrepancies between source and destination, one or more Merge windows may open to let you resolve the differences. If the provider, surveyors, or intakes do not exist in the state database, the export from ASE-Q will fail.

To export data:

1 Click any tab in the **Tree** view and locate the survey or provider you want to export.

2 Drag the survey/provider to the **Export** button in the toolbar, or simply click the survey/provider and then click the button.

3 In the **Export** window, use the appropriate option to specify the export location:

- **ASPEN Transfer Location**–Select the desired location.

Note: ASE-Q detects and lists any removable drives (such as USB drives) plugged in at the time of transfer.

-or-

- **Other Zip File Location**–Enter the path to the transfer file, or click Find (binoculars) to navigate to and select the location.

Note: The **Locate ASE Database** option is for ASE-Q to ASE-Q network transfers (wired or wireless).

ASPENTX.ZIP is the default transfer filename. You can assign another name if you wish. Renaming to provide meaningful descriptive information, such as event ID, is recommended.

Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

4 Click **OK** in the **Export** window.

5 In the **Survey Export** window, select the surveys you want to send to the transfer destination.

The title bar indicates the Source of the listed survey(s) and the export Destination. If just one survey is listed, it is selected by default. If multiple surveys are listed, no survey is selected by default.

➥ Use **Select All** or **Select None** to select or deselect all surveys in the list.

➥ To use source values for all fields, click **Always Use Source** to toggle it to Yes.

TIP: Set to Yes only if you are certain the destination does not have more current survey information.

When set to No (the default), you will be prompted to resolve conflicts between the export source and destination.

Note: Many fields have predefined merge rules that may override the Always Use Source setting.

6 Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

Include Attachments is selected by default.

7 Click **Continue with Export**.

If there are differences between source and destination content, one or more Merge windows may appear.

8 Resolve source/destination differences and continue the transfer.

The survey(s), any survey-level attachments (unless you deselected Include Attachments), and linked intake(s) are compressed, encrypted, and stored in the transfer file. The Finalize Transfer window appears for each exported survey. It displays a log of changes made during the export.

9 Click **Apply** to complete the export process, or **Cancel** to reverse the transfer.

When the export is complete, you can import the survey(s) and intake(s) into ACO or ACTS.

In several situations, imports of data exported from ASE-Q into ACO or ACTS will fail:

- A survey imported into ACO or ACTS has an event ID matching that of a survey associated with a certification kit for another provider.
- Intake data is imported into a finalized intake in ACTS or ACO.

More ...

Screen: "Export window" on page 364
Procedure: “Direct Transfer: ASE-Q to ASE-Q” on page 191
Screen: "Survey Export window" on page 364

Email Data from ASE-Q

When a survey is complete, you have the option of emailing the survey and citations from ASE-Q to a recipient. ASE-Q creates a transfer file containing the survey (and citations) as an attachment to the email.

The recipient can then import the survey from the transfer file back into ACO or ACTS. You can email a single survey and linked intake(s) from ASE-Q, or email a provider in order to transfer all associated surveys and linked complaint/incident intakes, but not the provider information. If the provider, surveyors, or intakes do not exist in the state database, you will not be able to import the items from the emailed transfer file into ACO/ACTS.

TIP: Your agency's email system must be configured to support the MAPI email interchange protocol. Most email systems are pre-configured with this feature.

To email data:

1. Click any tab in the **Tree** view and locate the survey/provider you want to email.
2. Drag the survey/provider to the **E-Mail** button in the toolbar, or simply click the survey and then click the button.

   A blank email message is created and the survey(s) and any linked complaint/incident intake(s) are compressed and transferred to ASPENTx.zip, which is included as an attachment to the email.

   Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

3. In the **Message** window, specify recipients and message text.
4. When recipients receive the message, they should save the transfer file to the location of choice, then import its contents into ACO or ACTS.

   The survey(s) and intake(s) in the transfer file will be decompressed during the import. As with any standard data transfer process, one or more Merge windows may appear if there are differences between source and destination content.

Import ASE-Q Sybase Database Patch

ASPEN includes a mechanism for deploying database changes to ASE-Q without going through a software release process. Changes to the Sybase database are posted to the state Oracle server (ACO) and your agency is notified that an ASE-Q patch file can be created. You can then use standard transfer functions to update your ASE-Q database with the patch. This process is designed to streamline maintenance of the distributed ASE-Q database.

To import a Sybase database patch into ASE-Q:

1. First, export the DB patch from **ACO** using a transfer file (like that for survey transfer).
2. To import the patch, select **Import Database Patch** from the **File** menu in **ASE-Q**.

3 In the **Import** window, indicate the location of the transfer file containing the patch.

- Select **ASPEN Transfer Location** and then choose the applicable location from the drop-down list.

  Note: ASE-Q detects and lists any removable drives (such as USB drives) plugged in at the time of transfer.

  -or-

- Select **Other Zip File Location** and enter the path to the transfer file, or click **Find** (binoculars) to navigate to and select the location.

  ASPENTX.ZIP is the default transfer filename. The name may have been changed on export to be more descriptive.

Be aware that many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

Note: You can also use the direct-connect method (discussed in the following section) to import the patch from Oracle (ACO). For ASPEN Transfer Location, select the Oracle server (however it is named).

4 Click **OK** in the **Import** window.

A message indicates the patch was supplied successfully, or if problems occur, processing is terminated and an error message is displayed.

Note: ASPEN automatically tracks which database patches have been applied to ASE-Q on your machine to ensure you do not import a DB patch again after it has been successfully applied.

More ...

Procedure: “Export ASE-Q Sybase Database Patch” on page 180
Screen: "Import window - ASE-Q" on page 365

Direct Data Transfer

ASE-Q is capable of directly transferring survey, complaint/incident, and other information between its Sybase database and the central QIES State Oracle server, i.e., between field systems and ACO/ACTS. This approach can be especially useful when surveyors use the same laptop both in the office and in the field.

ASE-Q also supports direct-connect data transfers between two ASE-Q devices via wired or wireless network connections, provided they are properly configured. This streamlines data exchange between surveyors in the field by eliminating the need for file-based transfers using USB drives or other removable media.

You can use direct-connect data transfers to:

- Transfer pre-scheduled surveys from your state's Oracle database to ASE-Q.
- Merge survey findings from field laptops to the Oracle database.
- Update regulation sets on ASE-Q with the latest versions and patches.
- Update surveyor information on ASE-Q with recent changes entered in ACO/ARO.

To use the direct-connect feature, the ASE-Q device must have:

- Direct wired or wireless connection to the state agency's secure local area network that can access ASPEN's central Oracle server.
- Oracle client installed.

  Note: If you install the Oracle client onto a laptop with an existing ASE-Q installation, you will need to reinstall the ASE-Q client after installing Oracle.

- Oracle configuration in ASE-Q to support connecting to the Oracle server when logged into a state network.

More ...

Procedure: "Transfer Pre-scheduled Surveys" below
Procedure: "Merge Survey Findings" on page 190
Procedure: "Synchronize Regulations" on page 191
Refer to "Survey Teams" and "Configure an Oracle Connection" in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Direct Transfer: ASE-Q/ACO

You can use direct-connect data transfers to transfer pre-scheduled surveys from your state's Oracle database to ASE-Q.

Transfer Pre-scheduled Surveys

The My Surveys button on the ASE-Q toolbar uses a direct connection to pull scheduled surveys on which you are a team member and that are less than or equal to 90 days old (subject to future security) from the ACO/ACTS (Oracle) database into ASE-Q. This is a convenient way for you to quickly load your assigned surveys without having to use transfer files.

Note: You must have an Oracle connection configured in ASE-Q.

To load your pre-scheduled surveys:

1. On the ASE-Q toolbar, click the **My Surveys** button.

   ASE-Q generates a connection to the Oracle database and locates your surveys. Give it a minute to do this. The standard data transfer process then takes place.

2. In the **Survey Import** window, select the surveys you want to import.
3. Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

   Include Attachments is selected by default.

4. Click **Continue with Import**.

   If there are differences between source and destination content, one or more Merge windows may appear.

5. Resolve source/destination differences and continue the transfer.

   If the survey(s) and associated provider record(s) do not already reside in ASE-Q, they are imported from the export transfer file and decompressed. The Finalize Transfer window appears for each imported survey. It displays a log of changes made during the import.

6. Click **Apply** to complete the import process, or **Cancel** to reverse the transfer.

   The imported survey(s) and provider(s) are now included on tabs in the Tree view. Any linked intakes are listed under the applicable surveys. All attachments to the survey(s) are imported unless you deselected Include Attachments.

More ...

Refer to "Configure an Oracle Connection" in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Procedure: "Data Merge" on page 194

Merge Survey Findings

When a survey is completed, you and other team members can use the standard ASE-Q Export function in direct-connect mode to quickly merge the survey findings entered in ASE-Q on your field device into the central Oracle database.

Note: When you export CLIA surveys from ASE-Q using direct-connect, specialty data is not transferred.

To export findings via direct-connect:

1. Locate and drag the completed survey to the **Export** button in the toolbar, or simply click the survey and then click the button.
2. In the **Export** window, select the Oracle server (however it is named) as the **ASPEN Transfer Location** (must be configured to be listed).
3. Click **OK** in the **Export** window.

   The standard data transfer process then takes place.
4. In the **Survey Export** window, select the completed survey.

   If it is the only survey listed, it is selected by default.
5. Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

   Include Attachments is selected by default.
6. Click **Continue with Export**.

   If there are differences between source and destination content, one or more Merge windows may appear.
7. Resolve source/destination differences and continue the transfer.

   The survey, any survey-level attachments (unless you deselected Include Attachments), and linked intake(s) are compressed, encrypted, and stored in the transfer file. The Finalize Transfer window appears for the exported survey. It displays a log of changes made during the export.
8. Click **Apply** to complete the export process, or **Cancel** to reverse the transfer.

   The survey is replicated from your ASE-Q Sybase database into the Oracle database.

More ...

Screen: "Export window" on page 364

Refer to “Configure an Oracle Connection” in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Screen: "Survey Export window" on page 364

Procedure: “Data Merge” on page 194

Synchronize Regulations

ASE-Q supports automatic detection and loading of regulation set changes over a network. If ASE-Q is connected to your agency's network and has access to the ASPEN Oracle database, you can synchronize ASE-Q regulation sets. This option does not supersede the basic Import Regulations function, which is available for standard regulation transfers.

As with direct survey transfers between ASE-Q and ACO/ACTS, the Synchronize Regulations utility uses your Oracle repository. If an Oracle repository is not configured, you will receive a warning.

To sync ASE-Q reg sets using direct-connect:

1. In ASE-Q, select **System**, then **Synchronize Regulations**.

   A message indicates the number of regulation sets, patches, and reg set status changes to be imported.

2. Click **Yes** to continue.

   If ASE-Q cannot connect to the Oracle server, a warning appears.

3. Click **OK** in the confirmation window.

   New active regulation sets are added to the ASE-Q database and the applicable existing reg sets are updated. The most recent version of each regulation is set as "current" and the appropriate facility types are assigned. If a regulation set in ACO is inactive or deleted, Synchronize Regulations automatically sets the Status of the corresponding regulation set in ASE-Q, if present, to Inactive.

Note: If you lose the connection during the update process, unsuccessfully imported regulations revert back to their original state.

More ...

Procedure: "Import Regulations into ACO" on page 197

Refer to "Configure an Oracle Connection" in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Direct Transfer: ASE-Q to ASE-Q

ASE-Q supports direct-connect data transfers between two ASE-Q devices via wired or wireless network connections, provided they are properly configured. This streamlines data exchange between surveyors in the field by eliminating the need for file-based transfers using USB drives or other removable media.

Wireless Data Exchange

From ASE-Q on one laptop, you can wirelessly export one or more surveys to another ASE-Q laptop. ASE-Q creates the wireless connection between the two computers. This wireless connection times out after 5 minutes or after the transfer is complete.

ASE-Q to ASE-Q transfer–wireless

1. ASE-Q on Sender (Export) ***and*** ASE-Q on Receiver: Click the **Wireless** button on the ASE-Q toolbar.

   ASE-Q generates a wireless Windows network connection between the two ASE-Q devices. It may take a minute.

2. Check for a **Connected to ASPEN Wireless** message in the lower right corner of windows on your screen.

3. Sender: Drag and drop the survey on the **Export** button, or simply click the survey and then click the button.

4. In the **Export** window, select **Locate ASE Database**, then click **Find** (binoculars).

   All ASE-Q (Sybase) databases on the network that are candidates for direct-connect transfers (wired or wireless) are detected and listed.

5. In the **Select Database** window, select the database you are connecting to. If the screen is blank, click **Refresh List** and **OK**.

6. Click **OK** in the **Export** window.

7. In the **Survey Export** window, select the survey.

   If it is the only survey listed, it is selected by default.

8. Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.

   Include Attachments is selected by default.

9. Click **Continue with Export**.

   ASE-Q transfers the survey, any survey-level attachments (unless you deselected Include Attachments), and linked intake(s). This may take several minutes.

   If there are differences between source and destination content, one or more Merge windows may appear.

10. Resolve source/destination differences and continue the transfer.

11. In the **Finalize Transfer** window, click **Apply** to complete the export process.

    When the transfer is complete, ASE-Q terminates the wireless connection. The survey is now available on the receiving user's laptop.

More ...

Screen: "Survey Export window" on page 364
Procedure: "Data Merge" on page 194

Wired Data Exchange

A wired ASE-Q to ASE-Q transfer is a convenient method for data exchange between SA surveyors and RO observers. A crossover cable is required to connect the sender's and receiver's computers. In some cases a standard ethernet cable will suffice. Your IT support staff should determine the correct cable type for your configuration.

ASE-Q to ASE-Q transfer–wired

1. Connect the Sender (Export) and Receiver (Import) computers together using the appropriate Ethernet cable.
2. Sender: Drag and drop the survey on the Export button, or simply click the survey and then click the button.
3. In the **Export** window, select **Locate ASE Database**, then click **Find** (binoculars).

   All ASE-Q (Sybase) databases on the network that are candidates for direct-connect transfers (wired or wireless) are detected and listed.
4. In the **Select Database** window, select the database you are connecting to. If the screen is blank, click **Refresh List** and **OK**.

   Note: In the special case of an RO surveyor joining a state survey team, it is possible to directly enter the IP address or name of the destination database in the Locate ASE Database field.
5. Click **OK** in the **Export** window.
6. In the **Survey Export** window, select the survey.

   If only one survey is listed, it is selected by default.
7. Select or deselect the **Include Attachments** checkbox to include or exclude attachments in the transfer.
8. Include Attachments is selected by default.Click **Continue with Export**.

   ASE-Q transfers the survey, any survey-level attachments (unless you deselected Include Attachments), and linked intake(s). This may take several minutes.

   If there are differences between source and destination content, one or more Merge windows may appear.
9. Resolve source/destination differences and continue the transfer.
10. In the **Finalize Transfer** window, click **Apply** to complete the export process.

    When the transfer is complete, the exported survey is now available in the receiving computer's database.

More ...

Screen: "Survey Export window" on page 364
Procedure: "Data Merge" on page 194

Data Merge

When there are differences between source and destination text field content, field values, or row content, the applicable Merge window may open to let you resolve the differences by indicating how the content should be merged.

Note: In many cases, merge rules are predefined and Merge windows will not appear when there are source/destination conflicts.

Merge Fields

If certain field values differ between source and destination—perhaps you are re-exporting a survey after changing some field values—the Merge fields window displays the differences. You can specify how to merge the conflicting values.

For 670 Workload values, the window displayed for resolving differences in surveyor workload data is not called Merge fields. Rather, the title bar shows the staff member's name and ID, and the name of the "problem" 670 area.

Fields marked with an asterisk in the Data Field column have a Yoke ID. When several fields relate to the same business rule, they are "yoked" together and must be selected as a group from either source or destination. Fields that share a common Yoke ID are moved as a group between source and destination: select one, move all.

To merge fields:

1. In the **Merge fields** window, examine the **Source Value** and **Destination Value** for fields that differ.

   ➥ To see all the fields being exported, not just the ones that differ, select **Show all fields**.

2. To overwrite **Destination Value** with **Source Value** for an individual field, choose the **Select Source** checkbox.
3. To keep the Destination Value for an individual field, choose the **Select Destination** checkbox.
4. To overwrite Destination Value with Source Value for all fields with differing values, click the **Use All Source** button.
5. To keep Destination Value for all fields with differing values, click the **Use All Dest** button.
6. Click **Continue with Transfer** to save the current values and continue the data transfer.

   If there are 670 discrepancies for multiple surveyors, you merge values for one surveyor at a time. When you select Continue with Transfer, the 670 Merge fields window for the next surveyor opens.

Merge Rows

When you import Contacts data into ACO, the Multiple Row Merge window opens if there are conflicts in source and destination between information in rows; e.g., a field in row 2 in the destination has the same value as in row 4 in the source. You can specify how the conflicts should be resolved.

To merge rows:

1. In the **Multiple Row Merge** window, identify the conflicting row information in **Source** and **Destination**.
2. To include a row in the merge, select the checkbox to its left.

   All Source rows are selected by default as are Destination rows that do not conflict with Source rows.
3. To include only Source rows in the merge, click **Check All Source**.

   All Source rows are selected (checked) and the checkboxes for all Destination rows are cleared.
4. To include only Destination rows in the merge, click **Check All Destination**.

   All Destination rows are selected (checked) and the checkboxes for all Source rows are cleared.
5. To revert to the default selections, click **Autoselect**.
6. Click **Continue with Transfer** to save the current merge selections and continue the data transfer.

Merge Text

If there are differences between source and destination in certain text entries, e.g., citation text, the Merge Text window shows the differences and lets you specify how to resolve the differences. Since the content of attachments and letters is assumed to be static, the Merge Text window does not appear for them during transfers.

To merge text:

1. In the **Merge Text** window, examine the differences between **Source** and **Destination** text.
2. To replace all the Destination text with all the Source text, click **Replace Destination**.
3. To add selected Source text at the end of the Destination text, click **Append Selected**.
4. To insert selected Source text at the cursor position in the Destination text, click **Insert Selected**.

5. To undo any changes you have made to the original Destination text, click **Restore Original Destination**.
6. Click **Save Final Version** to save the current version of the Destination text and continue the data transfer.

Regulation Set Transfer and Updates

You can use the standard export and import functions to transfer both state and Federal regulation sets as needed from /to ACO and ASE-Q. When you transfer surveys, associated regulation sets are not transferred along with them. If a regulation set does not exist on the target database, you need to export it separately.

REG PATCH AND SYNCING REGS IN ASE-Q

ASPEN includes a mechanism for deploying database changes to ASE-Q. Changes to the Sybase database are posted to the state Oracle server (ACO), then you can use standard transfer functions to apply the update to ASE-Q without going through a software release process.

ASE-Q supports automatic detection and loading of regulation set changes over a network. If ASE-Q is connected to your agency's network and has access to the ASPEN Oracle database, you can synchronize ASE-Q regulation sets. This option does not supersede the basic Import Regulations function, which is available for standard regulation transfers.

Export Regulations from ACO

Before you export a regulation set, we recommend you make it active (in the Regulation Set Properties window) so that each user who imports the reg set does not have to change the setting to be able to use the regulations.

To export a regulation set:

1. Click the **Alpha** or **Type** tab and locate the regulation set.
2. Drag the regulation set you want to export to the **Export** button on the toolbar.

TIP: You can also export a regulation set by right-clicking it, selecting Send To, and then clicking Export.

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3. In the **Export** window, indicate your transfer location.
   - ➥ Select **ASPEN Transfer Location** and then select the applicable location from the drop-down list (defaults are usually the root of the C and A drives).

     -or-

   - ➥ **Select Other Location**. Enter the transfer location path, or click **Find** (Binoculars) to navigate to and select the location.

The default transfer filename is ASPENTX.ZIP, which is changed to REGTX.ZIP when you actually export the reg set. You can assign another name if you wish.

Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

4 Click **OK**.

The regulation set is exported to the transfer file at the specified location and a message appears indicating that the export is complete.

Note: You can export more than one reg set to the same transfer file.

More ...

Screen: "Export window" on page 364

Import Regulations into ACO

You can import regulation sets as needed. You may need to add updated Federal regulations or new or revised state regulations to ACO.

Note: Do not use the Import function to load a regulation patch unless you delete the existing regulation set first. It will not be possible to delete the existing set if any surveys have been created with that set, so in most cases it is easier to use the patch utility: right-click reg set | Import Patch File.

To import regulations:

1 Click the **Import** button on the toolbar.

2 In the **Import** window, select **Regulations** as **Import Type**.

3 Use the appropriate **Import From** option to indicate the location of the transfer file.

➥ Select **ASPEN Transfer Location** and then select the applicable location from the drop-down list (defaults are usually the root of the C and A drives).

-or-

➥ Select **Zip or mdb file**. Enter the transfer location path, or click **Find** (Binoculars) to navigate to and select the location.

REGTX.ZIP is the default transfer filename when you import regulation sets. The name may have been changed on export to be more descriptive.

Note: Many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

4 Click **OK**.

The regulation sets in the transfer file are imported. A message appears indicating the import was successful.

Note: If any regulation set you are importing already exists, you are asked if you want to abort the transfer.

More ...

Screen: "Import window - ACO/ARO" on page 365

Export Regulations from ASE-Q

When you finish creating the tags for your state regulation set, you can export the set. Other ASE-Q users can then import it into their systems. You can also export Federal regulation sets.

Before you export a regulation set, we recommend you make it active so that each user who imports the reg set does not have to change the setting to be able to use the regulations.

Note: You can export state regulations, then import them into ACO, which then serves as the central repository from which ASE-Q users download them, i.e., export them to a transfer file, then import them to their laptops.

To export a regulation set:

1 If you are exporting regulations to a USB drive, insert it into your USB port.

2 Click the **Alpha** or **Type** tab and locate the regulation set.

3 Drag the regulation set you want to export to the **Export** button on the toolbar.

TIP: You can also export a regulation set by right-clicking it, selecting Send To, and then clicking Export.

4 In the **Export** window, use the appropriate option to specify the location of the transfer file:

- **ASPEN Transfer Location**–Select the desired location.

  Note: ASE-Q detects and lists any removable drives (such as USB drives) plugged in at the time of transfer.

  -or-

- **Other Zip File Location**–Enter the path to the transfer file, or click **Find** (binoculars) to navigate to and select the location.

The default transfer filename is ASPENTX.ZIP, which is changed to REGTX.ZIP when you actually export the reg set. You can assign another name if you wish.

Be aware that many anti-virus programs, email servers, and firewalls block .ZIP files. If this is an issue, contact your ASPEN administrator for assistance.

Note: The **Locate ASE Database** option is for ASE-Q to ASE-Q network transfers (wired or wireless).

5 Click **OK**.

The regulation set is exported to the transfer file at the specified location and a message appears indicating that the export is complete.

Note: You can export more than one reg set to the same transfer file.

More ...

Refer to "Modify State Tags" in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Screen: "Export window" on page 364

Procedure: "Direct Transfer: ASE-Q to ASE-Q" on page 191

Import Regulations into ASE-Q

You can import regulation sets as needed. You may need to add updated Federal regulations or new or revised state regulations to your version of ASPEN Survey Explorer-Quality.

Note: Do not use the Import function to load a regulation patch unless you delete the existing regulation set first. It will not be possible to delete the existing set if any surveys have been created with that set, so in most cases it is easier to use the patch utility.

To import regulations:

1 If you are importing regulations from a transfer file on a USB drive, insert it into your USB port.

2 Click the **Import** button on the toolbar.

3 In the **Import** window, select Regulations as Import Type.

4 Use the appropriate **Import From** option to indicate the location of the transfer file.

- **ASPEN Transfer Location**–Select the applicable location.

Note: ASE-Q detects and lists any removable drives (such as USB drives) plugged in at the time of transfer.

-or-

- **Other Zip File Location**–Enter the path to the transfer file, or click **Find** (binoculars) to navigate to and select the location.

Note: The **Locate ASE Database** option is for ASE-Q to ASE-Q network transfers (wired or wireless).

5 Click **OK**.

The regulation sets in the transfer file are imported. A message appears indicating the import was successful.

Note: If any regulation set you are importing already exists, you are asked if you want to abort the transfer.

More ...

Procedure: "Import a Regulation Patch into ASE-Q" on page 201
Screen: "Import window - ASE-Q" on page 365
Procedure: "Direct Transfer: ASE-Q to ASE-Q" on page 191

Synchronize Regulations in ASE-Q

As with direct survey transfers between ASE-Q and ACO/ACTS, the Synchronize Regulations utility uses your Oracle repository. If an Oracle repository is not configured, you will receive a warning.

To sync ASE-Q reg sets using direct-connect

1 In ASE-Q, select **System**, then **Synchronize Regulations**.

A message indicates the number of regulation sets, patches, and reg set status changes to be imported.

2 Click **Yes** to continue.

If ASE-Q cannot connect to the Oracle server, a warning appears.

3 Click **OK** in the confirmation window.

New active regulation sets are added to the ASE-Q database and the applicable existing reg sets are updated. The most recent version of each regulation is set as "current" and the appropriate facility types are assigned. If a regulation set in ACO is inactive or deleted, Synchronize Regulations automatically sets the Status of the corresponding regulation set in ASE-Q, if present, to Inactive.

Note: If you lose the connection during the update process, unsuccessfully imported regulations revert back to their original state.

More ...

Procedure: "Import Regulations into ACO" on page 197

Refer to "Configure an Oracle Connection" in the *ASE-Q Procedures Guide*, which is posted at https://qtso.cms.gov.

Import a Regulation Patch into ASE-Q

The Regulation Patch utility is used to apply updates to existing state or Federal regulation sets.

To use the import patch:

1 Click the **Alpha** or **Type** tab and locate the regulation set you want to update.

2 Right-click the regulation set and select **Import Patch File**.

3 In the **ASPEN Regulation Patch Utility** window, enter the location of the patch utility in the **Source Information** section, or click **Find** to locate and select the file.

The patch filename is RegPatch.zip. The default location for the patch is in the directory where you installed ASE-Q.

4 In the **Log Information** section, enter the location where you want to save the log file, or click **Find** to locate and select the file.

5 Select the **Click Here to Begin Transfer** button. The transfer process occurs. A log file of the patch process is created by the utility.

CLIA 116: AO

The CLIA 116 web application runs in a web browser (Internet Explorer) over the CMS intranet. It directly accesses the national CLIA database.

There are two methods of access to the CLIA 116 web application (web app) for Accrediting Organizations (AOs): direct data entry and data uploads. When you enter data directly, you will see only the labs with which your organization is affiliated, i.e., X-matches.

With the appropriate permissions, you can use the CLIA 116 web app to:

- Update laboratory director fields on the Demographics tab
- Enter Y-matches
- Enter AO survey dates
- Enter AO remarks
- View and update survey specialties
- View 116 specialties
- Delete active survey specialties
- Close out survey specialties
- Delete closed-out survey specialties
- View the CLIA Certificate and Billing Inquiry window
- Search all laboratories and view them in Inquiry (read-only) mode and in Certificate and Billing Inquiry.

Certain AOs prefer to automate updates to accreditation information in the national CLIA database. An upload procedure is provided for those AOs.

Access the 116 Web Application

You will generally open ASPEN Web CLIA in a browser to access the 116 web application. To open ASPEN Web CLIA, you need to know the URL for the ASPEN Access page and have a current national system login.

To access the CLIA 116 web app:

1. Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen
2. Click the **ASPEN Web** link.

3 In the **Login** window, enter your national **User ID** and **Password** and click **Login**.

4 Click **OK** in the startup warning message to continue.

ASPEN Web opens and the Select Application window appears.

5 Select **CLIA**.

ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

6 In the **Select Application** window, click **116 Application**.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

116 Data Validation

The CLIA 116 web app validates data and informs you if there are validation errors when you go from one tab to another or save a lab record. Validation errors occur when you do not provide required data, or provide invalid data.

Required Fields

Required fields are marked with an asterisk (*).

Figure 39: Required field

The CLIA 116 web app checks to see that data is entered in all required fields on a tab when you go to another tab or save a lab record. If required data is missing or invalid, you will receive validation error messages.

Note: You will not be populating any of the required fields marked with an asterisk since they are on tabs that are read-only for AOs. The data is entered by SA, RO, or CO users, or automatically entered by the system. For example, Reason for 116 always defaults to 04 Other Changes for AO users.

Some fields are required only under certain conditions. Those fields may not be marked with an asterisk, as is the case on the Accred Org Info and Specialties tabs that you will be using. If you try to save a lab record without completing conditionally required fields, you will receive error messages.

Tab Validation

If the CLIA 116 web app finds validation errors when you go to another tab, it lets you know. You can choose OK to override until you save the lab record, or Cancel to go back to the original tab and correct any problems. Field-specific error messages are displayed in red on the tab. There may not be messages for all fields with errors.

Lab Record Validation

Whenever you save a lab record, all data validation edits are applied. If validation errors are found, the system identifies the tabs that have errors. You can either cancel all data entry you have done, or go to the tabs that contain errors and correct them. Field-specific error messages are displayed in red on the applicable tabs. There may not be messages for all fields with errors. You need to correct all errors, explicitly identified or not, and save the record again.

When you save a lab record, an Add or Update transaction record is created and processed overnight. Errors occasionally occur in the nightly processing. In that case, the lab records involved will be read-only until the errors are resolved. If a lab record is read-only, check the top (header) of the record for an upload failure message.

Locate Labs

A comprehensive set of search criteria is available in the CLIA 116 Find window, enabling you to quickly locate existing labs in the national CLIA database. You can specify criteria that make the search as broad or narrow as you need. For example, a broad search specifying a major city and the area code portion of a phone number would return all labs in the city with that area code. Generally, the narrower (more specific) the search, the quicker you will find the lab you want.

The CLIA 116 web app supports single site and multiple site searches. It searches the entire national database.

You can search and update records for labs that have an X-match for your accrediting organization, i.e., labs sponsored by your AO. You can also search all laboratories and view–but not update–their records.

To search for a laboratory:

1. Open the CLIA 116 web app.
2. In the **CLIA 116 Find** window, enter any combination of search criteria.

   You can enter all or part of any search element (e.g., all or part of a CLIA #), and use the % (percent) character as a wildcard.

   If you do not specify State or Zip, the search will be nationwide.

3 If you do not want to include terminated labs in the search, select **Exclude Terminated Laboratories**.

The search will return only Active and Pending labs.

4 To run the search, click **Find Now**.

All labs that meet your search criteria are displayed in the CLIA 116 Search Results window.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Multiple Sites Searches” just below
Procedure: “Partial Text and Wildcard Searches” below
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302

Multiple Sites Searches

A Multiple Sites Search must include the lab Name or at least one of the Physical Address fields in the search criteria. Search results list all lab sites, including the primary, that match your search criteria.

Until full detail is entered in the CLIA 116 web app for labs with multiple sites, you will be limited in the criteria you can specify for multiple sites searches. To identify labs with multiple sites for which detail has not been entered, you can run the Number of Sites Mismatch report.

➥ To locate all sites for a lab, enter the search criteria including **Name** or at least one **Physical Address** element, select the **Multiple Sites Search** checkbox, and click **Find Now**.

More ...

Procedure: “Locate Labs” on page 205
Procedure: “Partial Text and Wildcard Searches” just below
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302
Supporting Materials: “No. of Sites Mismatch” on page 562

Partial Text and Wildcard Searches

When you search for a lab, you can enter just a part of any search element e.g., part of a lab Name and CLIA #. You can use the percent sign (%) as a wildcard in your partial search text, whether it is alphabetic, numeric, or both.

No wildcard

If you do not include a wildcard, the CLIA 116 web app finds all items that start with the search text.

➥ Type **BU** to find all items that begin with BU, like **Bu**ckley and **Bu**ena; or type **23** to return all items beginning with 23, such as **23**7711.

Wildcard at start

If you place the % character at the start of the search text, the CLIA 116 web app finds all items that include the search text anywhere.

➥ Type **%BU** to find items like **Bu**ckley, **Bu**ena, and Am**bu**lance; or type **%23**, to return items like **23**7711 and 461**23**6.

Wildcard between characters

If you place the % character between two characters in the search text, the CLIA 116 web app finds items that contain the two characters in the order you typed them, but allows other characters to occur between them.

➥ Type **B%U** to find **Bu**ckley, **Bu**ena, and Am**bu**lance, and also **B**ertho**u**d, **B**e**u**lah, and **B**aca Co**u**nty; or type **2%3** to return **23**7711, 461**23**6, and 3**2**987**3**.

Update Lab Director Information

Authorized AO personnel can ensure the lab director information stored on national is current for their sponsored laboratories without involving SAs.

Note: AOs can also update lab director information in the AO Upload application.

To update lab director information:

1. Open the CLIA 116 web app.
2. Search the national CLIA database for the lab.
3. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.
4. On the **Demographics** tab of the lab record, go to the **Director Information** section.
5. Enter the lab director's **Last Name**, **First** name, and middle initial (**M.I.**).

   The First name and M.I. fields are not enabled until the Last Name field is populated.

6 Select the lab director's **Title** and salutation (**Sal**). If you choose 17 Other for Title, enter the applicable position title in the **Other** text field.

Other is enabled only if 17 Other is selected for Title.

WARNING! Do not include duplicate title information in the Last Name and Title fields.

More ...

Procedure: "Upload Data" on page 217
Fields: "Director Information", on page 395

Enter Accreditation Information

If a lab chooses to be accredited, it can designate more than one AO for CLIA purposes, but only one AO can accredit each specialty or subspecialty. The lab will receive a Certificate of Accreditation after the AO surveys the lab and confirms that the lab is in compliance, i.e., enters a Y-match. AO users can enter Y-matches, survey dates, and AO remarks through the CLIA 116 web app on the Accred Org Info tab of the lab record.

Enter Y-Matches

A lab applying for a Certificate of Accreditation starts with a Registration certificate. After you inspect the lab and find it to be in compliance, you enter a Y-match. In the CLIA 116 web app, all you have to do–with appropriate access rights–is select a checkbox to confirm compliance. The compliance effective date becomes the effective date for the Certificate of Accreditation and sets the 2-year accreditation cycle for a lab.

Note: Lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

To enter a Y-match:

1 Open the CLIA 116 web app.

2 Search the national CLIA database for the lab.

3 In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

-or-

Right-click the lab and select **Update 116**.

-or-

Double-click the lab.

The record for the lab is displayed in Update mode.

4 Go to the **Accred Org Info** tab of the lab record.

5 In the **Accrediting Organization Affiliations** section, select the **Confirmed** checkbox.

The system enters today's date in the **Confirmed Date** field. This will be the effective date for the Certificate of Accreditation.

Edits are applied to prevent overlapping certificates. For example, if the application is still new (not yet pending), you will not be able to enter the Y-match, i.e., select the Confirmed checkbox.

More ...

Procedure: "Access the 116 Web Application" on page 203
Procedure: "Locate Labs" on page 205
Screen: "Accred Org Info tab" on page 306

Enter AO Survey Dates

After you inspect a lab applying for a Certificate of Accreditation, you enter the survey date in the CLIA 116 web app. The system maintains dates of the current and 1st-3rd prior AO surveys.

Note: Lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

To enter AO survey dates for a lab:

1 Open the CLIA 116 web app.

2 Search the national CLIA database for the lab.

3 In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

-or-

Right-click the lab and select **Update 116**.

-or-

Double-click the lab.

The record for the lab is displayed in Update mode.

4 Go to the **Accred Org Info** tab of the lab record.

5 In the **Accrediting Organization Affiliations** section, enter the date of the most recent survey in the **AO Survey Entry** field.

If the AO Survey Entry date is more than 12 months after the existing Current date, it becomes the Current date after you save the lab record, and all other dates switch to the right into the appropriate Prior slot. If the AO Survey Entry date is less than 12 months after the existing Current date, it replaces the existing Current date after you save the lab record and Prior dates stay the same.

Note: The AO Survey Entry field is disabled until there is a Y-match, i.e., the Confirmed checkbox is selected.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "Accred Org Info tab" on page 306

Enter Remarks

Although AOs cannot terminate a lab, you can update or upload a Remarks code entered in the CLIA 116 web app that a lab has withdrawn, or was never affiliated. CMS then generates a letter to the lab asking them to contact their SA and provide more current information. If the SA hasn't heard from the lab and their renewal fee comes due, CMS will send a second letter. If there is no response, the system will terminate the lab’s certificate.

Note: Lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

To enter remarks:

1 Open the CLIA 116 web app.

2 Search the national CLIA database for the lab.

3 In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

-or-

Right-click the lab and select **Update 116**.

-or-

Double-click the lab.

The record for the lab is displayed in Update mode.

4 Go to the **Accred Org Info** tab of the lab record.

5 In the **Accrediting Organization Affiliations** section, select the appropriate **Remarks** code.

The Remarks list contains non-00 Remarks codes.

6 Enter the **Remarks Date**.

This field is not enabled until you enter a Remarks code. If the Remarks code needs to be corrected, change it to blank and the Letter Sent to Lab date is cleared.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "Accred Org Info tab" on page 306

Specialty Information

The Specialties tab both replicates sections VI, VII, and VIII of the CMS-116 form and captures survey specialties data. The 116 specialties are those the lab has identified on the CMS-116, which are entered (usually by the SA) on the Specialties tab of the lab record. Survey specialties come from a lab’s most recent certification kit. They reflect what surveyors determined the lab’s specialties to be.

The Specialties tab for 3-Accreditation/9-Reg (3) applications contains the Schedule Codes, Specialty Source, Total Annual test volume and Sub-specialty sections.

The Sub-specialty section displays 116 specialties, current survey specialties, or survey specialty history depending on the selected Specialty Source. You can update survey specialty information for Accredited labs in the CLIA 116 web app. 116 specialty information is read-only.

Update Survey Specialties

The survey specialty data shown on the Specialties tab in the CLIA 116 web app is drawn from a lab’s most recent certification kit. It does not include specialty data gathered from a lab prior to performing a status change. You can modify, delete, and close out survey specialties for Accredited labs.

Modify Survey Specialty Information

For Accredited labs, you can update survey specialties that your AO accredits. You cannot enter survey specialties in new lab records.

Note: Lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

To update survey specialties for an Accredited lab:

1. Open the CLIA 116 web app.
2. Search the national CLIA database for the lab.
3. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed in Update mode.
4. Go to the **Specialties** tab of the lab record.
5. Make sure **Specialty Source** is **Survey Specialties**; for AO users, this is the default.

   Survey specialty information includes the Accrediting Org (must be a Y-match, i.e., Confirmed is selected for the AO on the Accred Org Info tab), Effective Date, and Expiration Date (if closed out) for each selected sub-specialty. At the bottom is the annual Test Volume for each AO, and Total Annual Test Volume.
6. Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.

   Your AO is automatically assigned as the Accrediting Org.

   You cannot select sub-specialties unless there is a Y-match.
7. Enter the **Effective Date** for each selected sub-specialty.
8. Enter the annual **Test Volume** (at the bottom of the window) for all selected sub-specialties accredited by your AO.

   Total Annual Test Volume for all AOs is calculated by the system.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "Specialties tab" on page 307

Delete Active Survey Specialties

To delete a survey specialty, you simply deselect it. You can delete active survey specialties for Accredited labs in the CLIA 116 web app.

WARNING! Delete a survey specialty only if it was listed in error.

To delete an active survey specialty on an Accredited lab:

1. Open the CLIA 116 web app.
2. Search the national CLIA database for the lab.
3. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed in Update mode.
4. Go to the **Specialties** tab of the lab record.
5. Make sure **Specialty Source** is **Survey Specialties**; for AO users, this is the default.
6. In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

   The deleted specialty is highlighted in red for the rest of the session.

Note: After you save a lab record, data for all deleted specialties is removed from the Sub-specialty grid.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "Specialties tab" on page 307

Close Out Survey Specialties

Closing out a survey specialty is not the same thing as deleting it. To close out a specialty, you must enter an expiration date for it. You can delete survey specialties for Accredited labs on the Specialties tab in the CLIA 116 window.

To close out a survey specialty on an Accredited lab:

➥ Enter its **Expiration Date** in the **Sub-specialty grid**.

Note: After you save a lab record, data for all deleted and closed out specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

Delete Closed-Out Survey Specialties

Only CO Super Users can delete closed-out survey specialties in the CLIA 116 web app.

View Survey Specialty History

You can view a complete read-only history of survey specialties for Accredited labs that your AO accredits.

To view survey specialty history:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Specialty History**.

   The survey specialty history for the lab is displayed in an unlabeled section below Total Annual test volume

More ...

Screen: "Specialties tab" on page 307

View 116 Specialties

116 specialty information is what a lab includes on the CMS-116 it submits. In the CLIA 116 web app, you can view 116 specialties, but you cannot update them.

To view 116 specialties for a lab:

1. Open the CLIA 116 web app.
2. Search the national CLIA database for the lab.
3. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed in Update mode.
4. Go to the **Specialties** tab of the lab record.
5. For **Specialty Source**, select **116 Specialties**.

   For Accredited labs, 116 specialty information includes the Accrediting Org for each selected sub-specialty (must be an X-match), and Test Volume for selected specialty groups. At the bottom is the Total Annual Test Volume.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "Specialties tab" on page 307

Lab Record Inquiry

The Inquiry function accessed from CLIA 116 Search Results provides a read-only view of lab records for informational purposes. You can view the record for any lab in the national CLIA database.

Note: You can update records only for labs with an X-match for your accrediting organization, i.e., labs sponsored by your AO.

To view a lab record:

1. Open the CLIA 116 web app.
2. Search the national CLIA database.
3. In the **CLIA 116 Search Results** list, select a lab and click **Inquiry** at the bottom of the window.

   -or-

   Right-click the lab and select **Inquiry 116**.

   The record for the lab is displayed in read-only Inquiry mode.

More ...

Procedure: “Access the 116 Web Application” on page 203
Procedure: “Locate Labs” on page 205
Screen: "CLIA 116 window" on page 304

Certificate and Billing Inquiry

The Cert/Bill Inquiry function, which you can access from the lab record, displays the lab’s certificate and billing history in the CLIA Certificate and Billing Inquiry window. You can view the certificate and billing information for any lab in the national CLIA database.

CLIA Certificate Status

Pending - The lab has applied for a new certificate type or a continuing certificate. The current certificate expiration date is more than 30 days in the future and the lab has not yet paid fees for the new or continuing certificate. A pending certificate period depends on application type: 12 months prior to expiration of app type 1 renewals, 6 months prior to expiration for app type 2, 3, and 4 renewals. Pending certificate information is not sent to Medicare or Medicaid.

Current - When the lab has paid the required fees and its current certificate is due to expire within 30 days, its pending certificate becomes the current certificate.

History - This is a certificate the lab held in the past.

View Certificate and Billing Information

The Certificate Inquiry section of the CLIA Certificate and Billing Inquiry window displays details about the lab's future (pending), current, and prior (historical) certificates.

The Billing Inquiry section is ordered by certificate date and provides various billing details such as transaction date and description, payment amount, and lockbox date. If no certificate is issued, the line is marked with an asterisk.

To view certificate and billing info for a lab:

➥ Open a lab record in **Update** or **Inquiry** mode and click **Certificate/Billing Inquiry** at the bottom of the window.

More ...

Screen: "CLIA Certificate and Billing Inquiry window" on page 314

Print CLIA 116 Search Results

You can generate the Search Results list in the CLIA 116 web app as a report.

WARNING! Surveyors are strongly cautioned NOT to release this information publicly, to use it carefully and only to assist with your routine regulatory and survey-related duties.

To print CLIA 116 search results:

1. Open the CLIA 116 web app.
2. Search the national CLIA database.
3. Click **Print** at the bottom of the **CLIA 116 Search Results** window.
4. In the **Report Selection** window, click **CLIA Search Results List**.

   The CLIA Search Results List report is generated in PDF format. It lists labs in the order they are displayed in the CLIA 116 Search Results window.

   Note: The Search Results list and the report include only labs associated with the AO performing the search.

More ...

Procedure: "Access the 116 Web Application" on page 203
Procedure: "Locate Labs" on page 205
Screen: "CLIA 116 Search Results window" on page 302
Screen: "Report Selection window" on page 303
Supporting Materials: "CLIA Search Results List" on page 570

Upload Data

AOs can open the 116, view lab records with which they are affiliated, and make certain changes as detailed previously in this chapter. If approved by CMS, you can automate entry of changes by uploading batch files. The AO Upload function provides mechanisms for uploading or downloading these batch text files. Uploaded AO files are processed weekly.

The following procedure summarizes use of the AO Upload function. For details, refer to the *User Guide for ASPEN 9.5 - CLIA AO Upload* from Telligen (formerly Iowa Foundation for Medical Care).

To use the AO Upload function:

1. Open **ASPEN Web CLIA**.
2. In the **Select Application** window, choose **AO Upload**.
3. Select the **File Upload** option to upload a text file containing AO information to the CLIA 116 web app.

   -or-

   Select the **File Download** option to download successfully uploaded files or files with validation errors.

   Note: Data validation is the same whether the data is added through the AO Upload process or directly in the CLIA 116 web app. For example, specialty test volumes over the allowed annual maximum are not accepted; offending specialty records are not processed and the associated labs are not uploaded.

More ...

Procedure: “Access the 116 Web Application” on page 203, steps 1-5
Screen: "ASPEN Web CLIA - Select Application window" on page 299

System Information

The System Information window displays current QIES and ASPEN system information. It indicates any state databases or providers set to read-only due to overnight processing errors, and displays messages posted about system status or processing errors. It also provides access to batch billing job logs (audit files).

To view system information:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **System Information**.

   Current system information and a list of batch billing job logs from the past week are displayed.

3. In the **Batch Jobs** section, enter **From Date** and **To Date** to specify the date range you want and click **Find** to update the list of audit files.
4. in the **View Audit Messages** column, click **View** for the audit file you want to view.

   It opens in a text editor, which you can close when you are done.
5. To print the contents of the System Information window, click the **Print** button.
6. To close the System Information window and return to the Select Application window, click **Done**.

More ...

Procedure: “Access the 116 Web Application” on page 203, steps 1-5
Screen: "ASPEN Web CLIA - Select Application window" on page 299
Screen: "System Information window" on page 316

CLIA 116: Exempt

The CLIA 116 web application runs in a web browser (Internet Explorer) over the CMS intranet. It directly accesses the national CLIA database.

With the appropriate permissions, Exempt state users (NY, WA) can:

- Add exempt labs
- Enter new CMS-116 application data for exempt labs
- View and enter 116 specialties for exempt labs
- View and update survey specialties for exempt labs
- Update exempt lab records

Note: Exempt state users can create both exempt and regular (non CLIA-exempt) lab records.

Access the 116 Web Application

You will generally open ASPEN Web CLIA in your browser to access the 116 application (web app) when you are creating and maintaining exempt lab records. To open ASPEN Web CLIA, you need to know the URL for the ASPEN Access page and have a current national system login.

To access the CLIA 116 web app:

1. Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen
2. Click the **ASPEN Web** link.
3. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
4. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.wySelect **CLIA**.

   ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

5 In the **Select Application** window, click **116 Application**.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

116 Data Validation

The CLIA 116 web app validates data and informs you if there are validation errors when you go from one tab to another or save a lab record. Validation errors occur when you do not provide required data, or provide invalid data.

Required Fields

Required fields are marked with an asterisk (*).

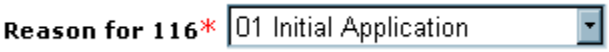


Figure 40: Required field

The CLIA 116 web app checks to see that data is entered in all required fields on a tab when you go to another tab or save a lab record. If required data is missing or invalid, you will receive validation error messages.

Some fields are required only under certain conditions. Those fields may not be marked with an asterisk, but if you try to save a lab record without completing conditionally required fields, you will receive error messages.

Tab Validation

If the CLIA 116 web app finds validation errors when you go to another tab, it lets you know. You can choose OK to override until you save the lab record, or Cancel to go back to the original tab and correct any problems. Field-specific error messages are displayed in red on the tab. There may not be messages for all fields with errors.

Lab Record Validation

Whenever you save a lab record, all data validation edits are applied. If validation errors are found, the system identifies the tabs that have errors. You can either cancel all data entry you have done, or go to the tabs that contain errors and correct them. Field-specific error messages are displayed in red on the applicable tabs. There may not be messages for all fields with errors. You need to correct all errors, explicitly identified or not, and save the record again.

When you save a lab record, an Add or Update transaction record is created and processed overnight. Errors occasionally occur in the nightly processing. In that case, the lab records involved will be read-only until the errors are resolved. If a lab record is read-only, check the top (header) of the record for an upload failure message.

Adding Exempt Lab Records

To create a record for an exempt lab (Class Code = 05) in the national CLIA database, you enter application data from the CMS-116 form in the CLIA 116 web app. When the application is accepted, a new lab record is generated and downloaded to your state's ACO database during nightly processing.

Note: You can add new lab records at any time. There is no restriction due to batch processing as there is for updating records.

Exempt state users can create both exempt and regular (non CLIA-exempt) lab records.

Locate Labs

A comprehensive set of search criteria is available in the CLIA 116 Find window, enabling you to quickly locate existing exempt labs in the national CLIA database. You also *must* use the search function to verify that a lab you are planning to add is not already in the system.

You can specify criteria that make the search as broad or narrow as you need. For example, a broad search specifying a major city and the area code portion of a phone number would return all labs in the city with that area code. Generally, the narrower (more specific) the search, the quicker you will find the lab you want.

The CLIA 116 web app supports single site and multiple site searches. It searches the entire national database. However, your user type determines which lab records you can add or update. For example, Exempt state users can change data only for labs (exempt or regular, i.e., non CLIA-exempt) in their state.

To search for an exempt lab:

1. Open the CLIA 116 web app.
2. In the **CLIA 116 Find** window, enter any combination of search criteria.

   You can enter all or part of any search element (e.g., all or part of a CLIA #), and use the % (percent) character as a wildcard.

   To enter a lab director's name, you must first enter all or part of Director Last Name to activate the Director First Name field.

   If you do not specify State or Zip, the search will be nationwide.
3. If you do not want to include terminated labs in the search, select **Exclude Terminated Laboratories**.

   The search will return only Active and Pending labs.
4. To run the search, click **Find Now**.

   All labs that meet your search criteria are displayed in the CLIA 116 Search Results window. Exempt labs are identified by 05 in the Class column; you may need to scroll to the right to see this column.

More ...

Procedure: "Access the 116 Web Application" on page 219
Procedure: "Multiple Sites Searches" just below
Procedure: "Partial Text and Wildcard Searches" on page 223
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302

Multiple Sites Searches

A Multiple Sites Search must include the lab Name or at least one of the Physical Address fields in the search criteria. Search results list all lab sites, including the primary, that match your search criteria.

Until full detail is entered in the CLIA 116 web app for exempt labs with multiple sites, you will be limited in the criteria you can specify for multiple sites searches. To identify labs with multiple sites for which detail has not been entered, you can run the Number of Sites Mismatch report.

➥ To locate all sites for a lab, enter the search criteria including **Name** or at least one **Physical Address** element, select the **Multiple Sites Search** checkbox, and click **Find Now**.

More ...

Procedure: "Locate Labs" on page 221
Procedure: "Partial Text and Wildcard Searches" (just below)
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302
Supporting Materials: "No. of Sites Mismatch" on page 562

Partial Text and Wildcard Searches

When you search for a lab, you can enter just a part of any search element e.g., part of a lab Name and CLIA #. You can use the percent sign (%) as a wildcard in your partial search text, whether it is alphabetic, numeric, or both.

No wildcard

If you do not include a wildcard, the CLIA 116 web app finds all items that start with the search text.

➥ Type **BU** to find all items that begin with BU, like **Bu**ckley and **Bu**ena; or type **23** to return all items beginning with 23, such as **23**7711.

Wildcard at start

If you place the % character at the start of the search text, the CLIA 116 web app finds all items that include the search text anywhere.

➥ Type **%BU** to find items like **Bu**ckley, **Bu**ena, and Am**bu**lance; or type **%23**, to return items like **23**7711 and 461**23**6.

Wildcard between characters

If you place the % character between two characters in the search text, the CLIA 116 web app finds items that contain the two characters in the order you typed them, but allows other characters to occur between them.

➥ Type **B%U** to find **Bu**ckley, **Bu**ena, and Am**bu**lance, and also **B**ertho**u**d, **B**e**u**lah, and **B**aca Co**u**nty; or type **2%3** to return **23**7711, 461**23**6, and 3**2**987**3**.

Add Exempt Lab Records

To add a record for an exempt lab (Class Code = 05) to the national CLIA database, you enter data in the CLIA 116 web app from the CMS-116 application submitted by the lab. You must first do a search–by lab name at least–to verify that a record for the lab does not already exist. For the lab's application to be accepted, you must enter all required data and it must pass validation checks.

When an exempt lab is added, a certificate cycle is created with an effective date equal to the date the record is added and an expiration date equal to the date the state's exemption approval expires.

Note: You can add new lab records at any time. There is no restriction due to batch processing as there is for updating records.

To add an exempt lab to the database:

1. Search the national CLIA database for the lab you want to add, to make sure it is not already in the database.
2. If the lab is not listed in the CLIA 116 Search Results window, click the **Add** button at the bottom.

   A new lab record opens in Add mode with the Demographics tab selected. Some fields may already be populated based on what you entered in the CLIA 116 Search window.

   For a new lab record, the CLIA 116 web app will warn you if it found a duplicate address, phone number, or Federal Tax ID in another lab record. You can choose to continue or cancel.
3. Create the lab record by entering data from the hardcopy CLIA application, the CMS-116 form, submitted by the lab and click **Save** when you are done.

   If the application is accepted, i.e., there are no data validation errors, a message tells you what the system-generated provider (CLIA) number is for the lab. This is entered as the CLIA # when you return to the CLIA 116 Find window.

   An Add transaction for the lab is created and processed overnight, and the new lab record is downloaded to the applicable state database (ACO).

Note: CLIA fees are not assessed for exempt labs.

More ...

Procedure: “Locate Labs” on page 221
Procedure: “Entering New CMS-116 Applications” (just below)
Screen: "CLIA 116 window" on page 304

Entering New CMS-116 Applications

The CLIA 116 web app screens closely follow the layout of the printed CLIA application form, the CMS-116. The information you provide in the CLIA 116 web app depends on lab (application) type. The tab structure of the CLIA web app screens allows you to skip areas that may not apply. For example, unless you are adding an Accredited lab, you can skip the Accred Org Info tab. Fields that do not apply do not appear, or are disabled.

Note: Exempt state users can enter 116 application data for both exempt and regular (non CLIA-exempt) lab records.

Enter Demographics Information

The Demographics tab replicates sections I, II, III and IV of the hardcopy CMS-116. The information captured here includes basic application and identification information for the lab, lab director identity, and the lab's testing schedule.

To enter basic information about an exempt lab:

1. Go to the **Demographics** tab of the lab record.

General Information

2. Select the applicable **Reason for 116**.

   Initial Application is the default for new labs.

3. Select the **App Type Requested**.

   This is the certificate (application) type requested by the lab. Fields are enabled or disabled according to the selected type. If you change App Type Requested on a new lab record and have already entered data that is invalid for the new type, you will receive an error message. The invalid data must be replaced or removed before you can change the application type.

4. Enter the **State Agency Received Date**.

   This is the date the hardcopy CMS-116 was actually received at the SA office.

5. Enter identifying information for the lab: **Name**, contact **Email Address**, **Fed Tax ID**, **Phone** and **Fax** numbers.

   Enter only numeric characters for the Federal tax ID, and phone and fax numbers. The system will format the phone and fax numbers as needed.

6. For **Class Code**, select **05 Exempt**, the class for labs exempt from CLIA requirements.

   05 Exempt is the default tor Washington state (WA) users. 00 Regular is the default for New York (NY) users. For exempt labs, be sure to select 05 Exempt. For non CLIA-exempt labs, choose 00 Regular.

   Note: If you did not specify State as a search criterion, this field is read-only until you enter a Zip code in your state for the lab.

Director Information

7. Enter the lab director's **Last Name**, **First** name, and middle initial (**M.I.**)

   The First name and M.I. fields are not enabled until you enter something in the Last Name field.

8 Select the lab director's **Title** and salutation (**Sal**). If you choose 17 Other for Title, enter the applicable position title in the **Other** text field.

Other is enabled only if 17 Other is selected for Title.

WARNING! Do not include duplicate title information in the Last Name and Title fields.

Physical Address

9 Enter the lab's physical address, i.e., the location where tests are performed. Type the **Street** address and **Zip** code.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

Mailing Address (if different than physical address)

10 Enter the lab's mailing address: type the **Street** address and **Zip** code and select the **City** if necessary.

State is system-generated based on Zip code.

Corporate Address

11 Enter the **Street** address and **Zip** code of the corporate entity that owns the lab; select the **City** if necessary.

Form Mailing

12 Choose whether to send bills and certificates to the lab's Physical or Corporate address.

Type of Laboratory

13 Select the applicable option. If you choose 29 Other as Type, enter the applicable lab type in the Other text field. Other is enabled only if 29 Other is selected for Type of Laboratory.

Hours of Laboratory Testing

14 Specify the lab's testing schedule: enter **FROM** and **TO** hours for each day the lab is open. If it is always open, click the **24x7** button and the hours are automatically filled in.

More ...

Screen: "Demographics tab" on page 305.

Identify Multiple Sites

The Multiple Sites tab replicates section V of the hard-copy CMS-116. A separate record in the CLIA 116 web app is required for each of a lab's locations with the following exceptions.

- Temporary Testing Sites

  The lab moves from testing site to testing site, e.g., mobile units, health screening fairs.

- Non-profit, Federal, State or Local Government Labs

  The lab performs 15 or fewer different tests, including waived. None of the tests is of high complexity.

- Hospital-based Labs

  The labs are all located within a hospital in contiguous buildings on the same campus and under common direction.

If a lab's multiple testing sites or separate locations qualify for the Multiple Sites exception provision, you use the Multiple Sites tab to provide information about them. Multiple sites all have the same CLIA number as the primary lab, which is included in the count of multiple sites.

To enter information about a lab's multiple sites:

1. Go to the **Multiple Sites** tab of the lab record.

General Information

2. Select **Yes** for **Multiple Sites** if the lab has multiple locations and they qualify for a multiple sites exception.

   When the Multiple Sites field is initially marked Yes, the primary (current) lab is automatically entered as the first multiple site.

3. For **Number of Sites**, enter the number reported by the lab on the CMS-116.

   Active Sites Entered displays a read-only count of active additional sites (Status is Active).

   When the Multiple Sites field is initially marked Yes, Number of Sites is set to 2 and Active Sites is set to 1.

Exceptions

4. Indicate whether any Multiple Site exception applies:

   Lab with temporary testing sites?

   Non-profit, Federal, state or local government lab?

   Hospital with several labs at the same address?

Multiple Sites

5 In the **Multiple Sites section**, select **Active** to view only active lab sites, or **All** to view all lab sites including moved and removed labs.

6 **Add**, **Modify**, or **Remove** labs in the Multiple Sites list as needed.

Note: If you change the Multiple Sites field to No after adding multiple sites, all active sites are removed. Moved and removed sites remain in the list.

More ...

Procedure: “Add a Site” (just below)
Procedure: “Update a Site” on page 229
Procedure: “Remove a Site” on page 229
Screen: "Multiple Sites tab" on page 305

Add a Site

To enter detailed information about each of a lab's multiple sites, use the Add button on the Multiple Sites tab.

To add a site:

1 In the **Multiple Sites section** of the **Multiple Sites tab**, click **Add**.

-or-

Right-click in the list and select **Add Site**.

The Add button is not enabled if No is selected in the Multiple Sites field. Number of Sites must be at least the number of Active Sites Entered +1 before you can add a site.

2 Enter the **Name**, **Street** address, **Zip** code, **Phone** number, and **NPI** (National Provider Identifier) of the additional lab site.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

3 Select the **Status** of the additional site.

ID is a system-generated sequence number. It indicates the order in which additional sites were added.

4 In the **Tests Performed/Specialties** text box, describe **Tests Performed** at the site and its **Specialties**.

5 Click **Save** to save the information and add the site to the Multiple Sites list.

Note: When a laboratory is terminated, any multiple site locations with a Status of Active will remain Active.

More ...

Screen: "Add/Modify Site window" on page 306

Update a Site

Use the Update button on the Multiple Sites tab to correct information in existing multiple site records.

To update site information:

1. In the **Multiple Sites section** of the **Multiple Sites tab**, select a site and click **Modify**.

   -or-

   Right-click a site and select **Modify Site**.

2. Make changes as needed.

   For the primary site, you can only make changes to Tests Performed/Specialties text. To change basic demographic information about the primary lab site, go to the Demographics tab.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Screen: "Add/Modify Site window" on page 306
Procedure: "Enter Demographics Information" on page 225

Remove a Site

If a lab reports it is no longer testing at a site, you can remove the applicable multiple site record. You cannot remove the primary site.

To remove a site:

➥ In the **Multiple Sites section** of the Multiple Sites tab, select a site and click **Remove**.

-or-

➥ Right-click a site and select **Remove Site**.

The Status of the site changes to Removed. If you are displaying only active sites, the removed site disappears from the Multiple Sites list.

TIP: You can also change Status to Removed through the Update function, or directly on the grid.

To include removed sites in the **Multiple Sites section**, select the **All** radio button.

Enter Accreditation Information

The Accred Org Info tab replicates section II of the hardcopy CMS-116. It also displays information not on the form, such as AO Confirmed (Y-match) and Remarks.

If a lab chooses to be accredited, it can designate more than one AO for CLIA purposes, i.e., enter more than one X-match, but only one AO can accredit each specialty or subspecialty.

Add an AO (X-match)

When you add an Accredited lab (app type 3), you need to select at least one accrediting organization on the Accred Org Info tab in order to save the record. All fields on this tab are disabled for Compliance, Waiver, and PPM labs.

To add an AO:

1. Go to the **Accred Org Info** tab of the lab record.
2. In the **Accrediting Organization Affiliations** section, click **Add**.

   A new row is added to the list of AOs.
3. Select the appropriate **Accred Org** (accrediting organization).

   You cannot add an AO here more than once.

More ...

Screen: "Accred Org Info tab" on page 306

Delete an AO

To delete an AO:

1. Go to the **Accred Org Info** tab of the lab record.
2. In the **Accrediting Organization Affiliations** section, select an AO and click **Delete**.

   The AO is marked for removal (crossed out). All fields in the row are immediately disabled and the row is removed when the lab record is saved.

More ...

Screen: "Accred Org Info tab" on page 306

Specialty Information

The Specialties tab both replicates sections VI, VII, and VIII of the CMS-116 form and captures survey specialties data. The 116 specialties are those the lab has identified on the CMS-116, which you enter on the Specialties tab of the lab record. Survey specialties are those entered on the 1557 Specialties tab in the ACO certification kit. They reflect what surveyors determined the lab’s specialties to be.

View and Enter Specialty Information

What you see on this tab and what is required depends on the type of application as described below. You can at least view (as applicable) a lab's 116 specialties, survey specialties, and survey specialty history.

1-Compliance/9-Reg (1)

The Specialties tab for Certificate of Compliance applications includes the Schedule Codes, Specialty Source, Total Annual test volume, and Sub-specialty sections.

Annual test volumes for All Waived/PPM Tests are optional. If you enter 0 for either test volume, you must also select the No Testing checkbox.

The Sub-specialty section displays 116 specialties, current survey specialties, or survey specialty history depending on the selected Specialty Source. You must enter at least one 116 sub-specialty and associated test volume in the Sub-specialty section (when Specialty Source is 116 Specialties) unless the lab is downgrading its certificate from Compliance to Waiver or PPM.

2-Waiver

The Specialties tab for Certificate of Waiver applications has the Total Annual test volume and Specialty History sections.

Total annual volume for All Waived Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. The All PPM Tests field is disabled.

Note: It is not currently possible to enter the tests being performed by Waiver labs except as notes.

The Specialty History section displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

3-Accreditation/9-Reg (3)

The Specialties tab for Certificate of Accreditation applications includes the Schedule Codes, Specialty Source, Total Annual test volume and Sub-specialty sections.

Annual test volumes for All Waived/PPM Tests are optional. If you enter 0 for either test volume, you must also select the No Testing checkbox.

The Sub-specialty section displays 116 specialties, current survey specialties, or survey specialty history depending on the selected Specialty Source. You must enter at least one 116 sub-specialty with associated accrediting organization and test volume in the Sub-specialty section (when Specialty Source is 116 Specialties).

4-PPM

The Specialties tab for Certificate of PPM applications has the Total Annual test volume and Specialty History sections.

Total annual volume for All PPM Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008.

Annual volume for All Waived Tests is optional. If you enter 0, you must also select the No Testing checkbox.

Note: It is not currently possible to enter the tests being performed by PPM labs except as notes.

The Specialty History section displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

TIP: You do not have to memorize all these rules. The CLIA 116 web app will not let you save a lab record if required fields are not complete, and the edit messages will tell you what is missing.

To view or enter specialty information for an exempt lab:

1 Go to the **Specialties** tab of the lab record.

Schedule Codes

Schedule codes for Compliance and Accredited laboratories are system-generated and read-only.

Specialty Source

2 To display 116 specialty data in the Sub-specialty grid, select **116 Specialties**. To display current survey specialty data, select **Survey Specialties**. To display survey specialty history for a Compliance or Accredited lab, select **Specialty History**.

116 Specialties is the default, except for AO users. Last Update Date (of 116 or survey specialties depending on selected source) is system-generated and read-only.

This section does not appear for Waiver or PPM labs.

Note: A Specialty History section is automatically displayed below Total Annual test volume for PPM and Waiver labs. If a lab previously held an Accreditation or Compliance certificate, it displays specialty history data; otherwise, it is blank.

Total Annual test volume

3 Enter the number of **All Waived Tests** and **All PPM Tests** performed annually, as applicable.

This section appears for all labs. Whether annual test volumes are required depends on lab type.

Waiver labs - Annual test volume for All Waived Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. All PPM Tests is disabled.

PPM labs - Annual test volume for All PPM Tests is required and must be greater than 0 if State Agency Received Date is after 1/19/2008. All Waived Tests is optional.

Compliance, Accredited labs - Annual test volumes are optional.

When test volume is not required but the field is enabled, you can enter a test volume, or enter 0 and select No Testing if the checkbox is enabled.

Sub-specialties

4 In the Sub-specialty grid, view and enter 116 specialties, view and update survey specialties, or view survey specialty history for a Compliance or Accredited lab, depending on the selected Specialty Source.

The Sub-specialty grid does not appear for Waiver or PPM labs since they do not have specialties. However, the Specialty History section is automatically displayed in its place.

More ...

Screen: "Specialties tab" on page 307
Fields: "Total Annual test volume", on page 407
Procedure: “View and Enter 116 Specialties” just below
Procedure: “View and Update Survey Specialties” on page 235
Procedure: “View Survey Specialty History” on page 236

View and Enter 116 Specialties

Depending on your user class and permissions, you can view and enter 116 specialties for exempt Compliance and Accredited labs in the Sub-specialty grid. 116 specialty information is what a lab includes on the CMS-116 it submits.

To view and enter 116 specialties for an exempt lab:

1 Go to the **Specialties** tab of the lab record.

2 Be sure **Specialty Source** is **116 Specialties**.

For Compliance labs, you will see Test Volume for selected 116 specialty groups. For Accredited labs, 116 specialty information includes the Accrediting Org for each selected sub-specialty (must be an X-match), and Test Volume for selected specialty groups.

3. Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.
4. For Accredited labs, select the **Accrediting Org** for each sub-specialty.

   The options in the drop-down list are the AOs entered on the Accred Org Info tab, i.e., X-matches.
5. Enter the annual **Test Volume** for each selected specialty group.

   This is the number of tests for all selected sub-specialties in the specialty group.

   Total Annual Test Volume is calculated by the system.

More ...

Screen: "Specialties tab" on page 307

Delete 116 Specialties

When an existing exempt lab with active 116 specialties stops offering a specific specialty, you can delete it.

To delete a 116 specialty:

1. Go to the **Specialties** tab of the lab record.
2. Be sure **Specialty Source** is **116 Specialties**.
3. In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

   The deleted specialty is highlighted in red for the rest of the session.
4. Adjust the applicable **Test Volume** as necessary.

   If you delete all sub-specialties under a specialty, the Test Volume field is cleared and disabled.

Note: After you save a lab record, data for all deleted specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

View and Update Survey Specialties

Depending on your user class and permissions, you can view and update survey specialties for exempt Compliance and Accredited labs in the Sub-specialty grid. Survey specialties are entered on the 1557 Specialties tab in ACO certification kits. You cannot enter them in new lab records in the CLIA 116 web app.

The survey specialty data shown on the Specialties tab is drawn from a lab's most recent certification kit. It does not include specialty data gathered from a lab prior to performing a status change.

To view and update survey specialties for an exempt lab:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Survey Specialties**.

   For Compliance labs, survey specialty information includes the Effective Date and Expiration Date (only if closed out) for each selected sub-specialty, and Test Volume for selected specialty groups.

   For Accredited labs, you will see the Accrediting Org for each selected sub-specialty (must be a Y-match), Effective Date, and Expiration Date (only if a specialty has been closed out).
3. Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.
4. For Accredited labs, select the **Accrediting Org** for each sub-specialty.

   The options in the drop-down list are the AOs entered on the Accred Org Info tab, i.e., X-matches.
5. Enter the **Effective Date** for each selected sub-specialty.
6. For Compliance and Accredited labs, enter the annual **Test Volume** for each selected specialty group.

   This is the number of tests for all selected sub-specialties in the specialty group.

   Total Annual Test Volume is calculated by the system.

More ...

Screen: "Specialties tab" on page 307

Delete Active Survey Specialties

Survey specialties are usually deleted on the 1557 Specialties tab in the applicable certification kit in ACO. However, you can delete active survey specialties for exempt Compliance and Accredited labs in the CLIA 116 web app if necessary. To delete a survey specialty, you simply deselect it on the Specialties tab.

To delete a survey specialty:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Survey Specialties**.
3. In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

   The deleted specialty is highlighted in red for the rest of the session.

More ...

Screen: "Specialties tab" on page 307

Close Out Survey Specialties

Closing out a survey specialty is not the same thing as deleting it. To close out a specialty, you must enter an expiration date for it.

Survey specialties are usually closed out on the 1557 Specialties tab in the applicable certification kit in ACO. However, you can close out survey specialties for exempt Compliance and Accredited labs on the Specialties tab in the CLIA 116 web app if necessary.

To close out a survey specialty:

➥ Enter its **Expiration Date** in the **Sub-specialty grid**.

Note: After you save a lab record, data for all deleted and closed out specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

View Survey Specialty History

You can view survey specialty history on the Specialties tab for all labs, regardless of certificate type. If the lab has open (active) and closed survey specialties, you will see a complete read-only history of those specialties.

PPM and Waiver labs

The Specialty History section displays a lab’s survey specialty history, if any.

Compliance and Accredited labs

You choose an option to display the survey specialty history for a lab.

To view survey specialty history for a PPM or Waiver lab:

1. Go to the **Specialties** tab of the lab record.
2. Look at the **Specialty History** section below Total Annual test volume,

   It displays survey specialty history if the lab previously held an Accreditation or Compliance certificate. Otherwise, it is blank.

To view survey specialty history for a Compliance or Accredited lab:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Specialty History**.

   The survey specialty history for the lab is displayed in an unlabeled section below Total Annual test volume.

More ...

Screen: "Specialties tab" on page 307

Enter Additional Information

On the Additional Info tab, you can enter supplementary information about the exempt lab such as:

- Lab Director Affiliations

  If the director of a laboratory serves as the director for other labs that are separately certified, you can specify those affiliations on the Additional Info tab. An individual can serve as the director for up to five non-Waiver labs–any combination of PPM, Compliance, or Accredited–and an unlimited number of Waiver labs.
- Type of Control

  This is the type of organization that operates the lab.
- Application Signature Date

  This is the date the application was received.
- Cyto PT (Proficiency Testing)

  This section has details about Cyto PT enrollment for Compliance and Accredited labs that are approved for cytology testing (630 spec code).

To enter additional information about the lab:

1. Go to the **Additional Info** tab of the lab record.

Director Affiliations

2 Enter the **CLIA number** of an affiliated lab (must be active) and click **Insert Affiliated Lab**, or use the **Find** function and select the applicable lab in the search results.

The lab is added to the list of affiliations. There is no limit on the number of affiliations you can enter, but only 8 are uploaded. There is currently no edit check to confirm that the affiliated lab you select actually has the same director.

Note: The Find Affiliated Providers window works just like the CLIA 116 Find window.

Other

3 Select **Type of Control** from the list. If you select **03 Other** or **09 Other Government**, enter the applicable control type in the **Other** text field.

4 Enter the **Application Signature Date**.

This date is required if the Reason for 116 is Initial Application or Survey.

5 Enter the **Cross Reference Provider Number**, i.e., the CLIA number previously assigned to a lab with multiple sites.

This field is required when the termination code for the lab is 13 Multiple to Single Site Certificate.

6 Enter the **CLIA Medicare Number** assigned to the lab.

7 The **Federal Jurisdiction** field is disabled.

8 Four read-only CASPER Inquiry fields display:

- Date the certification kit was successfully uploaded to CASPER (national reporting system).
- Date the kit passed ASPEN upload edits.
- Determination Approval date entered by the RO.
- Whether the certification kit requires RO review.

Cyto PT Enrollment

This section is relevant only for Compliance and Accredited labs that are approved for cytology testing (630 specialty code). The information is set by national batch jobs when they generate Cyto PT letters and is read-only.

More ...

Screen: "Additional Info tab" on page 308
Procedure: “Locate Labs” on page 221

Add Notes

The Notes function lets you add notes to a lab record. They can be as brief or extensive as you require. There are separate note panels for State, Regional Office, and Central Office users. You can view note text in all three panels, but enter and edit text only in the panel that is activated depending on your user type.

Note: The Notes function is unavailable until a new lab record is saved and a CLIA # (aka CLIA number, CLIA provider number, CCN, Medicare provider number, provider #/number) has been assigned.

To add notes to the lab record:

1. At the bottom of the lab record, click the **Notes** button.

   The active panel depends on your user type.

2. Enter your note text and click **Save**.

   Notes are saved immediately; you do not have to save the lab record. When note text is first saved, the Notes button label changes to NOTES(*) to indicate there are notes.

More ...

Screen: "Notes window" on page 312
Fields: "Notes", on page 416

Include Attachments

You can add supplemental materials in electronic format to lab records such as relevant document files and digital photos. For example, you can attach letters and documents from outside agencies.

When you attach a file, a copy of the original is compressed and stored in the national CLIA database, and can be viewed only in the CLIA 116 web app. If you move or delete the original, it does not affect the attachment.

Add Attachments

The CLIA 116 web app supports attachment of the following file types: .txt, .rtf, .doc, .docx, .html, .pdf, .gif, .jpeg, .jpg, .tif, and .xls.

Note: HIPAA compliance guidelines apply to attachments. Be sure to remove patient names and other identifying information from items you attach to lab records.

To add an attachment to the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, click **Add**.
3. Click **Add** to add a row in the **Attachments** grid.

4. In the **Entry Name** field, type a descriptive name for the attachment.
5. Press the **Tab** key and click **Browse** to the right of the Attach field.
6. Navigate to the folder containing the file you want to attach. select it, and click **Open**.

   The file name and path are inserted into the Attach field.
7. Press the **Tab** key and the CLIA 116 web app inserts the **File Name** of the attachment and **Date Attached**; the **Attach** field is cleared.
8. Click **Close** to save the attachment information.

   The attachment is saved immediately; you do not have to save the lab record. When the first attachment to the lab record is saved, the Attachments button label changes to ATTACHMENTS(*) to indicate there is at least one attachment.

More ...

Screen: "Attachments window" on page 312

View Attachments

To view an attached file, there must be an application registered on your system that can open it. For example, .doc files can be opened by MS Word, .bmp is usually associated with Paint, .jpg is usually associated with your web browser.

To view an attachment to the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, click anywhere in the applicable row and click the **View** button, or just click **View** twice.

   The attachment is displayed.
3. To return to the **Attachments** window, close the application displaying the attachment.

More ...

Screen: "Attachments window" on page 312

Remove Attachments

You can remove an attachment altogether or replace it with another.

To remove an attachment from the lab record:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, select an attachment and click **Remove**.

   The attachment is marked for removal; Entry Name and File Name are crossed out. The attachment is deleted when you close the Attachments window.

To replace one attached file with another:

1. At the bottom of the lab record, click **Attachments**.
2. In the **Attachments** window, select the attachment you want to replace and click **Browse**.
3. Navigate to the folder containing the file you want to attach instead, select it, and click **Open**.

   The file name and path of the replacement are inserted into the Attach field.
4. Press the **Tab** key and the CLIA 116 web app inserts the **File Name** and **Date Attached** of the replacement file.

   The Attach field is cleared and the Entry Name stays the same.

More ...

Screen: "Attachments window" on page 312

Updating Exempt Lab Records

When changes to the record of an exempt lab are necessary, you can open the record in Update mode.

Note: Existing lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

Update a Lab Record

You can update exempt or regular (non CLIA-exempt) labs in your state only. Use Inquiry to view other states' labs, exempt or not.

To update the record for an exempt lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed.
3. Update the lab record as needed.

   You must always enter Reason for 116 in Update mode.

   You cannot change App Type Requested. Use the Status Change window to change certificate (application) type.

You cannot change Zip code/City/State if there is a Survey Pending Date for the lab.

4 Click **Save** to save your changes. If you do not want to save the changes, click **Cancel**.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Procedure: "Locate Labs" on page 221
Procedure: "Entering New CMS-116 Applications" on page 224
Screen: "CLIA 116 window" on page 304
Procedure: "Enter Status Changes" on page 246

Change Class Code

You can change class code from 00 Regular (non CLIA-exempt) to 05 Exempt and vice versa (can't set it to 10) for active labs.

Note: To prevent the creation of overlapping certificates, you cannot perform a class code change and a status change for a lab on the same day.

To change class code for a lab:

1 On the **Demographics** tab of the lab record, change **Class Code** from 00 Regular to 05 Exempt, or from 05 Exempt to 00 Regular, as applicable.

2 Click **Save** to save the change.

More ...

Screen: "CLIA 116 window" on page 304

Exempt to Regular (non CLIA-Exempt)

When Class Code is changed from 05 Exempt to 00 Regular, special processing is done to ensure that all information is changed to correctly reflect the new regular (non CLIA-exempt) status. A pending certificate will be created and a 2-year certificate cycle is set.

Regular (non CLIA-Exempt) to Exempt

When Class Code is changed from 00 Regular to 05 Exempt, special processing is done to ensure that all information is changed to correctly reflect the new exempt status.

- If a pending certificate exists, it is updated to reflect the change to exempt. The pending expiration date is set to the date the state's exemption approval ends.

- If no pending certificate exists, it will be created and its expiration date will be set to the date the state's exemption approval ends.

When a lab goes from regular (non CLIA-exempt) to exempt, a billing audit is done to ensure that a lab is refunded any fees paid under the regular certificate that no longer apply. Cleanup is also performed. The billing audit and cleanup are done whether a pending certificate exists or not.

When a Lab Moves to Another State

For an exempt lab that physically relocates from one state to another, the Operating Status of the lab in the original facility record in ACO is set to CLOSED-MOVED. A new facility record with an ACTIVE status for the lab in its new location is automatically created in ACO.

You need to update the lab's physical and mailing address (if applicable) in the CLIA 116 web app. If the lab moved to a non-exempt state, you also need to change the class code.

To update the record for an exempt lab that moves out of state:

1. In the CLIA 116 web app, search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed.
3. On the **Demographics** tab, change the **Class Code** If the lab moved to a non-exempt state.
4. Update the lab's **Physical Address** and **Mailing Address** information.

   You cannot change Zip code/City/State if there is a Survey Pending Date for the lab.
5. Update **Corporate Address** and **Form Mailing** options if necessary.

6 Click **Save** to save your changes.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Procedure: "Locate Labs" on page 221
Screen: "Demographics tab" on page 305
Supporting Materials: "Survey Categories/Types" on page 552
Procedure: "Change Class Code" on page 242

Lab Record Inquiry

The Inquiry function accessed from CLIA 116 Search Results provides a read-only view of lab records for informational purposes. You can view the record for any lab in the national CLIA database.

To view a lab record:

1 Open the CLIA 116 web app.

2 Search the national CLIA database.

3 In the **CLIA 116 Search Results** list, select a lab and click **Inquiry** at the bottom of the window.

-or-

Right-click the lab and select **Inquiry 116**.

The record for the lab is displayed in read-only Inquiry mode.

More ...

Procedure: "Access the 116 Web Application" on page 219
Procedure: "Locate Labs" on page 221
Screen: "CLIA 116 window" on page 304

Certificate and Billing Inquiry

The Cert/Bill Inquiry function, which you can access from the lab record or Status Change window, displays the lab's certificate and billing history in the CLIA Certificate and Billing Inquiry window.

CLIA Certificate Status

Pending - The lab has applied for a new certificate type or a continuing certificate. The current certificate expiration date is more than 30 days in the future and the lab has not yet paid fees for the new or continuing certificate. A pending certificate period depends on application type: 12 months prior to expiration of app type 1 renewals, 6 months prior to expiration for app type 2, 3, and 4 renewals. Pending certificate information is not sent to Medicare or Medicaid.

Current - When the lab has paid the required fees and its current certificate is due to expire within 30 days, its pending certificate becomes the current certificate.

History - This is a certificate the lab held in the past.

Note: When an exempt lab is added, a certificate cycle is created with an effective date equal to the date the record is added and an expiration date equal to the date the state's exemption approval expires.

View Certificate and Billing Information

The Certificate Inquiry section of the CLIA Certificate and Billing Inquiry window displays details about the lab's future (pending), current, and prior (historical) certificates.

The Billing Inquiry section is blank for exempt labs unless there was a time when the lab was regular (non CLIA-exempt).

Note: CLIA fees are not assessed for exempt labs.

To view certificate and billing info for a lab:

➥ Open a lab record in **Update** or **Inquiry** mode and click **Certificate/Billing Inquiry** at the bottom of the window.

-or-

➥ At the bottom of a lab record, click **Status Change**, then click **Cert/Billing** at the bottom of the Status Change window.

More ...

Procedure: "Update a Lab Record" on page 241
Procedure: "Lab Record Inquiry" on page 244
Screen: "CLIA Certificate and Billing Inquiry window" on page 314

Print CLIA 116 Search Results

You can generate the Search Results list in the CLIA 116 web app as a report.

WARNING! Surveyors are strongly cautioned NOT to release this information publicly, to use it carefully and only to assist with your routine regulatory and survey-related duties.

To print CLIA 116 search results:

1. Open the CLIA 116 web app.
2. Search the national CLIA database.
3. Click **Print** at the bottom of the **CLIA 116 Search Results** window.
4. In the **Report Selection** window, click **CLIA Search Results List**.

   The CLIA Search Results List report is generated in PDF format. It lists labs in the order they are displayed in the CLIA 116 Search Results window.

More ...

Procedure: “Access the 116 Web Application” on page 219
Procedure: “Locate Labs” on page 221
Screen: "CLIA 116 Search Results window" on page 302
Screen: "Report Selection window" on page 303
Supporting Materials: “CLIA Search Results List” on page 570

Status Changes

A status change occurs when a lab asks to change its certificate type, usually because the lab has changed the type of tests it performs. The Status Change function is available when the lab’s physical address is in your state. It is unavailable if the lab is terminated.

Note: To prevent the creation of overlapping certificates, you cannot perform a status change and a class code change for a lab on the same day.

Enter Status Changes

Most status changes share the same basic steps. The CLIA 116 web app follows rules for various types of status change and will provide informational messages as necessary when you are processing a status change.

Status changes remain pending until they are processed during the batch program. You can remove a pending status change if necessary.

Within 6 months of Effective Date

If the lab has a current or pending certificate that is within six months of its effective date, you can use a status change to “correct” the certificate type. Corrected certificates retain the original effective date.

If you decide to enter a full status change rather than a correction, the edit checks on the lab record change to those for the new certificate type. If you change certificate type from Waiver to Compliance, you must enter specialties before you can save the record. The CLIA 116 web app will advise you about the date range allowed for the new effective date.

Over 6 months past Effective Date

If the lab's certificate has been in effect for more than six months, any change to the certificate type must be handled as a status change with a new effective date. Depending on the situation, the CLIA 116 web app will either generate the new effective date or let you know the allowable date range. It generally can never be earlier than the current effective date or later than the current expiration date plus one day.

Saving a status change

When you click Save in the Status Change window, you are saving the proposed status change. The CLIA 116 web app generates a warning message that summarizes the details. You have to save the lab record to actually save a status change. The CLIA 116 web app will apply all the edits for the new certificate type. When the lab record is successfully saved, the warning message is retained as an attachment to the record. You can review the message at any time by opening Attachments.

To change the requested application/certificate type:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.
3. As the **Reason for 116** (on the **Demographics tab**), select **02 Change in Certificate Type**.
4. Update **Name** if necessary.
5. On the **Specialties** tab, enter the applicable **Total Annual test volume** as necessary.

   For a status change to application/certificate type 2 Waiver or to 4 PPM, you must enter waived or PPM test volume respectively.
6. At the bottom of the window, click **Status Change**.
7. In the **Status Change section**, answer **Yes** to **Is this a correction?** if you want to "correct" the certificate type.

   The lab must have a current or pending certificate within six months of its Effective Date. If corrections are not allowed, you will receive a message.
8. Select the **New App Type**.

   You will receive a message if the lab director has to be qualified for the new application/certificate type.

9 Enter the **New Eff Date** as applicable.

The CLIA 116 web app will either generate the new effective date or tell you the allowable date range.

10 Click **Save**.

If you entered a status change rather than a correction and the new effective date is within six months of the current effective date, a message indicates the lab will be assessed new fees. Click **OK** to continue.

The CLIA 116 web app provides a warning message that summarizes details of the proposed status change including the new application type and effective date, when the current certificate ends, and information about the billing process.

11 Click **OK** in the warning message to save the details of the proposed status change.

WARNING! The status change itself is not saved yet.

12 For a status change to 3 Accreditation, go to the **Accred Org Info** tab and specify an affiliated AO.

13 To save the status change, click **Save** at the bottom of the lab record.

The warning summary is retained as an attachment to the lab record. You can review it at any time from the Attachments window.

The expiration date of the new certificate cycle equals the date the state's exemption approval expires.

Note: CLIA fees are not assessed for exempt labs.

More ...

Procedure: "Locate Labs" on page 221
Screen: "Demographics tab" on page 305
Screen: "Specialties tab" on page 307
Screen: "Status Change window" on page 315
Procedure: "View Attachments" on page 240

Row= Notation

A ROW= notation is added whenever there is a status change. This can be useful to the Help Desk if there is an error, so it is a good idea to note it. Each row in the system table represents a particular situation.

In the rare event that ROW=UNKNOWN appears, it means the CLIA 116 web app could not find a row that matches your situation. In this case, the change is not saved and you should contact the Help Desk.

Reverse Pending Status Changes

Status changes remain pending until they are processed during the batch program. You can remove a status change while it is pending, i.e., it is listed as New (see graphic).

Figure 41: Pending status change

To reverse a pending status change:

1. To remove a status change while it is pending, click **Status Change** at the bottom of the lab record.

   A message tells you a status change is pending and briefly details the specifics of the change.

2. Click **OK** to indicate you want to remove the pending status change.
3. Click **OK** in the confirmation message to remove the pending status change.

Note: If you remove a pending status change to 3 Accreditation, you must also remove the affiliated AO.

Termination and Reactivation

Both terminations and reactivations are entered in the Termination window. As is generally the case in the CLIA 116 web app, the fields that are enabled depend on the situation and your user type and permissions.

Terminate an Exempt Lab

The conditions under which you perform terminations vary a good deal. Most terminations share the same basic steps. The CLIA 116 web app follows rules for terminations in various circumstances and activates fields as necessary when processing a termination.

To terminate a lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.

5 In the **Termination** window, select the appropriate **Term Code** from the list.

Note: Exempt users cannot select termination codes 80 (Awaiting State Approval), 33 (Accreditation not Confirmed), 99 (Do Not Reactivate Without Checking with RO), and 08 (Non-Payment of Fees).

Termination Date is now enabled.

Note: If you select 13 Multiple to Single Site Certificate, then Cross Reference Provider Number on the Additional Info tab will be required.

6 For **Termination Date**, enter the expiration date for the lab.

7 Click **Save** to save the details of the termination and close the Termination window.

WARNING! The termination is not saved yet.

8 To save the termination, click **Save** at the bottom of the lab record.

When a laboratory is terminated, any multiple site location with a Status of Active will remain Active.

Note: AO information for Accredited labs is removed after 6 months of termination.

More ...

Procedure: “Locate Labs” on page 221
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Supporting Materials: “Termination/Reactivation Scenarios” on page 535

Terminating Labs with Specialties

When you terminate a Compliance or Accredited lab that has specialties, the 116 specialties will be read-only until the termination is processed, at which point they are deleted. Waived/PPM test volume values are set to null.

Survey specialties are closed out and no longer appear on the Specialties tab except in Specialty History. The expiration date for survey specialties is set to the termination date you enter for the certificate. The schedule code and Waived/PPM test volume values are set to null. You can still view these prior survey specialties:

➥ In the CLIA 116 web app, select the **Specialty History** button on the **Specialties** tab.

-or-

➥ In ACO, right-click the facility in the tree and select **Specialties**.

Note: If you reactivate a lab without a gap, the CLIA 116 web app reopens the lab's survey specialties and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

Reactivate a Terminated Exempt Lab

You can reactivate a lab with or without a gap depending primarily on whether it has been more or less than 6 months since the termination date. The CLIA 116 web app calculates the 6 month cutoff date by adding 6 months to the termination date. If the resulting date is invalid (February 30, for instance), it goes back to the first valid date (February 28).

There are many rules governing the reactivation of terminated labs. The CLIA 116 web app looks at the days since termination, certificate type and status, and activates fields as needed. It also either generates the new effective date for you or advises you of appropriate date ranges.

Reactivate a Lab with a Gap

If it has been less than six months since the termination date, the lab can be reactivated with a gap, except for Accredited labs with AO confirmation. If it has been more than six months since the termination date, the system forces a gap in the certificate period, regardless of certificate type.

If a gap in the certificate cycle is chosen or forced, you can select either a different certificate (application) type in the Gap App Type field, or the same type the lab held previously. If it has been more than six months since the lab was terminated, all other fields are disabled. After you save the Termination window, then save the lab record, the system sets the pending effective date to today's date.

If it has been less than six months since the lab was terminated, enter the date that will start the new certificate period in the Gap Eff Date field. The current certificate remains terminated, and the termination code appears in certificate history.

If you select a new certificate (application) type, the lab record must pass all edits for that certificate type to be saved successfully. If you change the application type from Waiver to Compliance, at least one specialty and test volume must be selected on the Specialties tab.

To reactivate a lab with a gap in certificate cycles:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.

5 For **Term Code**, select **00 Active Provider**.

6 As appropriate, set **Gap?** to **Yes**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.

7 As appropriate, enter the **Gap Effective Date**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date. In that case, the Gap Effective Date should not be later than 6 months from today. The termination code for the pending certificate is set to 00 and the pending effective date is set to this date.

8 As appropriate, select **Gap App Type**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.

9 Enter information on the **Accred Org Info** and **Specialties** tabs as appropriate.

Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

10 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate Labs" on page 221
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Reactivate a Lab without a Gap

If there is no gap in the certificate cycle, the reactivated lab cannot change certificate (application) type. The system re-opens the former certificate and retains the original certificate effective date (*except* for a lab with a current and pending certificate reactivated with a fake gap after more than 6 months).

Note: If you reactivate an Accredited lab with AO confirmation within 6 months, you must reactivate it without a gap.

To reactivate a lab without a gap in certificate cycles:

1 Search the national CLIA database for the lab.

2 In the **CLIA 116 Search Results** list, select the lab.

3 As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.

4 Click **Termination** at the bottom of the window.

5 For **Term Code**, select **00 Active Provider**.

6 As appropriate, set **Gap?** to **No**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate, and there is no gap between the current expiration date and the pending effective date.

7 As appropriate, select **Gap App Type**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate more than 6 months after the current expiration date, and there is no apparent gap between the current expiration date and the pending effective date. This is known as a fake gap.

In that case, select the lab's previous application type. The termination code for the pending certificate is set to 00 and the pending effective date is set to today.

8 As needed, enter information on the **Accred Org Info** and **Specialties** tabs.

For example, when you reactivate a lab without a gap, the CLIA 116 web app reopens the lab's survey specialties that were closed during termination and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

9 Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

10 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate Labs" on page 221
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Row= Notation

A ROW= notation is added whenever a termination or reactivation is done. This can be useful to the Help Desk if there is an error, so it is a good idea to note it. Each row in the system table represents a particular situation.

In the rare event that ROW=UNKNOWN appears, it means the CLIA 116 web app could not find a row that matches your situation. In this case, the termination or reactivation is not saved and you should contact the Help Desk.

View Audit History

The Audit History window is available from all tabs and gives a complete history of changes made to values of audited fields. The header provides general information about the lab record. The fields in each section vary, but always include:

- Date/time of each change
- ID of user who made the change
- Old and/or current value

To view the audit history for a lab record:

➥ Open a lab record in **Update** or **Inquiry** mode and click **Audit History** at the bottom of the window.

The Audit History window opens. All audited fields are listed. If no changes have been made, the field is blank. If values have changed, they are listed in reverse chronological order with the original value at the bottom and the current value at the top.

More ...

Screen: "Audit History window" on page 313
Procedure: “Updating Exempt Lab Records” on page 241
Procedure: “Lab Record Inquiry” on page 244

Audit History - Physical Address example

This example shows the audit history for a lab’s physical address.

Physical Address

Date of Change	User ID	Address 1	Address 2	City	State	Zip	Ext	County
Current	N/A	MAIN STREET SUITE 180		COLORADO SPRINGS	CO	80909		200
03/22/2007 19:17	H35V	MAIN STREET SUITE #180						
04/01/2005 18:33	W28K	402 WEST STREET						

Figure 42: Physical Address section

The value of Address 1 under Physical Address has changed twice. The original value was 402 West Street. On 04/01/2005 (April 1, 2005) at 18:33 (6:33 p.m.), a user whose ID was W28K changed it to Main Street Suite #180. On 03/22/2007 (March 22, 2007) at 19:17 (7:17 p.m.), a user whose ID was H35V changed it to Main Street Suite 180 (deleted # before 180), which is the Current value.

Audit History - AO Information examples

In the AO Information section, AOs are sorted numerically by Accreditation Code and data is listed chronologically in descending order, starting with the X-match (first entry of an AO for a laboratory) to provide a full history of changes.

Audit information for all AOs currently sponsoring the laboratory is shown at the top of the AO Information section with the word Current for Date of Change and time and N/A for User ID. Historical information follows.

For any laboratory where the X-match was entered prior to ASPEN 11.3, there will be no audit history for the X-match. All auditing will begin with the first change after the X-match, either Y-match confirmation or remarks code entry.

In the following example, X-match was audited for TJC (01) but not CAP (04), because the X-match was entered before the ASPEN 11.3 release.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01				
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 43: AO Information section

Here is the audit history after a Y-match was entered for TJC.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01	Y	04/17/2018		
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 44: AO Information after Y-match entered

Then a remarks code was entered for TJC.

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01	Y	04/17/2018	31	04/17/2018
Current	N/A	04	Y	04/10/2013		
2018-04-17 14:47:12	HELP DESK,HELP DESK	01	Y	04/17/2018	31	04/17/2018
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 45: AO Information after remarks code entered

All AO Information deleted in the cleanup process is audited with the user ID of CLAB in order to accurately track where the removal occurred. Historical information follows in AO code order.

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	04	Y	04/10/2013		
2018-04-18 14:27:50	CLAB	01				
2018-04-17 14:47:12	HELP DESK,HELP DESK	01	Y	04/17/2018	31	04/17/2018
2018-04-17 14:43:46	HELP DESK,HELP DESK	01	Y	04/17/2018		
2018-04-17 14:41:05	HELP DESK,HELP DESK	01				
2013-04-10 20:02:59	ARCK,LINDA	04	Y	04/10/2013		

Figure 46: AO Information after cleanup

Audit History - AO Survey Dates examples

The AO Survey Dates section lists dates of AO surveys in descending chronological order grouped by AO code. Information from audited records includes:

- Date of change - add date for surveys created in ASPEN 11.3 and later, survey date for pre-11.3 surveys
- User who made the change
- AO survey date

All surveys listed on the Accred Org Info tab of the 116 (up to four) are included in the top "current" section; Date of Change is Current and User ID is N/A. The four current surveys are also listed in the "history" section below the current section, but with Date of Change and User ID specified. Any surveys with dates prior to the four current surveys are displayed in the history section below the current surveys.

The example below shows the audit history for a lab with five recorded AO surveys.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date
Current	N/A	04	02/02/2016
Current	N/A	04	04/09/2014
Current	N/A	04	02/06/2013
Current	N/A	04	02/04/2011
02/02/2016 00:00	UACR	04	02/02/2016
04/09/2014 00:00	UACR	04	04/09/2014
02/06/2013 00:00	UACR	04	02/06/2013
02/04/2011 00:00	UACR	04	02/04/2011
02/04/2009 00:00	UACR	04	02/04/2009

Figure 47: AO Survey Dates section

When an AO adds a survey with a date at least one year after the latest current AO survey date, it is added to both the current and history lists. When the fourth oldest AO survey becomes the fifth oldest, it will be removed from the current list, but will remain on the history list. These two points are illustrated below.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date	
Current	N/A	04	04/15/2018	new survey
Current	N/A	04	02/02/2016	
Current	N/A	04	04/09/2014	
Current	N/A	04	02/06/2013	
04/18/2018 15:08	HELP DESK,HELP DESK	04	04/15/2018	new survey
02/02/2016 00:00	UACR	04	02/02/2016	
04/09/2014 00:00	UACR	04	04/09/2014	
02/06/2013 00:00	UACR	04	02/06/2013	
02/04/2011 00:00	UACR	04	02/04/2011	no longer current
02/04/2009 00:00	UACR	04	02/04/2009	

Figure 48: AO Survey Dates - survey added 1 year+ later, 5th oldest survey not current

When an AO changes a survey date within one year of entering the original date, both survey dates are included in the history list as separate entries. The current list will show only the new date.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date	
Current	N/A	04	04/17/2018	new date
Current	N/A	04	02/02/2016	
Current	N/A	04	04/09/2014	
Current	N/A	04	02/06/2013	
04/18/2018 15:59	HELP DESK,HELP DESK	04	04/17/2018	new date
04/18/2018 15:29	HELP DESK,HELP DESK	04	04/15/2018	original date
02/02/2016 00:00	UACR	04	02/02/2016	
04/09/2014 00:00	UACR	04	04/09/2014	
02/06/2013 00:00	UACR	04	02/06/2013	
02/04/2011 00:00	UACR	04	02/04/2011	
02/04/2009 00:00	UACR	04	02/04/2009	

Figure 49: AO Survey Dates - survey date changed within one year

When an AO no longer sponsors the lab, the system deletes all surveys for that AO during cleanup. There will be no current surveys listed for the AO, but the deleted surveys still appear in the history section.

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date
04/18/2018 15:59	HELP DESK,HELP DESK	04	04/17/2018
04/18/2018 15:29	HELP DESK,HELP DESK	04	04/15/2018
02/02/2016 00:00	UACR	04	02/02/2016
04/09/2014 00:00	UACR	04	04/09/2014
02/06/2013 00:00	UACR	04	02/06/2013
02/04/2011 00:00	UACR	04	02/04/2011
02/04/2009 00:00	UACR	04	02/04/2009

Figure 50: AO Survey Dates after cleanup

System Information

The System Information window displays current QIES and ASPEN system information. It indicates any state databases or providers set to read-only due to overnight processing errors, and displays messages posted about system status or processing errors. It also provides access to batch billing job logs (audit files).

To view system information:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **System Information**.

   Current system information and a list of batch billing job logs from the past week are displayed.
3. In the **Batch Jobs** section, enter **From Date** and **To Date** to specify the date range you want and click **Find** to update the list of audit files.
4. In the **View Audit Messages** column, click **View** for the audit file you want to view.

   It opens in a text editor, which you can close when you are done.
5. To print the contents of the System Information window, click the **Print** button.
6. To close the System Information window and return to the Select Application window, click **Done**.

More ...

Procedure: “Access the 116 Web Application” on page 219, steps 1-5
Screen: "ASPEN Web CLIA - Select Application window" on page 299
Screen: "System Information window" on page 316

CLIA 116: VA

The CLIA 116 web application runs in a web browser (Internet Explorer) over the CMS intranet. It directly accesses the national CLIA database. Veterans Affairs users see only VA labs. With the appropriate permissions, you can:

- Add VA labs
- Enter new CMS-116 application data for VA labs
- View and enter 116 specialties for VA labs
- View and update survey specialties for VA labs
- Update VA lab records
- Terminate and reactivate VA labs

Access the CLIA 116 Web Application

You will generally open ASPEN Web CLIA in a browser to access the 116 web application (web app). To open ASPEN Web CLIA, you need to know the URL for the ASPEN Access page and have a current national system login.

To access the CLIA 116 web app:

1. Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen
2. Click the **ASPEN Web** link.
3. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.
4. Click **OK** in the startup warning message to continue.

   ASPEN Web opens and the Select Application window appears.
5. Select **CLIA**.

   ASPEN Web CLIA opens and the Select Application window appears.
6. In the **Select Application** window, click **116 Application** (the only option).

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

116 Data Validation

The CLIA 116 web app validates data and informs you if there are validation errors when you go from one tab to another or save a lab record. Validation errors occur when you don't provide required data, or provide invalid data.

Required Fields

Required fields are marked with an asterisk (*).

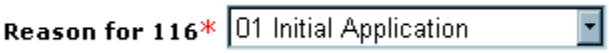


Figure 51: Required field

The CLIA 116 web app checks to see that data is entered in all required fields on a tab when you go to another tab or save a lab record. If required data is missing or invalid, you will receive validation error messages.

Some fields are required only under certain conditions. Those fields may not be marked with an asterisk, but if you try to save a lab record without completing conditionally required fields, you will receive error messages.

Tab Validation

If the CLIA 116 web app finds validation errors when you go to another tab, it lets you know. You can choose OK to override until you save the lab record, or Cancel to go back to the original tab and correct any problems. Field-specific error messages are displayed in red on the tab. There may not be messages for all fields with errors.

Lab Record Validation

Whenever you save a lab record, all data validation edits are applied. If validation errors are found, the system identifies the tabs that have errors. You can either cancel all data entry you have done, or go to the tabs that contain errors and correct them. Field-specific error messages are displayed in red on the applicable tabs. There may not be messages for all fields with errors. You need to correct all errors, explicitly identified or not, and save the record again.

When you save a lab record, an Add or Update transaction record is created and processed overnight. Errors occasionally occur in the nightly processing. In that case, the lab records involved will be read-only until the errors are resolved. If a lab record is read-only, check the top (header) of the record for an upload failure message.

Adding VA Lab Records

To create a record for a VA lab in the national CLIA database, you enter application data from the CMS-116 form into the CLIA 116 web app. When the application is accepted, a new VA lab record is generated and downloaded to the applicable state ACO database during nightly processing.

Note: You can add new lab records at any time. There is no restriction due to batch processing as there is for updating records.

Locate VA Labs

A comprehensive set of search criteria is available in the CLIA 116 Find window, enabling you to quickly locate existing VA labs in the national CLIA database. You also *must* use the search function to verify that a lab you are planning to add is not already in the system.

You can specify criteria that make the search as broad or narrow as you need. For example, a broad search specifying a major city and the area code portion of a phone number would return all labs in the city with that area code. Generally, the narrower (more specific) the search, the quicker you will find the lab you want.

The CLIA 116 web app supports single site and multiple site searches. It searches the entire national database, but for VA users it returns only VA labs, i.e., labs with Class Code = 10 VA.

To search for a VA lab:

1. Open the CLIA 116 web app.
2. In the **CLIA 116 Find** window, enter any combination of search criteria.

   You can enter all or part of any search element (e.g., all or part of a CLIA #), and use the % (percent) character as a wildcard.

   If you do not specify State or Zip, the search will be nationwide.

   Note: You cannot search by laboratory director (Director Last Name, Director First Name fields) or Federal Tax ID.

3. If you don’t want to include terminated labs in the search, select **Exclude Terminated Laboratories**.

   The search will return only Active and Pending labs.

4 To run the search, click **Find Now**.

All labs that meet your search criteria are displayed in the CLIA 116 Search Results window.

More ...

Procedure: “Access the CLIA 116 Web Application” on page 259
Procedure: “Multiple Sites Searches” just below
Procedure: “Partial Text and Wildcard Searches” below
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302

Multiple Sites Searches

A Multiple Sites Search must include the lab Name or at least one of the Physical Address fields in the search criteria. Search results list all lab sites, including the primary, that match your search criteria.

Until full detail is entered in the CLIA 116 web app for VA labs with multiple sites, you will be limited in the criteria you can specify for multiple sites searches. To identify labs with multiple sites for which detail has not been entered, you can run the Number of Sites Mismatch report.

➥ To locate all sites for a lab, enter the search criteria including **Name** or at least one **Physical Address** element, select the **Multiple Sites Search** checkbox, and click **Find Now**.

More ...

Procedure: “Locate VA Labs” on page 261
Procedure: “Partial Text and Wildcard Searches” (just below)
Screen: "CLIA 116 Find window" on page 301
Screen: "CLIA 116 Search Results window" on page 302
Supporting Materials: “No. of Sites Mismatch” on page 562

Partial Text and Wildcard Searches

When you search for a lab, you can enter just a part of any search element e.g., part of a lab Name and CLIA #. You can use the percent sign (%) as a wildcard in your partial search text, whether it’s alphabetic, numeric, or both.

No wildcard

If you don’t include a wildcard, the CLIA 116 web app finds all items that start with the search text.

➥ Type **BU** to find all items that begin with BU, like **Bu**ckley and **Bu**ena; or type **23** to return all items beginning with 23, such as **23**7711.

Wildcard at start

If you place the % character at the start of the search text, the CLIA 116 web app finds all items that include the search text anywhere.

➥ Type **%BU** to find items like **Bu**ckley, **Bu**ena, and Am**bu**lance; or type **%23**, to return items like **23**7711 and 461**23**6.

Wildcard between characters

If you place the % character between two characters in the search text, the CLIA 116 web app finds items that contain the two characters in the order you typed them, but allows other characters to occur between them.

➥ Type **B%U** to find **Bu**ckley, **Bu**ena, and Am**bu**lance, and also **B**ertho**u**d, **B**e**u**lah, and **B**aca Co**u**nty; or type **2%3** to return **23**7711, 461**23**6, and 3**2**987**3**.

Add VA Lab Records

To add a record for a VA lab to the national CLIA database, you enter data in the CLIA 116 web app from the CMS-116 application submitted by the lab. You must first do a search–by lab name at least–to verify that a record for the lab doesn't already exist. For the lab's application to be accepted, you must enter all required data and it must pass validation checks.

When a VA lab is added, a certificate cycle is created with an effective date equal to the date the record is added and an expiration date equal to the date the state's exemption approval expires.

Note: You can add new lab records at any time. There is no restriction due to batch processing as there is for updating records.

To add a VA lab to the database:

1. Search the national CLIA database for the lab you want to add, to make sure it isn't already in the database.
2. If the lab isn't listed in the CLIA 116 Search Results window, click the **Add** button at the bottom.

   A new lab record opens in Add mode with the Demographics tab selected. Some fields may already be populated based on what you entered in the CLIA 116 Find window.

   For a new lab record, the CLIA 116 web app will warn you if it found a duplicate address, phone number, or Federal Tax ID in another lab record. You can choose to continue or cancel.

3 Create the lab record by entering data from the hardcopy CLIA application, the CMS-116 form, submitted by the lab and click **Save** when you are done.

If the application is accepted, i.e., there are no data validation errors, a message tells you what the system-generated provider (CLIA) number is for the lab. This is entered as the CLIA # when you return to the CLIA 116 Find window.

An Add transaction for the lab is created and processed overnight, and the new lab record is downloaded to the applicable state database (ACO).

Note: International labs are discussed in a separate section.

More ...

Procedure: "Locate VA Labs" on page 261
Procedure: "Entering New CMS-116 Applications" (just below)
Screen: "CLIA 116 window" on page 304

Entering New CMS-116 Applications

The CLIA 116 web app screens closely follow the layout of the printed CLIA application form, the CMS-116. The information you provide in the CLIA 116 web app depends on lab (application) type. The tab structure of the CLIA 116 web app screens allows you to skip areas that may not apply. Fields that don't apply do not appear, or are disabled.

Note: CLIA fees are not assessed for VA labs.

Enter Demographics Information

The Demographics tab replicates sections I, II, III and IV of the hardcopy CMS-116. The information captured here includes basic application and identification information for the lab, lab director identity, and the lab's testing schedule.

To enter basic information about a VA lab:

1 Go to the **Demographics** tab of the lab record.

General Information

2 Select the applicable **Reason for 116**.

Initial Application the default for new labs.

3 Select the **App Type Requested**.

This is the certificate (application) type requested by the lab. Fields are enabled or disabled according to the selected type. If you change App Type Requested on a new lab record and have already entered data that is invalid for the new type, you will receive an error message. The invalid data must be replaced or removed before you can change the application type.

4 Enter the **State Agency Received Date**.

This is the date the hardcopy CMS-116 was actually received.

5 Enter identifying information for the lab: **Name**, contact **Email Address**, **Fed Tax ID**, **Phone** and **Fax** numbers.

Enter only numeric characters for the Federal tax ID, and phone and fax numbers. The system will format the phone and fax numbers as needed.

6 **Class Code** is automatically set to **10 VA**.

10 VA is the class for Veterans Affairs labs.

Director Information

7 Enter the lab director's **Last Name**, **First** name, and middle initial (**M.I.**)

The First name and M.I. fields are not enabled until you enter something in the Last Name field.

8 Select the lab director's **Title** and salutation (**Sal**). If you choose 17 Other for Title, enter the applicable position title in the **Other** text field.

Other is enabled only if 17 Other is selected for Title.

WARNING! Do not include duplicate title information in the Last Name and Title fields.

9 Physical Address

10 Enter the lab's physical address, i.e., the location where tests are performed. Type the **Street** address and **Zip** code.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

Note: International labs are discussed in a separate section.

Mailing Address (if different than physical address)

11 Enter the lab's mailing address: type the **Street** address and **Zip** code and select the **City** if necessary.

State is system-generated based on Zip code.

Corporate Address

12 Enter the **Street** address and **Zip** code of the corporate entity that owns the lab; select the **City** if necessary.

Form Mailing

13 Choose whether to send bills and certificates to the lab's Physical or Corporate address.

Type of Laboratory

14 Select the applicable option. If you choose 29 Other as Type, enter the applicable lab type in the Other text field. Other is enabled only if 29 Other is selected for Type of Laboratory.

Hours of Laboratory Testing

15 Specify the lab's testing schedule: enter **FROM** and **TO** hours for each day the lab is open. If it is always open, click the **24x7** button and the hours are automatically filled in.

More ...

Screen: "Demographics tab" on page 305.

Identify Multiple Sites

The Multiple Sites tab replicates section V of the hardcopy CMS-116. A separate record in the CLIA 116 web app is required for each of a lab's locations with the following exceptions.

- Temporary Testing Sites

  The lab moves from testing site to testing site, e.g., mobile units, health screening fairs.

- Non-profit, Federal, State or Local Government Labs

  The lab performs 15 or fewer different tests, including waived. None of the tests is of high complexity.

- Hospital-based Labs

  The labs are all located within a hospital in contiguous buildings on the same campus and under common direction.

If a lab's multiple testing sites or separate locations qualify for the Multiple Sites exception provision, you use the Multiple Sites tab to provide information about them. Multiple sites all have the same CLIA number as the primary lab, which is included in the count of multiple sites.

To enter information about a lab's multiple sites:

1 Go to the **Multiple Sites** tab of the lab record.

General Information

2 Select **Yes** for **Multiple Sites** if the lab has multiple locations and they qualify for a multiple sites exception.

When the Multiple Sites field is initially marked Yes, the primary (current) lab is automatically entered as the first multiple site.

3 For **Number of Sites**, enter the number reported by the lab on the CMS-116.

Active Sites Entered displays a read-only count of active additional sites (Status is Active).

When the Multiple Sites field is initially marked Yes, Number of Sites is set to 2 and Active Sites is set to 1.

Exceptions

4 Indicate whether any Multiple Site exception applies:

Lab with temporary testing sites?

Non-profit, Federal, state or local government lab?

Hospital with several labs at the same address?

Multiple Sites

5 In the **Multiple Sites section**, select **Active** to view only active lab sites, or **All** to view all lab sites including moved and removed labs.

6 **Add**, **Modify**, or **Remove** labs in the Multiple Sites list as needed.

Note: If you change the Multiple Sites field to No after adding multiple sites, all active sites are removed. Moved and removed sites remain in the list.

More ...

Procedure: "Add a Site" (just below)
Procedure: "Update a Site" on page 268
Procedure: "Remove a Site" on page 269
Screen: "Multiple Sites tab" on page 305

Add a Site

To enter detailed information about each of a lab's multiple sites, use the Add button on the Multiple Sites tab.

To add a site:

1 In the **Multiple Sites section** of the **Multiple Sites tab**, click **Add**.

-or-

Right-click in the list and select **Add Site**.

The Add button is not enabled if No is selected in the Multiple Sites field. Number of Sites must be at least the number of Active Sites Entered +1 before you can add a site.

2 Enter the **Name**, **Street** address, **Zip** code, **Phone** number, and **NPI** (National Provider Identifier) of the additional lab site.

City and **County** are system-generated based on Zip code. When the Zip code covers more than one city or county, select the appropriate one from the list.

State is also system-generated based on Zip code.

3 Select the **Status** of the additional site.

ID is a system-generated sequence number. It indicates the order in which additional sites were added.

4 In the **Tests Performed/Specialties** text box, describe **Tests Performed** at the site and its **Specialties**.

5 Click **Save** to save the information and add the site to the Multiple Sites list.

Note: When a laboratory is terminated, any multiple site locations with a Status of Active will remain Active.

More ...

Screen: "Add/Modify Site window" on page 306

Update a Site

Use the Update button on the Multiple Sites tab to correct information in existing multiple site records.

To update site information:

1 In the **Multiple Sites section** of the **Multiple Sites tab**, select a site and click **Modify**.

-or-

Right-click a site and select **Modify Site**.

2 Make changes as needed.

For the primary site, you can only make changes to Tests Performed/Specialties text. To change basic demographic information about the primary lab site, go to the Demographics tab.

Note: If the physical address of a laboratory changes from one state to another, the Status for a lab's Active multiple sites changes automatically to Moved. The Status Date will be set to the current date.

More ...

Screen: "Add/Modify Site window" on page 306
Procedure: "Enter Demographics Information" on page 264

Remove a Site

If a lab reports it is no longer testing at a site, you can remove the applicable multiple site record. You cannot remove the primary site.

To remove a site:

➥ In the **Multiple Sites section** of the **Multiple Sites tab**, select a site and click **Remove**.

-or-

➥ Right-click a site and select **Remove Site**.

The Status of the site changes to Removed. If you are displaying only active sites, the removed site disappears from the Multiple Sites list.

TIP: You can also change Status to Removed through the Update function, or directly on the grid.

To include removed sites in the **Multiple Sites section**, select the **All** radio button.

Enter Accreditation Information

The Accred Org Info tab replicates section II of the hardcopy CMS-116. It also displays information not on the form, such as AO Confirmed (Y-match) and Remarks.

If a lab chooses to be accredited, it can designate more than one AO for CLIA purposes, i.e., enter more than one X-match, but only one AO can accredit each specialty or subspecialty. The lab will receive a Certificate of Accreditation after the AO surveys the lab and confirms that the lab is in compliance, i.e., enters a Y-match. The compliance effective date becomes the effective date for the Certificate of Accreditation and sets the 2-year accreditation cycle.

Add an AO (X-match)

When you add an Accredited lab (app type 3), you need to select at least one accrediting organization on the Accred Org Info tab in order to save the record.

To add an AO:

1. Go to the **Accred Org Info** tab of the lab record.
2. In the **Accrediting Organization Affiliations** section, click **Add**.

   A new row is added to the list of AOs.
3. Select the appropriate Accred Org (accrediting organization).

   You cannot add an AO here more than once.

More ...

Screen: "Accred Org Info tab" on page 306

Delete an AO

To delete an AO:

1. Go to the **Accred Org Info** tab of the lab record.
2. In the **Accrediting Organization Affiliations** section, select an AO and click **Delete**.

   The AO is marked for removal (crossed out). All fields in the row are immediately disabled and the row is removed when the lab record is saved.

More ...

Screen: "Accred Org Info tab" on page 306

Specialty Information

The Specialties tab both replicates sections VI, VII, and VIII of the CMS-116 form and captures survey specialties data. The 116 specialties are those the lab has included on the CMS-116, which you enter on the Specialties tab of the lab record. The survey specialties are those entered on the 1557 Specialties tab in the ACO certification kit. They reflect what surveyors determined the lab's specialties to be.

View and Enter Specialty Information

The Specialties tab for Accredited VA labs contains the Schedule Codes, Specialty Source, Total Annual test volume and Sub-specialty sections. You can enter, modify, and delete 116 specialties and update, delete, and close out survey specialties. You can also optionally update Waived/PPM survey specialty test volume.

To view or enter specialty information for an Accredited VA lab:

1. Go to the Specialties tab of the lab record.

Schedule Codes

Schedule codes are system-generated and read-only.

Specialty Source

2. To display 116 specialty data in the Sub-specialty grid, select **116 Specialties**. To display current survey specialty data, select **Survey Specialties**. To display survey specialty history for an Accredited VA lab, select **Specialty History**.

   116 Specialties is the default, except for AO users. Last Update Date (of 116 or survey specialties depending on selected source) is system-generated and read-only.

Total Annual test volume

3 Optionally enter the number of **All Waived Tests** and **All PPM Tests** performed annually, as applicable.

When test volume is not required but the field is enabled, you can enter a test volume, or enter 0 and select No Testing if the checkbox is enabled.

Sub-specialties

4 In the Sub-specialty grid, depending on the selected Specialty Source:

- Enter, modify, and delete 116 specialties
- Update, delete, and close out survey specialties
- View survey specialty history

More ...

Screen: "Specialties tab" on page 307
Fields: "Total Annual test volume", on page 407
Procedure: “View and Enter 116 Specialties” just below
Procedure: “View and Update Survey Specialties” on page 272

View and Enter 116 Specialties

Depending on your user class and permissions, you can view and enter 116 specialties for Accredited VA labs in the Sub-specialty grid. 116 specialty information is what a lab includes on the CMS-116 it submits.

To view and enter 116 specialties for an Accredited VA lab:

1 Go to the **Specialties** tab of the lab record.

2 Be sure **Specialty Source** is **116 Specialties**.

116 specialty information includes the Accrediting Org for each selected sub-specialty (must be an X-match), and Test Volume for selected specialty groups.

3 Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.

4 Select the **Accrediting Org** for each sub-specialty.

The options in the drop-down list are the AOs entered on the Accred Org Info tab, i.e., X-matches.

5 Enter the annual **Test Volume** for each selected specialty group.

This should be the total test volume for the sub-specialties selected in a specialty group.

Total Annual Test Volume is calculated by the system.

More ...

Screen: "Specialties tab" on page 307

Delete 116 Specialties

When an existing Accredited VA lab with active 116 specialties stops offering a specific specialty, you can delete it.

To delete a 116 specialty:

1. Go to the **Specialties** tab of the lab record.
2. Be sure **Specialty Source** is **116 Specialties**.
3. In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

   The deleted specialty is highlighted in red for the rest of the session.
4. Adjust the applicable **Test Volume** as necessary.

   If you delete all sub-specialties under a specialty, the Test Volume field is cleared and disabled.

Note: After you save a lab record, data for all deleted specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

View and Update Survey Specialties

You can view and update survey specialties for Accredited VA labs in the Sub-specialty grid. Survey specialties are entered on the 1557 Specialties tab in ACO certification kits. You cannot enter them in new lab records in the CLIA 116 web app.

The survey specialty data shown on the Specialties tab is drawn from a lab's most recent certification kit. It does not include specialty data gathered from a lab prior to performing a status change.

To view and update survey specialties for an Accredited VA lab:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Survey Specialties**.

   You will see the Accrediting Org for each selected sub-specialty (must be a Y-match), the Effective Date, and the Expiration Date (only if a specialty has been closed out).
3. Select the checkbox next to each **Sub-specialty** test that the lab performs. For **010 Histocompatability**, also select **Transplant** or **Non Transplant**, or neither, as appropriate.

4. Select the **Accrediting Org** for each sub-specialty.

   The options in the drop-down list are the AOs entered on the Accred Org Info tab, i.e., X-matches.

5. Enter the **Effective Date** for each selected sub-specialty.
6. Enter the annual **Test Volume** (at the bottom of the window) for each AO.

   Total Annual Test Volume for all AOs is calculated by the system.

More ...

Screen: "Specialties tab" on page 307

Delete Active Survey Specialties

Survey specialties are usually deleted on the 1557 Specialties tab in the applicable certification kit in ACO. However, you can delete active survey specialties for Accredited VA labs in the CLIA 116 web app if necessary. To delete a survey specialty, you simply deselect it on the Specialties tab.

To delete a survey specialty:

1. Go to the Specialties tab of the lab record.
2. For **Specialty Source**, choose **Survey Specialties**.
3. In the **Sub-specialty grid**, clear the checkbox for the specialty you want to delete and choose **OK** in the confirmation message.

   The deleted specialty is highlighted in red for the rest of the session.

More ...

Screen: "Specialties tab" on page 307

Close Out Survey Specialties

Closing out a survey specialty is not the same thing as deleting it. To close out a specialty, you must enter an expiration date for it.

Survey specialties are usually closed out on the 1557 Specialties tab in the applicable certification kit in ACO. However, you can close out survey specialties for Accredited VA labs on the Specialties tab in the CLIA 116 web app if necessary.

To close out a survey specialty:

➥ Enter its **Expiration Date** in the **Sub-specialty grid**.

Note: After you save a lab record, data for all deleted and closed out specialties is removed from the Sub-specialty grid.

More ...

Screen: "Specialties tab" on page 307

View Survey Specialty History

You can view a complete read-only history of survey specialties for Accredited VA labs.

To view survey specialty history:

1. Go to the **Specialties** tab of the lab record.
2. For **Specialty Source**, choose **Specialty History**.

   The survey specialty history for the lab is displayed in an unlabeled section below Total Annual test volume.

Enter Additional Information

On the Additional Info tab, you can enter supplementary information about a VA lab such as:

- Lab Director Affiliations

  If the director of a VA laboratory serves as the director for other labs that are separately certified, you can specify those affiliations on the Additional Info tab. An individual can serve as the director for up to five non-Waiver labs–any combination of PPM, Compliance, or Accredited–and an unlimited number of Waiver labs.
- Type of Control

  This is the type of organization that operates the lab.
- Application Signature Date

  This is the date the application was received.
- Cyto PT (Proficiency Testing)

  This section has details about Cyto PT enrollment for VA labs that are approved for cytology testing (630 spec code).

To enter additional information about the lab:

1. Go to the **Additional Info** tab of the lab record.

Director Affiliations

2. Enter the **CLIA number** of an affiliated lab (must be active) and click **Insert Affiliated Lab**, or use the **Find** function and select the applicable lab in the search results.

   The lab is added to the list of affiliations. There is no limit on the number of affiliations you can enter, but only 8 are uploaded. There is currently no edit check to confirm that the affiliated lab you select actually has the same director.

   Note: The Find Affiliated Providers window works just like the CLIA 116 Find window.

Other

3. Select **Type of Control** from the list. If you select **03 Other** or **09 Other Government**, enter the applicable control type in the **Other** text field.
4. Enter the **Application Signature Date**.

   This date is required if the Reason for 116 is Initial Application or Survey.
5. Enter the **Cross Reference Provider Number**, i.e., the CLIA number previously assigned to a lab holding a multiple site certificate.

   This field is required when the termination code for the lab is 13 Multiple to Single Site Certificate.
6. Enter the **Clia Medicare Number** assigned to the lab.
7. The **Federal Jurisdiction** field is disabled.
8. Four read-only CASPER Inquiry fields display:
   - Date the certification kit was successfully uploaded to CASPER (national reporting system).
   - Date the kit passed ASPEN upload edits.
   - Determination Approval date entered by the RO.
   - Whether the certification kit requires RO review.

Cyto PT Enrollment

This section is relevant only for Accredited VA labs that are approved for cytology testing (630 specialty code). The information is set by national batch jobs when they generate Cyto PT letters and is read-only.

More ...

Screen: "Additional Info tab" on page 308
Procedure: “Locate VA Labs” on page 261

Updating VA Lab Records

When changes to the record of a VA lab are necessary, you can open the record in Update mode. You can update VA labs only. Use Inquiry to view non-VA labs.

Note: Existing lab records are read-only daily (including weekends) between 10PM ET and 4AM ET.

To update the record for a VA lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab and click **Update** at the bottom of the window.

   -or-

   Right-click the lab and select **Update 116**.

   -or-

   Double-click the lab.

   The record for the lab is displayed.
3. Update the lab record as needed.

   You must always enter Reason for 116 in Update mode. You cannot change App Type Requested or Class Code.
4. Click **Save** to save your changes. If don't want to save the changes, click **Cancel**.

More ...

Procedure: "Locate VA Labs" on page 261
Procedure: "Entering New CMS-116 Applications" on page 264
Screen: "CLIA 116 window" on page 304

Lab Record Inquiry

The Inquiry function accessed from CLIA 116 Search Results provides a read-only view of lab records for informational purposes. You can view the record for any lab in the national CLIA database.

To view a lab record:

1. Open the CLIA 116 web app.
2. Search the national CLIA database.

3 In the **CLIA 116 Search Results** list, select a lab and click **Inquiry** at the bottom of the window.

-or-

Right-click the lab and select **Inquiry 116**.

The record for the lab is displayed in read-only Inquiry mode.

More ...

Procedure: “Access the CLIA 116 Web Application” on page 259
Procedure: “Locate VA Labs” on page 261
Screen: "CLIA 116 window" on page 304

Print CLIA 116 Search Results

You can generate the Search Results list in the CLIA 116 web app as a report.

WARNING! Surveyors are strongly cautioned NOT to release this information publicly, to use it carefully and only to assist with your routine regulatory and survey-related duties.

To print CLIA 116 search results:

1 Open the CLIA 116 web app.

2 Search the national CLIA database.

3 Click **Print** at the bottom of the **CLIA 116 Search Results** window.

4 In the **Report Selection** window, click **CLIA Search Results List**.

The CLIA Search Results List report is generated in PDF format. It lists labs in the order they are displayed in the CLIA 116 Search Results window.

Note: The Search Results list and the report include only VA labs.

More ...

Procedure: “Access the CLIA 116 Web Application” on page 259
Procedure: “Locate VA Labs” on page 261
Screen: "CLIA 116 Search Results window" on page 302
Screen: "Report Selection window" on page 303
Supporting Materials: “CLIA Search Results List” on page 570

Termination and Reactivation

Both terminations and reactivations are entered in the Termination window. As is generally the case in the CLIA 116 web app, the fields that are enabled depend on the situation and your user type and permissions. As a VA user, you can terminate and reactivate only VA labs.

Terminate a VA Lab

The conditions under which you perform terminations vary a good deal. Most terminations share the same basic steps. The CLIA 116 web app "knows" the rules for terminations in various circumstances and activates fields as necessary when you are processing a termination.

When a lab has been terminated more than six months, the cleanup program clears certificate information. The assigned termination code can be changed for a cleaned-up lab.

To terminate a VA lab:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.
5. In the **Termination** window, select the appropriate **Term Code** from the list.

   Note: VA users cannot select termination codes 80 (Awaiting State Approval), 33 (Accreditation not Confirmed), 99 (Do Not Reactivate Without Checking with RO), and 08 (Non-Payment of Fees).

   Termination Date is now enabled.

   Note: If you select 13 Multiple to Single Site Certificate, then Cross Reference Provider Number on the Additional Info tab will be required.

6. For **Termination Date**, enter the expiration date for the lab.
7. Click **Save** to save the details of the termination and close the Termination window.

   WARNING! The termination is not saved yet.

8 To save the termination, click **Save** at the bottom of the lab record.

When a laboratory is terminated, any multiple site location with a Status of Active will remain Active.

Note: AO information for Accredited labs is removed after 6 months of termination.

More ...

Procedure: “Locate VA Labs” on page 261
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Supporting Materials: “Termination/Reactivation Scenarios” on page 535

Terminating Labs with Specialties

When you terminate an Accredited lab that has specialties, the 116 specialties will be read-only until the termination is processed, at which point they are deleted. Waived/PPM test volume values are set to null.

Survey specialties are closed out and no longer appear on the Specialties tab except in Specialty History. The expiration date for survey specialties is set to the termination date you enter for the certificate. The schedule code and Waived/PPM test volume values are set to null.

You can still view these prior survey specialties:

➥ In the CLIA 116 web app, select the **Specialty History** button on the **Specialties** tab.

-or-

➥ In ACO, right-click the facility in the tree and select **Specialties**.

Note: If you reactivate a lab without a gap, the CLIA 116 web app reopens the lab’s survey specialties and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

Reactivate a Terminated VA Lab

You can reactivate a lab with or without a gap depending primarily on whether it has been more or less than 6 months since the termination date. The CLIA 116 web app calculates the 6 month cutoff date by adding 6 months to the termination date. If the resulting date is invalid (February 30, for instance), it goes back to the first valid date (February 28).

There are many rules governing the reactivation of terminated labs. The CLIA 116 web app looks at the days since termination, certificate type and status, and activates fields as needed. It also either generates the new effective date for you or advises you of appropriate date ranges.

For labs terminated more than six months and past the certificate expiration date, the cleanup program has already cleared certificate information.

Reactivate a Lab with a Gap

Accredited labs cannot have a gap when reactivated within six months. If it has been more than six months since the termination date, the reactivated lab must have a gap in the certificate period.

If the situation calls for a gap in the certificate cycle, you can select a new certificate (application) type. If it’s been more than six months since the lab was terminated, all other fields are disabled. After you save the Termination window, then save the lab record, the system sets the pending effective date to today’s date.

If it’s been less than six months since the lab was terminated, enter the date that will start the new certificate period in the Gap Eff Date field. The current certificate remains terminated, and the termination code appears in certificate history.

Note: VA labs are all certificate (application) type 3 by choice.

To reactivate a lab with a gap in certificate cycles:

1. Search the national CLIA database for the lab.
2. In the **CLIA 116 Search Results** list, select the lab.
3. As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.
4. Click **Termination** at the bottom of the window.
5. For **Term Code**, select **00 Active Provider**.
6. As appropriate, set **Gap?** to **Yes**.

   This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.

7 As appropriate, enter the **Gap Effective Date**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date. In that case, the Gap Effective Date should not be later than 6 months from today. The termination code for the pending certificate is set to 00 and the pending effective date is set to this date.

8 As appropriate, select **Gap App Type**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current certificate within 6 months of the current expiration date.

9 Enter information on the **Accred Org Info** and **Specialties** tabs.

10 Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

11 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate VA Labs" on page 261
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Reactivate a Lab without a Gap

If there is no gap in the certificate cycle, the reactivated lab cannot change certificate (application) type. The system re-opens the former certificate and retains the original certificate effective date (*except* for a lab with a current and pending certificate reactivated with a fake gap after more than 6 months).

Note: If you reactivate an Accredited lab with AO confirmation within 6 months, you must reactivate it without a gap.

To reactivate a lab without a gap in certificate cycles:

1 Search the national CLIA database for the lab.

2 In the **CLIA 116 Search Results** list, select the lab.

3 As the **Reason for 116** (on the **Demographics** tab), select **04 Other Changes**.

4 Click **Termination** at the bottom of the window.

5 For **Term Code**, select **00 Active Provider**.

6 As appropriate, set **Gap?** to **No**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate, and there is no gap between the current expiration date and the pending effective date.

7 As appropriate, select **Gap App Type**.

This field is enabled only as rules permit. For example, it is enabled if you reactivate a lab with a current and pending certificate more than 6 months after the current expiration date, and there is no apparent gap between the current expiration date and the pending effective date. This is known as a fake gap.

In that case, select the lab's previous application type. The termination code for the pending certificate is set to 00 and the pending effective date is set to today.

8 As needed, enter information on the **Accred Org Info** and **Specialties** tabs.

For example, when you reactivate a lab without a gap, the CLIA 116 web app reopens the lab's survey specialties that were closed during termination and restores them on the Specialties tab. You will have to re-enter the 116 specialties.

9 Click **Save** to save the details of the reactivation and close the Termination window.

WARNING! The reactivation is not saved yet.

10 To save the reactivation, click **Save** at the bottom of the lab record.

More ...

Procedure: "Locate VA Labs" on page 261
Screen: "Demographics tab" on page 305
Screen: "Termination window" on page 315
Screen: "Accred Org Info tab" on page 306
Screen: "Specialties tab" on page 307

Row= Notation

A ROW= notation is added whenever a termination or reactivation is done. This can be useful to the Help Desk if there is an error, so it's a good idea to note it. Each row in the system table represents a particular situation.

In the rare event that ROW=UNKNOWN appears, it means the CLIA 116 web app could not find a row that matches your situation. In this case, the termination or reactivation is not saved and you should contact the Help Desk.

System Information

The System Information window displays current QIES and ASPEN system information. It indicates any state databases or providers set to read-only due to overnight processing errors, and displays messages posted about system status or processing errors. It also provides access to batch billing job logs (audit files).

To view system information:

1. Open **ASPEN Web CLIA**.
2. On the **Select Application** window, click **System Information**.

   Current system information and a list of batch billing job logs from the past week are displayed.
3. In the **Batch Jobs** section, enter **From Date** and **To Date** to specify the date range you want and click **Find** to update the list of audit files.
4. in the **View Audit Messages** column, click **View** for the audit file you want to view.

   It opens in a text editor, which you can close when you are done.
5. To print the contents of the System Information window, click the **Print** button.
6. To close the System Information window and return to the Select Application window, click **Done**.

More ...

Procedure: “Access the CLIA 116 Web Application” on page 259, steps 1-5
Screen: "ASPEN Web CLIA - Select Application window" on page 299
Screen: "System Information window" on page 316

Browse Accounts

The Browse Accounts module in ASPEN Web CLIA lets you locate and review CLIA accounting information.

Note: For complete information about the online billing modules of ASPEN Web CLIA, see the *CLIA Accounting Procedures Guide*, which is posted at https://qtso.cms.gov.

Access Browse Accounts

CLIA users must have a current national system login in order to open ASPEN Web CLIA and access Browse Accounts. There are two ways to do this:

- From within ACO
- From a browser, most likely Internet Explorer

Note: Your ASPEN coordinator defines application access permissions for staff members. If you have difficulty logging in, contact your coordinator. For information and procedures related to creating and maintaining personnel records in ASPEN, including CLIA-specific details, refer to the latest version of the *ACO Procedures Guide*, which is posted at https://qtso.cms.gov.

Open ASPEN Web CLIA from ACO/ARO

To open ASPEN Web CLIA, you need to have a current national system login.

To open ASPEN Web CLIA from ACO/ARO:

1. Click the **CLIA** button in the ACO/ARO toolbar:

Figure 52: CLIA button in the ACO/ARO toolbar

2. In the **Login** window, enter your national **User ID** and **Password** and click **Login**.

3 Click **OK** in the startup warning message to continue.

ASPEN Web opens and the Select Application window appears.

4 Select **CLIA**.

ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

Note: If you open ASPEN Web CLIA from ACO, then close ACO, ASPEN Web CLIA will shut down too.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

Open ASPEN Web CLIA from a Browser

To open ASPEN Web CLIA from your browser, you need to know the URL for the ASPEN Access page and have a current national system login.

To open ASPEN Web CLIA in your browser:

1 Enter the **URL** for the **ASPEN Access** page: https://web.qiesnet.org/aspen

2 Click the **ASPEN Web** link.

3 In the **Login** window, enter your national **User ID** and **Password** and click **Login**.

4 Click **OK** in the startup warning message to continue.

ASPEN Web opens and the Select Application window appears.

5 Select **CLIA**.

ASPEN Web CLIA opens and the Select Application window appears; available options are specific to your user type.

More ...

Screen: "Login window" on page 298
Screen: "ASPEN Web - Select Application window" on page 298
Screen: "ASPEN Web CLIA - Select Application window" on page 299

Open Browse Accounts

Depending on user type and permissions, the ASPEN Web CLIA - Select Application window includes a Browse Accounts option.

To open Browse Accounts:

➥ In the ASPEN Web CLIA - **Select Application** window, click **Browse Accounts**.

The Browse Accounts window opens.

More ...

Screen: "ASPEN Web CLIA - Select Application window" on page 299
Screen: "Browse Accounts window" on page 317

Locate and View Accounts

You can use Browse Accounts to search for CLIA accounting records by provider number or lockbox criteria, but not both simultaneously.

Locate Accounts by Provider

You can use the Provider Search section of the Browse Accounts window to search accounting records by provider number for up to three labs. ASPEN Web CLIA locates accounting records for the labs and displays the information on the read-only Certificates and Billing Inquiry window.

The following users can view the read-only Certificates and Billing Inquiry window for laboratories in all states:

- SA - Full Access
- SA - Read-Only
- RO - Full Access
- RO - Read-Only
- CO - Full Access
- CO - Read-Only

Note: When you perform a Provider Search, any Lockbox Search criteria also entered are ignored.

To locate accounting information by provider:

1. Open the **Browse Accounts** window.
2. In the **Provider Search** section, enter up to 3 valid CLIA provider numbers (**Provider #1-3**).

   A message is displayed if a number is not valid.
3. If you do not know a provider's CLIA number, click **116 Lookup** next to the Provider field to search for the provider and get the number.
4. Click **Find Provider** to locate account information for the specified labs and display it in the Certificates and Billing Inquiry window.

Note: With the migration of OSCAR/CLIA accounting functions to ASPEN Web CLIA, the billing category descriptions in the Certificates and Billing Inquiry window were updated.

More ...

Procedure: “Access Browse Accounts” on page 285
Screen: "Browse Accounts window" on page 317
Procedure: “116 Lookup” on page 290
Screen: "Certificates and Billing Inquiry window" on page 320
Supporting Materials: “Billing Category Descriptions” on page 533

Locate Accounts by Lockbox

To locate accounting information based on lockbox data, you use the Lockbox Search section of the Browse Accounts window. Lockbox search criteria include process date, batch number, item number, and check number.

ASPEN Web CLIA locates accounting records that meet the specified criteria and displays the read-only information in the Lockbox Inquiry window. By default, all accounting records are searched, but an option lets you limit the search to unresolved accounting records.

The following users can view the read-only Lockbox Inquiry window for laboratories in all states:

- SA - Full Access
- SA - Read-Only
- RO - Full Access
- RO - Read-Only
- CO - Full Access
- CO - Read-Only

Note: When you perform a Lockbox Search, any provider numbers entered in the Provider Search section of Browse Accounts are ignored.

To locate accounting information by lockbox:

1. Open the **Browse Accounts** window.
2. In the **Lockbox Search** section of the Browse Accounts window, enter one or more search criteria: **Lockbox Process Date** or date range, **Batch** number, **Item** number, and **Check #**.

   You must always enter a Lockbox Process Date or date range.
3. To search only unresolved accounting records, select **Show unresolved Only**.

   A message is displayed if the search criteria you specify are invalid. For example:

   - A Lockbox Process Date in the future is not allowed.
   - If you enter a Lockbox Process Date range, you must also enter a Check # and/or select Show unresolved Only.
4. Click **Find Lockbox** to locate accounting information that matches your criteria and display it in the Lockbox Inquiry window.

More ...

Procedure: “Access Browse Accounts” on page 285
Screen: "Browse Accounts window" on page 317

Open Lockbox Inquiry from Certificates and Billing Inquiry

You can open the Lockbox Inquiry window by selecting a payment record in the Certificates and Billing Inquiry window.

To open Lockbox Inquiry from Certificates and Billing Inquiry:

1. Open the **Certificates and Billing Inquiry** window and select a payment record in the **Billing Inquiry** section.
2. Click the **Lockbox Inquiry** button.
3. In the **Inquire By** window, choose to search lockbox records by **Process Date**, **Batch #**, or **Item #**.

   The values shown for these options are copied from the payment record you selected. You can choose only one option.

4 Click **Inquire** to search lockbox records and display matching records in the Lockbox Inquiry window.

A search by Process Date returns all lockbox records with that process date. Batch # returns all records with that process date and batch number. Item # returns all records with that process date, batch number, and item number.

5 Click **Exit** to return to the **Certificates and Billing Inquiry** window.

More ...

Procedure: “Locate Accounts by Provider” on page 287
Screen: "Certificates and Billing Inquiry window" on page 320
Screen: "Inquire By window" on page 321

Open Certificates and Billing Inquiry from Lockbox Inquiry

You can open the Certificates and Billing Inquiry window from a payment record selected in the Lockbox Inquiry window.

To open Certificates and Billing Inquiry from Lockbox Inquiry:

1 Open the **Lockbox Inquiry** window, select a payment record, and click the **Certificate/Billing Inquiry** button.

The Certificates and Billing Inquiry window for the CLIA lab associated with the selected payment record opens up.

2 Click **Exit** to return to the **Lockbox Inquiry** window.

More ...

Procedure: “Locate Accounts by Lockbox” on page 288
Screen: "Inquire By window" on page 321
Screen: "Certificates and Billing Inquiry window" on page 320

116 Lookup

To search accounting records by provider number, you must enter the CLIA provider number for one or more laboratories in the Provider Search section of the Browse Accounts window. If you do not have a lab’s CLIA number on hand, you can use the 116 Lookup function to search CLIA 116 forms in the database and return the provider number for the selected lab to Browse Accounts.

To use 116 Lookup to locate a provider number:

1 In the **Provider Search** section of the **Browse Accounts** window, click the **116 Lookup** button next to the **Provider #** field.

The Find Accounting Providers window opens. It has the same fields as the CLIA 116 Find window.

2 Enter your search criteria and click **Find Now**.

ASPEN Web CLIA searches the CLIA 116 forms in the database and opens the Find Accounting Providers window, which displays a list of the laboratories matching your search criteria.

3 Choose the row in the results list with the lab whose CLIA number you need, and click **Select**, or simply double-click the row/provider.

ASPEN Web CLIA enters the CLIA # from the selected lab's 116 record into the applicable Provider # field in Browse Accounts.

More ...

Screen: "Browse Accounts window" on page 317
Screen: "Find Accounting Providers window" on page 318
Screen: "Accounting Providers Find Results window" on page 319

Access Accounting Audit History

From Browse Accounts, authorized CLIA users can search for an audit trail of CLIA accounting transactions by lockbox. Search criteria include process date, batch number, item number, and check number.The Audit Inquiry window displays applicable accounting records based on search criteria entered.

Accounting transactions include:

- Cash applied
- Overpayment processed
- Money refunded
- Money moved to Unresolved
- Unresolved record deleted
- Payment canceled or deleted

Audit data includes:

- What changes were made
- When changes were made
- Who made the changes

To locate accounting audit history by lockbox:

1 Open the **Browse Accounts** window.

2 In the **Audit Search** section of the Browse Accounts window, enter one or more search criteria: **Lockbox Process Date**, **Batch** number, **Item** number, and **Check #**.

You must always enter a Lockbox Process Date.

A message is displayed if the search criteria you specify are invalid. For example, a Lockbox Process Date in the future is not allowed.

3 Click **Find Lockbox** to locate accounting audit information that matches your criteria and display it in the Audit Inquiry window.

More ...

Procedure: “Access Browse Accounts” on page 285
Screen: "Browse Accounts window" on page 317
Screen: "Audit Inquiry window" on page 322

Access Lab Records (116 Forms)

From the Certificates and Billing Inquiry window, opened directly or through the Lockbox Inquiry window, you can open a read-only copy of the CLIA 116 form for the lab on the active tab.

To open a read-only 116 from Certificates and Billing Inquiry:

1 Open the **Certificates and Billing Inquiry** window and select the **116 Detail** button at the bottom of the window.

The CLIA 116 web app opens and displays the lab record (CLIA 116 form) in Inquiry (read-only) mode for the provider on the active tab of the Certificates and Billing Inquiry window.

2 Click **Exit** to return to the **Certificates and Billing Inquiry** window.

Note: If you click the Certificate/Billing Inquiry button, it opens the CLIA Certificate and Billing Inquiry window in the CLIA 116 web app. It does not return you to the Certificates and Billing Inquiry window. The two windows contain similar, but not identical information.

More ...

Procedure: “Locate Accounts by Provider” on page 287
Procedure: “Open Certificates and Billing Inquiry from Lockbox Inquiry” on page 290
Screen: "Certificates and Billing Inquiry window" on page 320

Print Billing Inquiry Windows

Print the Certificates and Billing Inquiry window

The Print option in the Certificates and Billing Inquiry window prints a hard (paper) copy of all certificate and billing information for the laboratory on the active tab. Information you must scroll to view in the window is included in the printed version.

➥ To print the contents of the active tab in the Certificates and Billing Inquiry window, simply click the **Print** button at the bottom.

Print the Lockbox Inquiry window

The Print option in the Lockbox Inquiry window prints the contents on all pages of the Lockbox Inquiry window in PDF format.

To print the Lockbox Inquiry window:

1. Click the **Print** button at the bottom of the window.

   ASPEN Web CLIA generates a report in PDF format that captures all the content in the Lockbox Inquiry window.
2. To view the report, click **Open** in the **File Download** window, or click **Save** to save the report file.
3. To print a hard copy of the report, use the **Print** function in your PDF viewer.

Print the Audit Inquiry window

The Print option in the Audit Inquiry window prints a hard (paper) copy of the displayed accounting audit history.

➥ To print the contents of the Audit Inquiry window, simply click the **Print** button at the bottom.

Generate Fee Coupons

The following users can issue fee coupons:

- RO - Full Access
- CO - Super User
- Billing Contractor

To generate a fee coupon for a provider:

1. Open the **Certificates and Billing Inquiry** window for the provider.

   The lab must be active or terminated with termination code 08 (Non-Payment of Fees), non-exempt, and have an amount outstanding on a fee that was previously sent.

2. In the **Billing Inquiry** section, select a row with an outstanding Billing Amt and click the **Generate Fee Coupon** button at the bottom of the window.

   The button is enabled for billing records with a payment status code of 08 (fee sent), i.e., the fee was sent, but hasn't been paid.

3. Answer **OK** to the prompt to generate the fee coupon.

   The system indicates the fee coupon processing was successful.

4. Answer **OK** to the prompt.

   The system audits off the current billing record and creates a new fee. It adds a new billing item at the top of the Billing Inquiry section. The following Saturday, the fee will be included in the file sent to the Billing Contractor, who will resend the fee.

More ...

Procedure: "Locate Accounts by Provider" on page 287
Screen: "Certificates and Billing Inquiry window" on page 320

View Batch Bill Files

Central Office and Billing Contractor users can open the CLIA Billing Extract application from the ASPEN Web CLIA - Select Application window to view output files from the batch billing jobs that ASPEN runs.

The following procedure summarizes use of the Batch Bill Files function. For details, refer to the *CLIA Billing Extract User's Guide*.

To view batch bill files:

1. Open **ASPEN Web CLIA**.
2. In the **Select Application** window, click the **Batch Bill Files** button.

   The CLIA Billing Extract application opens.

3. Specify the **To Extract Date** and **Prior Days** number.
4. Click **Refresh** to update the list of extracted files.
5. Click the **Download** button for a file to download and view it in a separate window.

6 To close the CLIA Billing Extract application, select **Logout** at the top of the screen.

You are returned to the Login screen.

More ...

Supporting Materials: “Batch Billing Jobs” on page 572
Procedure: “Open ASPEN Web CLIA from a Browser” on page 286
Screen: "Login window" on page 298

CLIA Screens

This chapter contains pictures and brief descriptions of screens you will encounter when working in the CLIA 116 web app and with CLIA lab records and certification kits in ACO. They are grouped as follows: CLIA 116 web app screens, facility properties screens, certification kit screens, other certification-related windows, survey and other windows.

If you are viewing this document online, take advantage of the hyperlinks. You can click the cross-reference at the top of each graphic to jump to detailed descriptions of the fields in that section of window, as shown in the example below (page number may not be current).

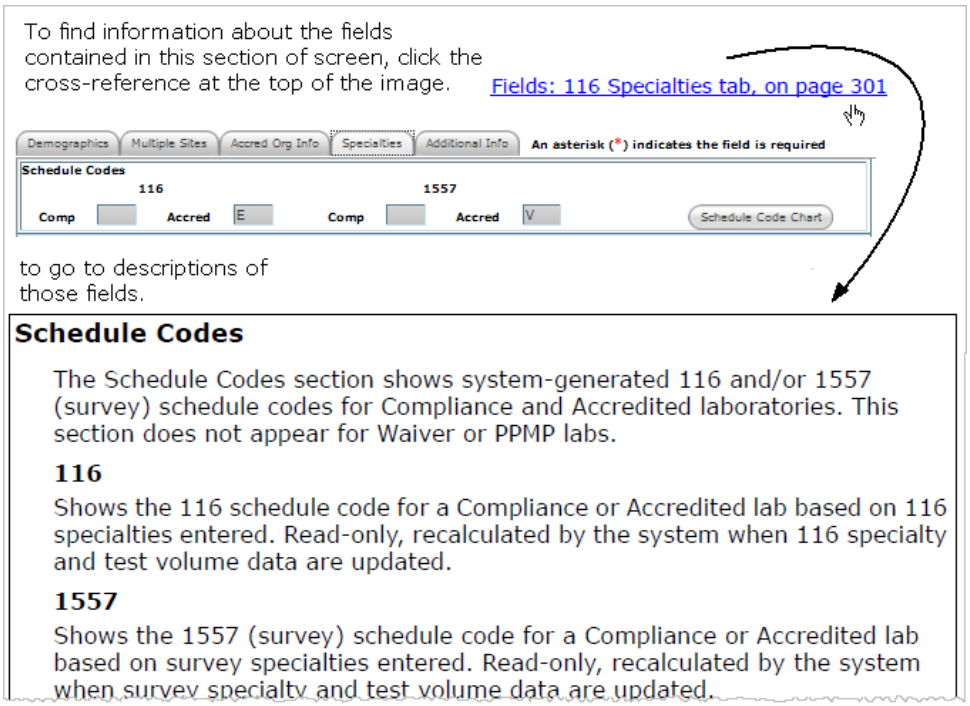


Figure 53: Cross-reference from screenshot to field descriptions

ASPEN Web CLIA Startup

You can access ASPEN Web CLIA from various entry points. Some users will select the CLIA button on the ACO toolbar, others will enter from the ASPEN Access web page. In any case, the next step is to enter your national system login.

Login window

Enter your national User ID and Password, and click Login to open the ASPEN Web - Select Application window.

Fields: "Login window", on page 437

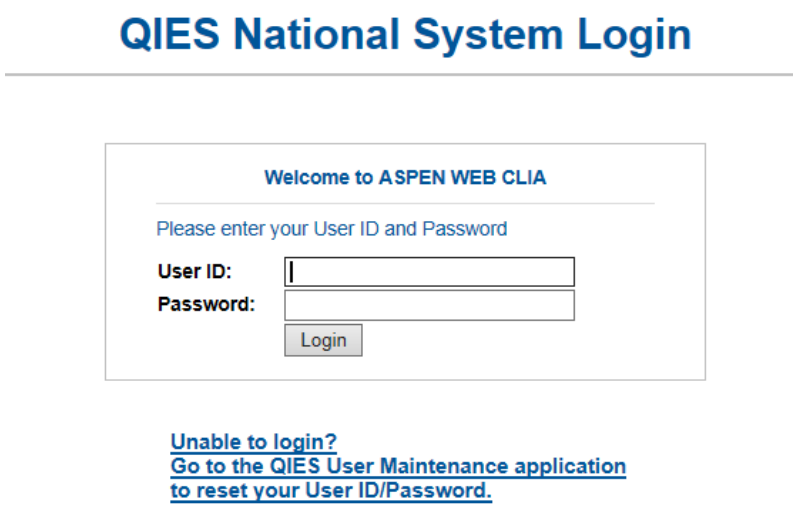


Figure 54: ASPEN Web CLIA Login window

ASPEN Web - Select Application window

Depending on your role, you can open the ASPEN Web CLIA or CLIA Maintenance - Select Application window from here.

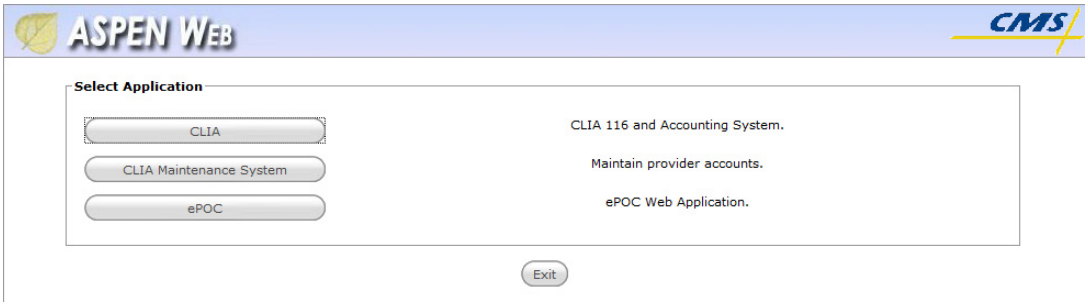


Figure 55: ASPEN Web - Select Application window

ASPEN Web CLIA - Select Application window

The following window appears after you log in to ASPEN Web on the web browser or click the CLIA button on the ACO toolbar, and select CLIA from the ASPEN Web - Select Application window. The options that appear, i.e., the applications/functions you can select, depend on your security access level.

For example, a CO Super User sees a full set of options:

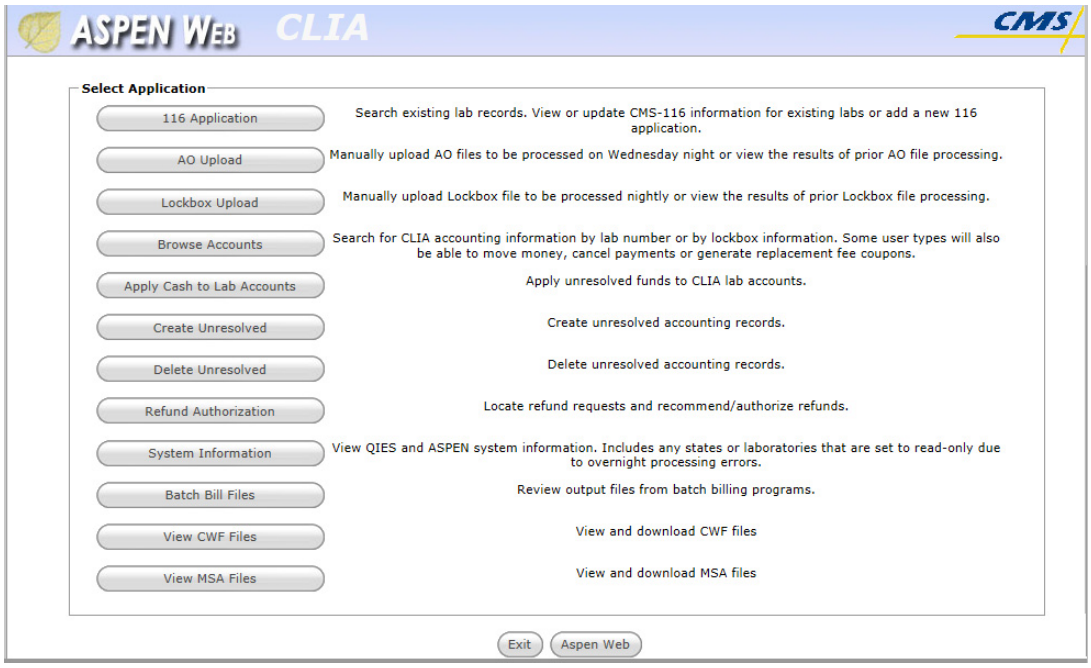


Figure 56: Select Application window–CO Super User

An SA user with Full Access sees three options:

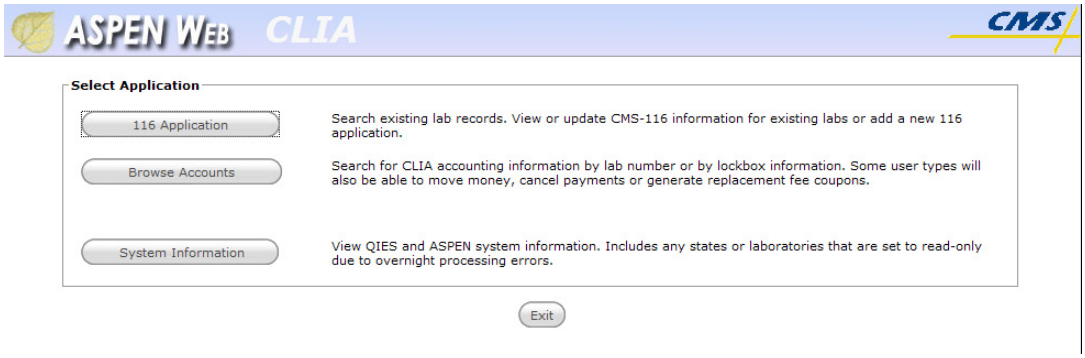


Figure 57: Select Application window–SA Full Access

ASPEN Web CLIA Maintenance - Select Application window

This window appears after you log in to ASPEN Web on the web browser or click the CLIA button on the ACO toolbar, and select CLIA Maintenance System from the ASPEN Web - Select Application window. The options that appear, i.e., the applications/functions you can access, depend on your security access level.

For example, a CO Super User sees a full set of options:

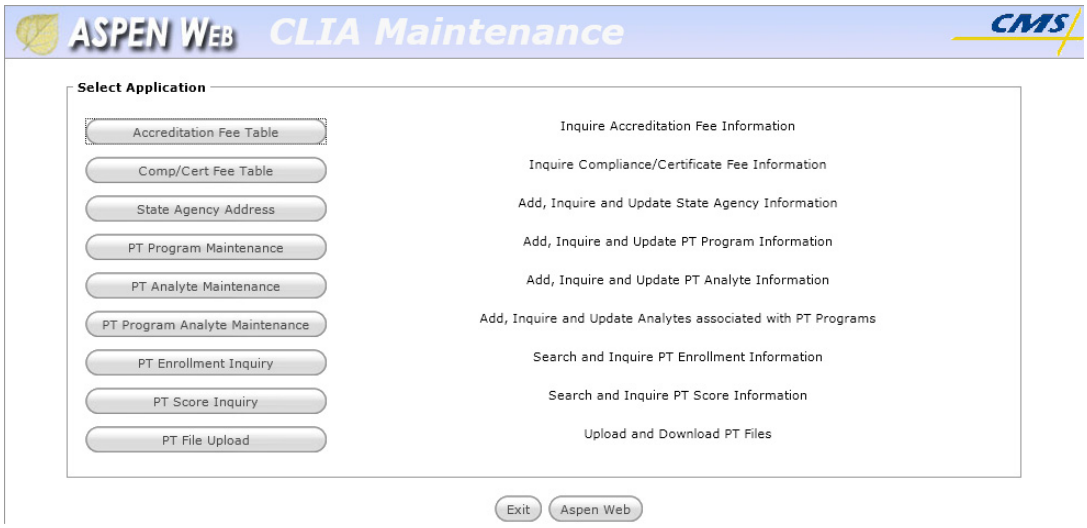


Figure 58: CLIA Maintenance menu - CO Super User window

An SA user with Full Access sees five options:

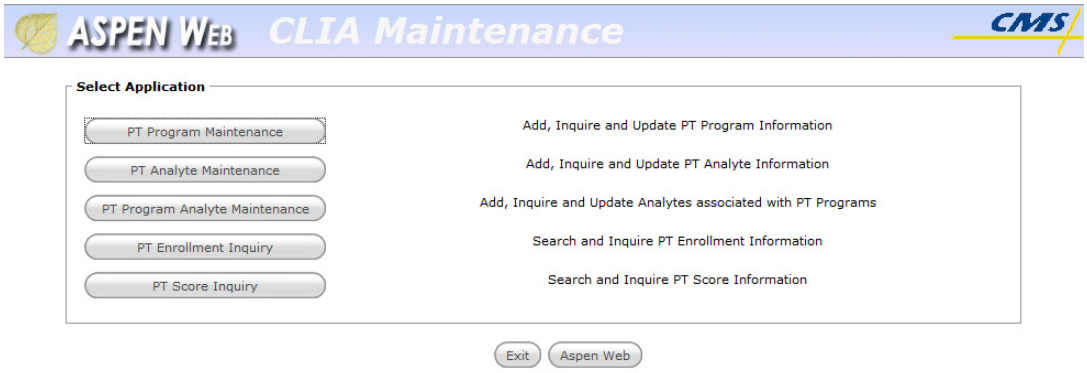


Figure 59: CLIA Maintenance menu - SA Full Access User window

CLIA 116 Web Application

CLIA 116 Find window

The CLIA 116 Find window lets you search the database for labs. You can specify any combination of search criteria.

Note: All alpha text appears in the field as uppercase.

Fields: "CLIA 116 Find window", on page 387

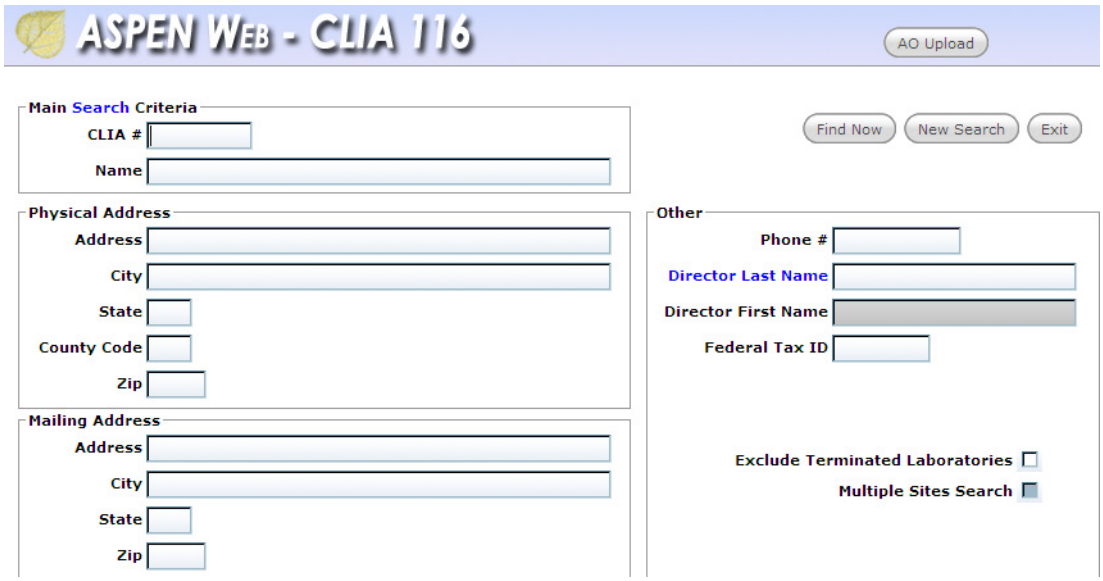


Figure 60: CLIA 116 Find window

CLIA 116 Search Results window

This window displays a list of the laboratories that match the search criteria entered in the CLIA 116 Find window.

Fields: "CLIA 116 Search Results window", on page 389

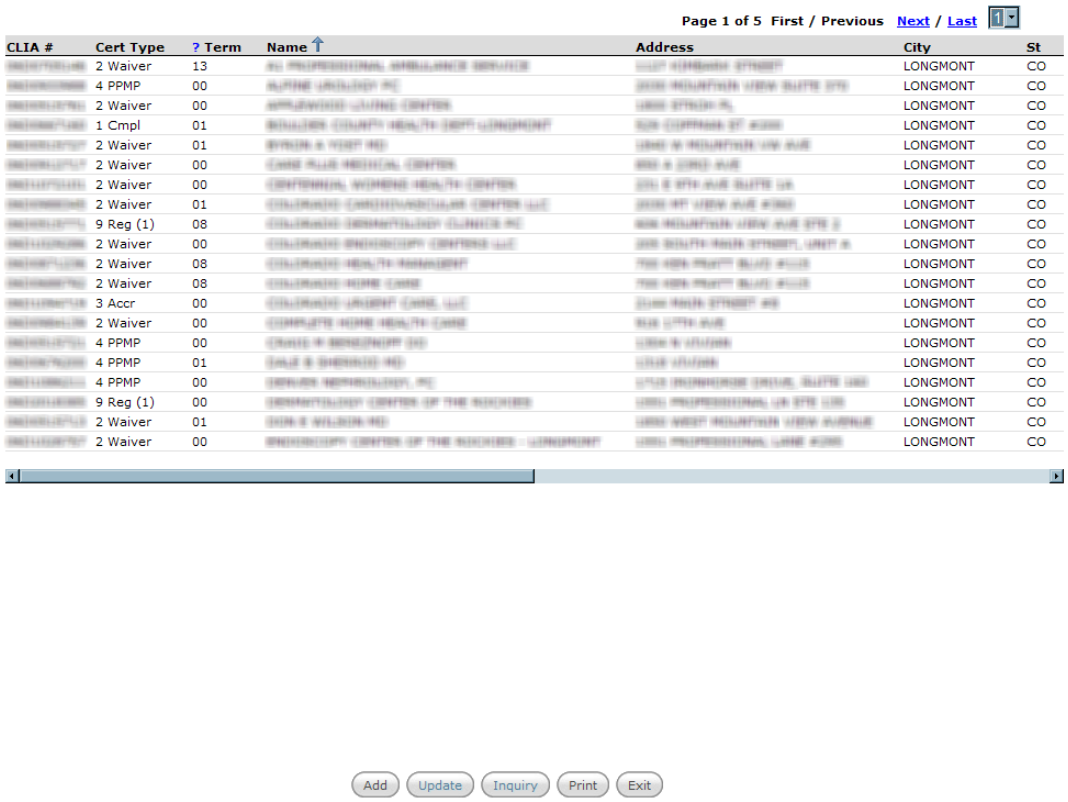


Figure 61: CLIA 116 Search Results window

Report Selection window

From this window, you can generate the CMS-116 form for a lab selected in the Search Results list, or generate the Search Results list as a report. If you choose to print the CMS-116, you can click the blue underlined text to display Hover Help information that is useful for understanding the specialty information included on the report (as shown below).

Fields: "Report Selection window", on page 391

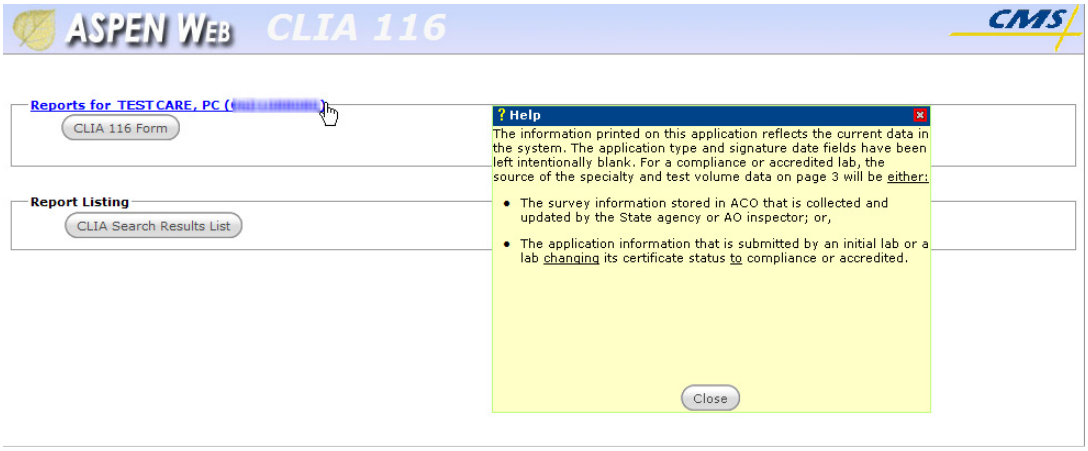


Figure 62: CLIA 116 Report Selection window

More ...

Supporting Materials: "CMS-116" on page 569
Supporting Materials: "CLIA Search Results List" on page 570
Supporting Materials: "CLIA Search Results List–Multiple Sites" on page 571

CLIA 116 window

When you click the Add, Update, or Inquiry button at the bottom of the CLIA 116 Search Results window, the CLIA 116 (lab record) for the selected lab opens to the Demographics tab. The Inquiry version is read-only; several "exit" buttons replace the Save and Cancel buttons.

Fields: "CLIA 116 Form window", on page 391

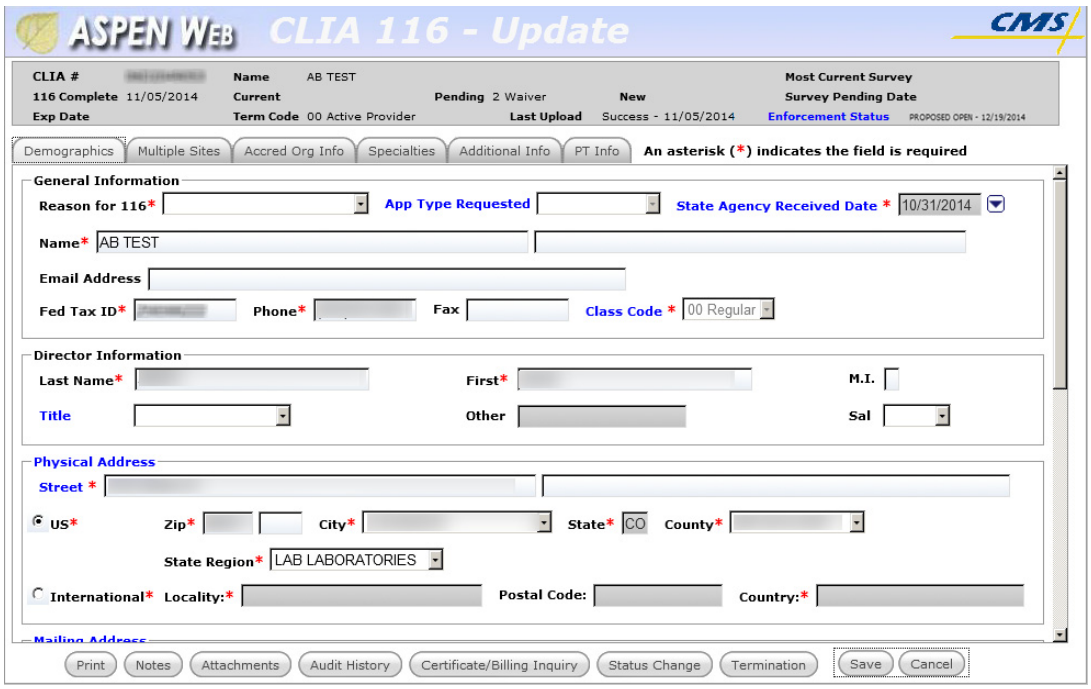


Figure 63: CLIA 116 window

Demographics tab

The Demographics tab replicates sections I, II, III and IV of the CMS-116 form. The information captured here includes basic application and identification information for the lab and the lab's testing schedule.

Fields: "Demographics tab", on page 394

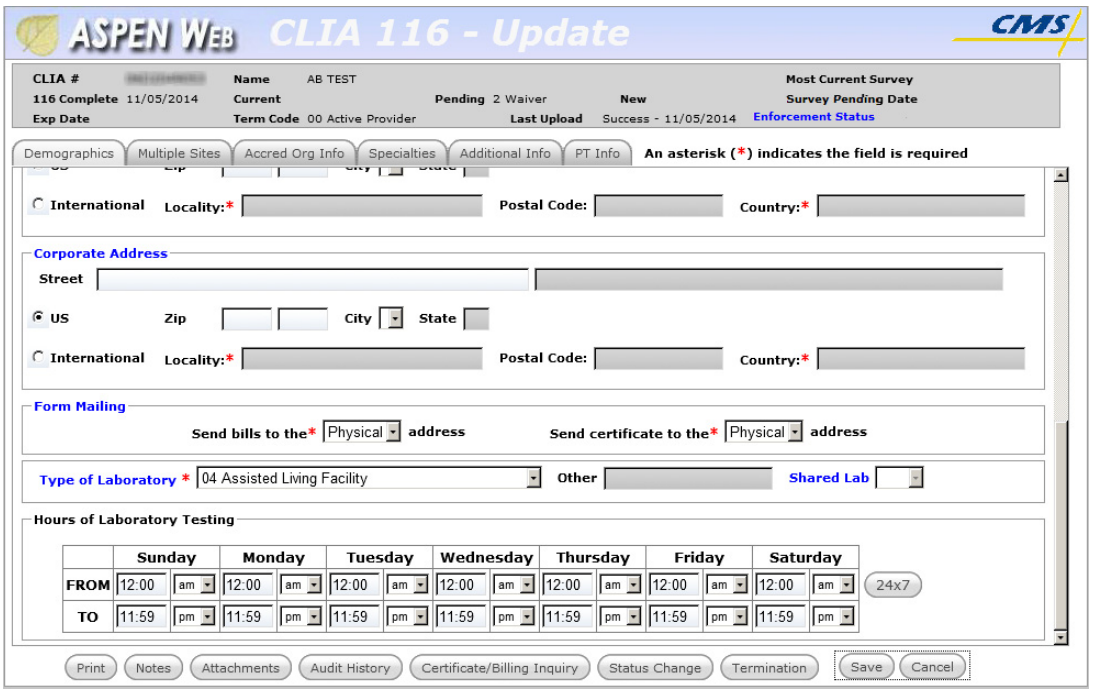


Figure 64: Demographics tab of the CLIA 116 screen

Multiple Sites tab

The Multiple Sites tab replicates section V of the CMS-116 form. Use it to identify multiple sites for a lab when they qualify for a Multiple Sites exception.

Fields: "Multiple Sites tab", on page 401

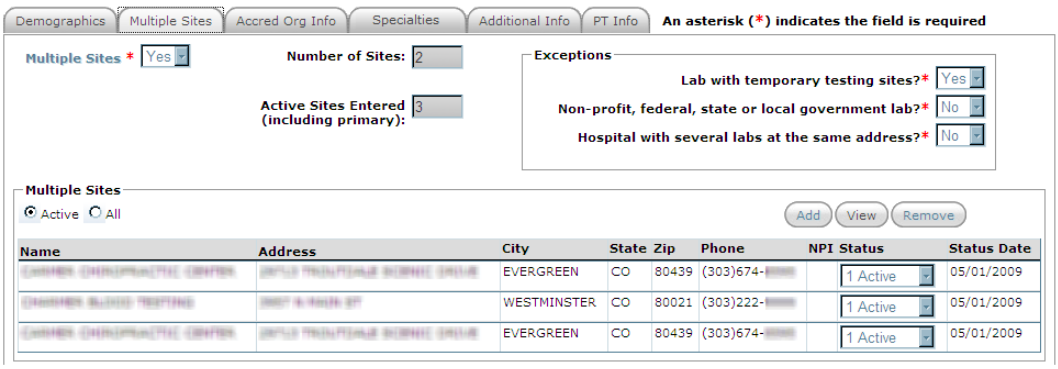


Figure 65: Multiple Sites tab of the CLIA 116 screen

Add/Modify Site window

Much of the data entered in this window is carried into the Multiple Sites section on the Multiple Sites tab.

Fields: "Add/Modify Site window", on page 403

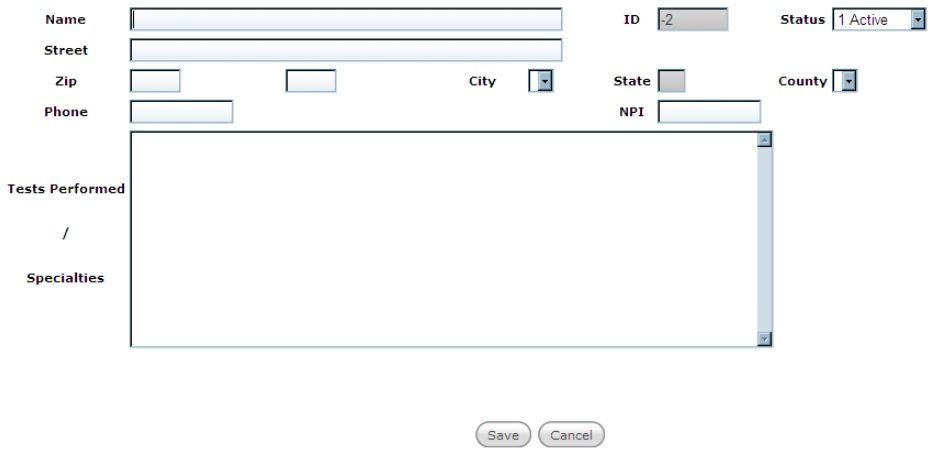


Figure 66: CLIA 116 Add/Modify Site window

Accred Org Info tab

The Accred Org Info tab replicates section II of the hard copy CMS-116. It also displays information not on the form, such as AO Confirmed (Y-match) and Remarks.

Fields: "Accred Org Info tab", on page 404

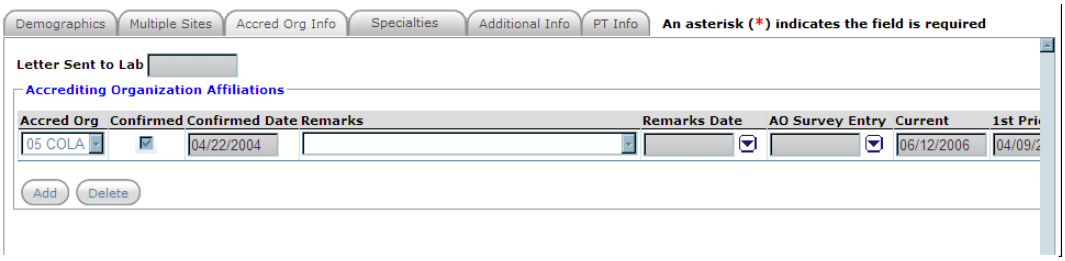


Figure 67: Accrediting Organization Information tab of the CLIA 116 window

Specialties tab

The tab both replicates sections VI, VII, and VIII of the CMS-116 form and captures survey specialties data. Use it to view and update 116 and survey specialties information. The fields you see on this tab depend on the application type.

Fields: "Specialties tab", on page 406

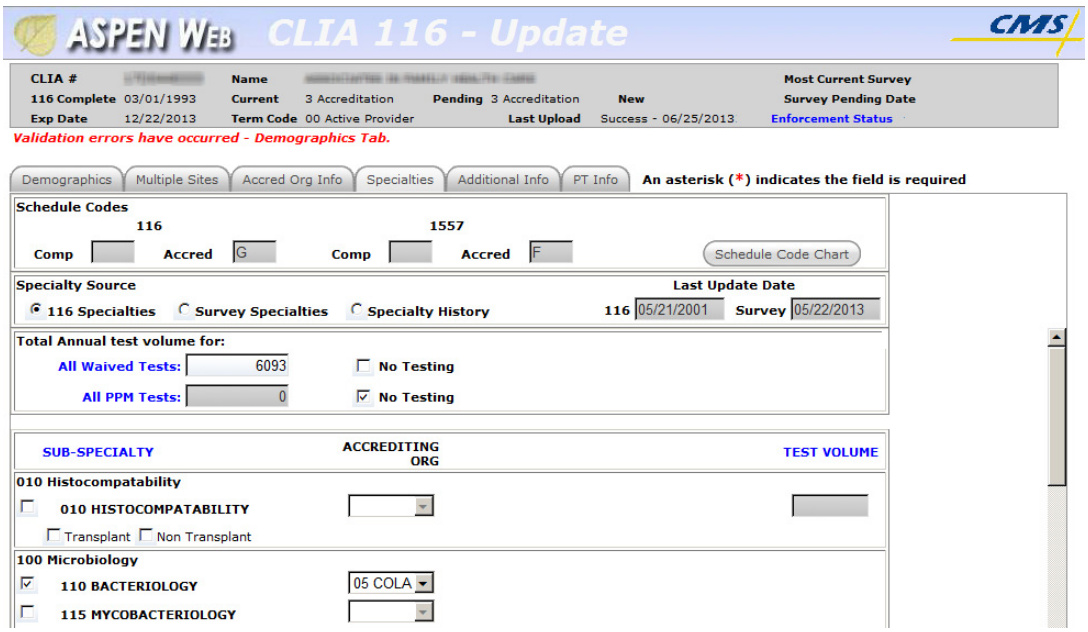


Figure 68: Specialties tab of the CLIA 116 window for an Accredited lab

The Specialty History section is automatically displayed on the Specialties tab for PPM and Waiver labs. It is populated if the lab previously held an Accreditation or Compliance certificate.

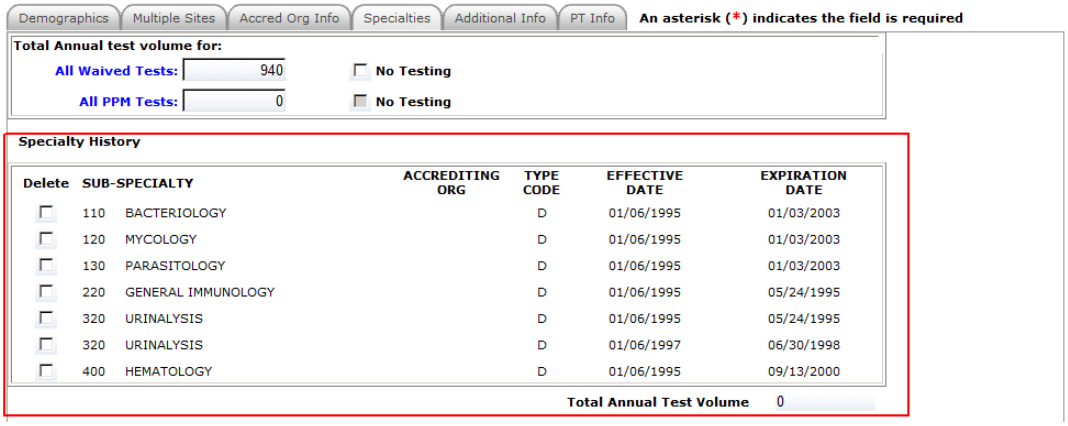


Figure 69: Specialty History section for a PPM lab

To display Specialty History for Accredited and Compliance labs, you select the Specialty History button.

Specialty Source
116 Specialties | Survey Specialties | Specialty History
Last Update Date
116 04/17/2008 Survey 05/03/2008

Total Annual test volume for:
All Waived Tests: 7000 No Testing
All PPM Tests: 953 No Testing

Delete	SUB-SPECIALTY		ACCREDITING ORG	TYPE CODE	EFFECTIVE DATE	EXPIRATION DATE
☐	320	URINALYSIS		D	10/20/2006	04/17/2008
☐	330	ENDOCRINOLOGY		D	10/20/2006	04/17/2008
	400	HEMATOLOGY		A	10/20/2006	

Total Annual Test Volume 7303

Figure 70: Specialty History section displayed for a Compliance lab

Additional Info tab

On this tab, you can enter further information about the lab such as the director's other lab affiliations and the type of organization that operates the lab.

Fields: "Additional Info", on page 410

Demographics | Multiple Sites | Accred Org Info | Specialties | Additional Info | PT Info
An asterisk (*) indicates the field is required

Director Affiliations with Other Laboratories

Provider #	Name	App Type	Term Code		Director Name
[illegible]	[illegible]		1 Compliance	00	[illegible] MD, JOHN R

Insert Affiliated Lab | Find | Delete

Other
Type of Control* 04 Proprietary
Cross Reference Provider Number
Other
Clia Medicare Number
Application Signature Date 12/26/2013
Federal Jurisdiction
CASPER Certification Add Date 03/09/2012
Certification Transaction Date 03/14/2012
Certification Approval Entered Date 03/14/2012
Certification Review Not flagged for review

Cyto PT Enrollment

Letter Sent Date	Enrollment Status	Year

Figure 71: Additional Information tab of the CLIA 116 window

Find Affiliated Providers window

This window opens when you click the Find button in the Director Affiliations section on the Additional Info tab. Use it to search lab records in the database. It has the same fields as the CLIA 116 Find window.

Fields: "CLIA 116 Find window", on page 387

Figure 72: CLIA 116 Find Affiliated Providers window

Affiliated Providers Find Results window

This window displays a list of the laboratories that match the search criteria entered in the Find Affiliated Providers window. You select a lab to add it to the Director Affiliations section on the Additional Info tab. It has the same fields as the CLIA 116 Search Results window.

Fields: "CLIA 116 Search Results window", on page 389

Figure 73: CLIA 116 Affiliated Providers Find Results window

PT Info tab

The PT Info tab displays read-only PT Enrollment and PT Score Lists. The data is sorted with the most current test year at the top. Paging (First/Previous, Next/Last) and the ability to jump to a specific page is available.

Fields: "PT Info tab", on page 412

Demographics | Multiple Sites | Accred Org Info | Specialties | Additional Info | PT Info

An asterisk (*) indicates the field is required

PT Enrollment List

Page 1 of 21 First / Previous Next / Last 1

Test Year	Analyte #	Program #	Effective Date	PT Score Submission Dates 1	2	3	Batch Date	Batch Seq #
2013	0005	009	06/13/2013	06/13/2013	10/03/2013	12/31/2013	07/23/2013	35882
2013	0045	009	05/17/2013	05/17/2013	09/26/2013	12/31/2013	07/23/2013	35883
2013	0115	009	05/17/2013	05/17/2013	09/26/2013	12/31/2013	07/23/2013	35884
2013	0215	009	05/17/2013	05/17/2013	10/03/2013	12/31/2013	07/23/2013	35885
2013	0255	009	05/02/2013	05/02/2013	07/26/2013	11/29/2013	07/23/2013	35886
2013	0265	009	05/02/2013	05/02/2013	07/26/2013	11/29/2013	07/23/2013	35887
2013	0275	009	05/02/2013	05/02/2013	07/26/2013	11/29/2013	07/23/2013	35888
2013	0285	009	05/02/2013	05/02/2013	07/26/2013	11/29/2013	07/23/2013	35889

PT Score List

All Failed/Unsuccessful

Page 1 of 47 First / Previous Next / Last 1

Test Year	Analyte #	Group	Event #	Score Submsn Date	Prog #	Score #	Batch Seq #	Reason Codes	Batch Date	Dup Score	Failed	Unsuccessful	Rmvd Ind
2013	0005		1	06/13/2013	009	100	256580	, , , ,	07/23/2013		N	N	A
2013	0045		2	09/26/2013	009	100	256581	01, , , ,	07/23/2013		N	N	A
2013	0215		1	05/17/2013	009	100	256582	01, , , ,	07/23/2013		N	N	A
2013	0255		1	05/02/2013	009	100	256583	, , , ,	07/23/2013		N	N	A
2013	0265		1	05/02/2013	009	100	256584	, , , ,	07/23/2013		N	N	A
2013	0275		1	05/02/2013	009	100	256585	, , , ,	07/23/2013		N	N	A
2013	0285		1	05/02/2013	009	100	256586	, , , ,	07/23/2013		N	N	A
2013	0295		1	05/02/2013	009	100	256587	, , , ,	07/23/2013		N	N	A

Figure 74: PT Info tab

Notes window

The Notes window lets you view or enter notes about a lab's application. There are separate note panels for State, Regional Office, and Central Office users. The active panel depends on your user type and permissions.

Fields: "Notes", on page 416

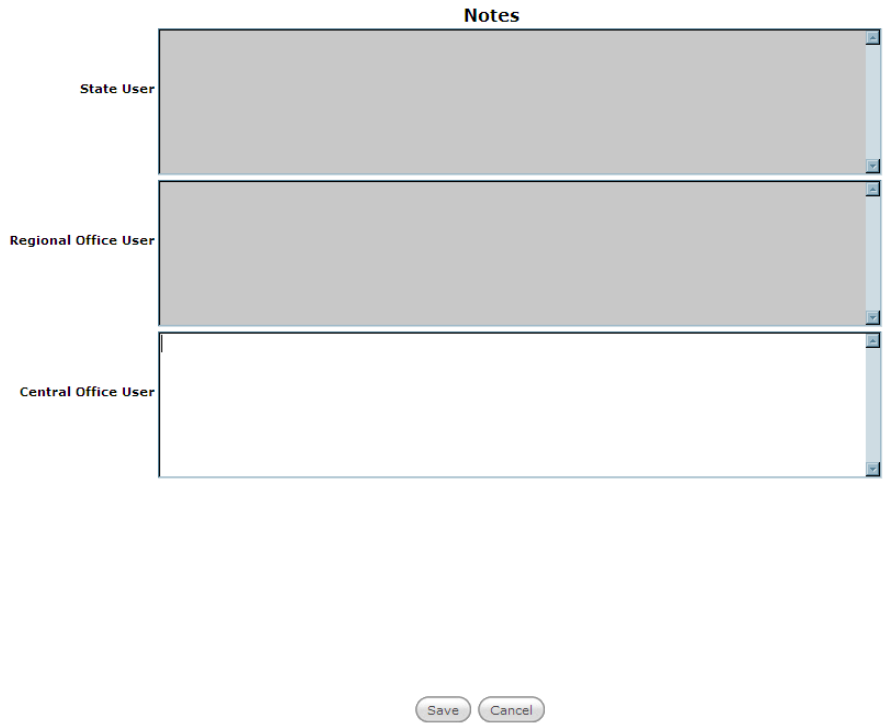


Figure 75: CLIA 116 Notes window

Attachments window

Fields: "Attachments", on page 416

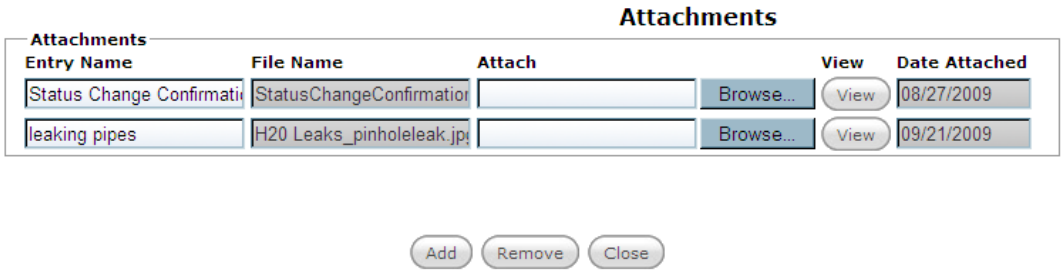
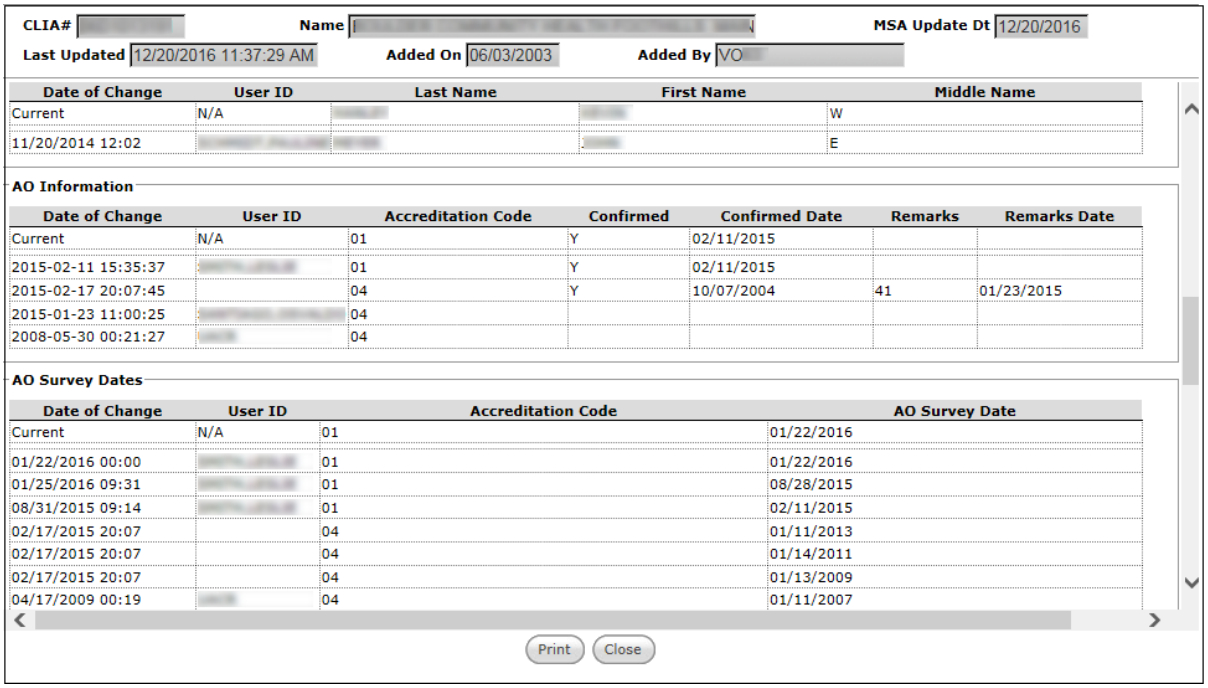


Figure 76: CLIA 116 Attachments window

Audit History window

For each audited section of a lab record, the current field value is given followed by past values with the date/time of the change and the ID of the user who made the change.

Fields: "Audit History window", on page 417



CLIA# [illegible] Name [illegible] MSA Update Dt 12/20/2016

Last Updated 12/20/2016 11:37:29 AM Added On 06/03/2003 Added By VO[illegible]

Date of Change	User ID	Last Name	First Name	Middle Name
Current	N/A	[illegible]	[illegible]	W
11/20/2014 12:02	[illegible]	[illegible]	[illegible]	E

AO Information

Date of Change	User ID	Accreditation Code	Confirmed	Confirmed Date	Remarks	Remarks Date
Current	N/A	01	Y	02/11/2015		
2015-02-11 15:35:37	[illegible]	01	Y	02/11/2015		
2015-02-17 20:07:45		04	Y	10/07/2004	41	01/23/2015
2015-01-23 11:00:25	[illegible]	04				
2008-05-30 00:21:27	[illegible]	04				

AO Survey Dates

Date of Change	User ID	Accreditation Code	AO Survey Date
Current	N/A	01	01/22/2016
01/22/2016 00:00	[illegible]	01	01/22/2016
01/25/2016 09:31	[illegible]	01	08/28/2015
08/31/2015 09:14	[illegible]	01	02/11/2015
02/17/2015 20:07		04	01/11/2013
02/17/2015 20:07		04	01/14/2011
02/17/2015 20:07		04	01/13/2009
04/17/2009 00:19	[illegible]	04	01/11/2007

Print Close

Figure 77: CLIA 116 Audit History window

CLIA Certificate and Billing Inquiry window

This window displays the lab's certificate and billing history. The Certificate Inquiry section displays details about the lab's future (pending), current, and prior certificates. The Billing Inquiry section provides various details about a lab's billing history.

Note: This window contains information similar, but not identical to that in the Certificates and Billing Inquiry window, opened from Browse Accounts.

Fields: "CLIA Certificate and Billing Inquiry window", on page 421

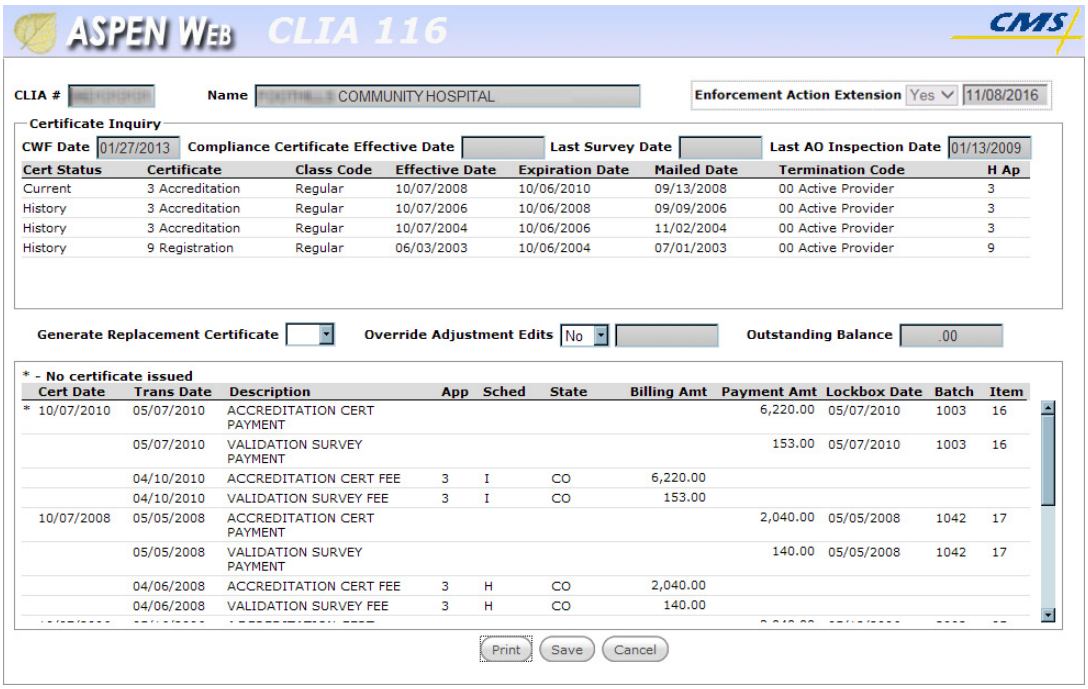


Figure 78: CLIA Certificate and Billing Inquiry window opened from CLIA 116

Status Change window

Use this window to enter changes to application type. The Status Change window has two sections. The Laboratory Information section displays read-only details about the lab's recent certificate history and other useful information when you're considering a status change. The Status Change section is where you change or correct the application type.

Fields: "Status Change window", on page 425

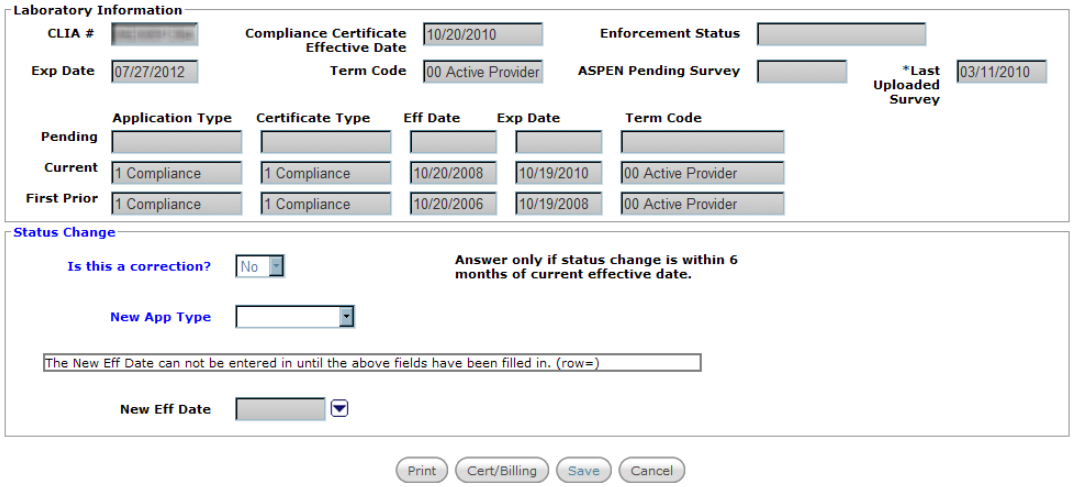


Figure 79: CLIA 116 Status Change window

Termination window

Use this window to enter terminations and reactivations. The Laboratory Information section displays read-only details about the lab's recent certificate history and other useful information when you're considering a termination or reactivation. The Termination/Reactivation section is where you enter details of the termination or reactivation.

Fields: "Termination window", on page 427

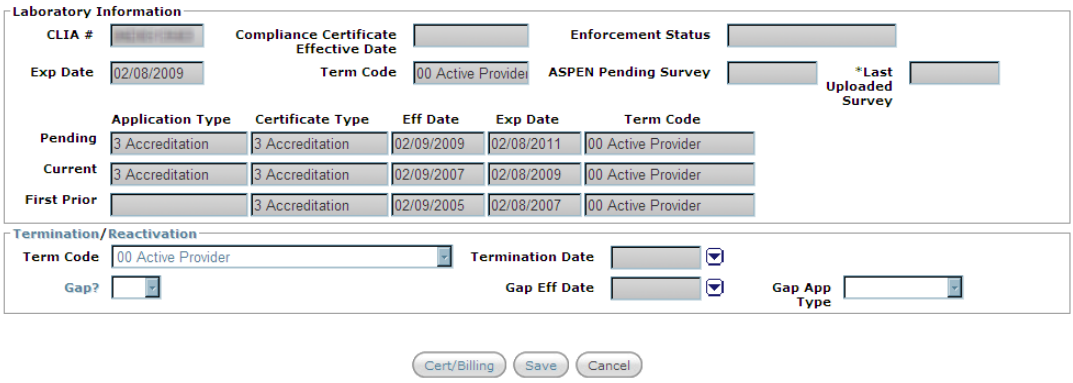


Figure 80: CLIA 116 Termination window

System Information window

The System Information window displays:

- System status notes
- Failed CLIA transaction details
- Current user information
- Batch billing job logs (audit files) for a specified date range

Fields: "System Information window", on page 438

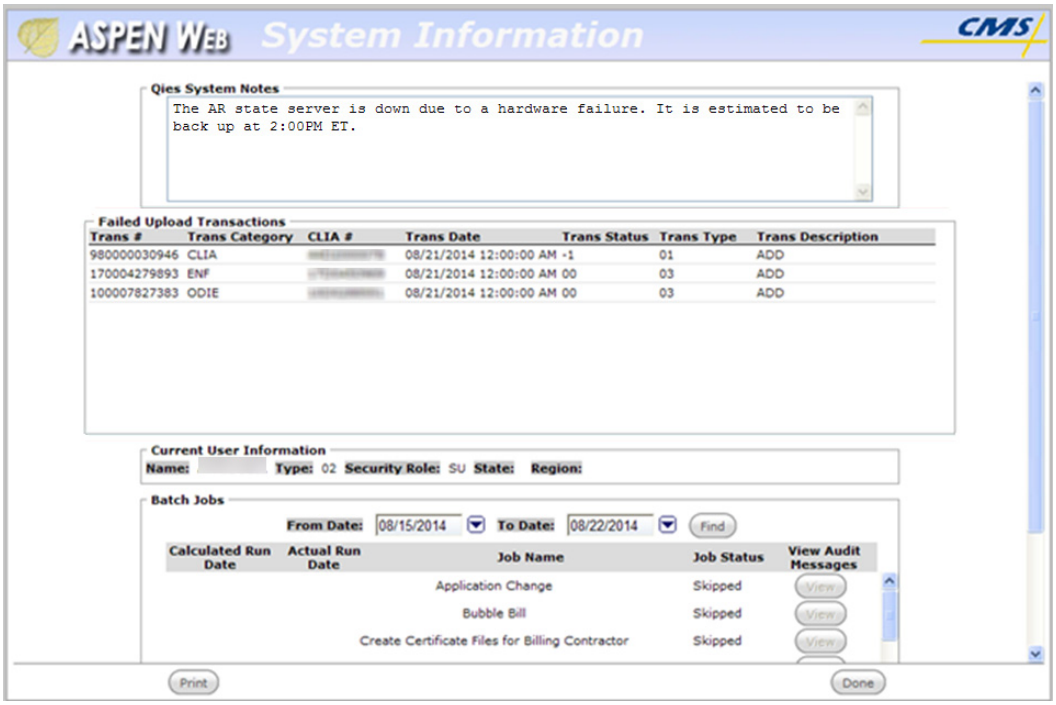


Figure 81: System Information window

Browse Accounts

Browse Accounts window

Fields: "Browse Accounts window", on page 429

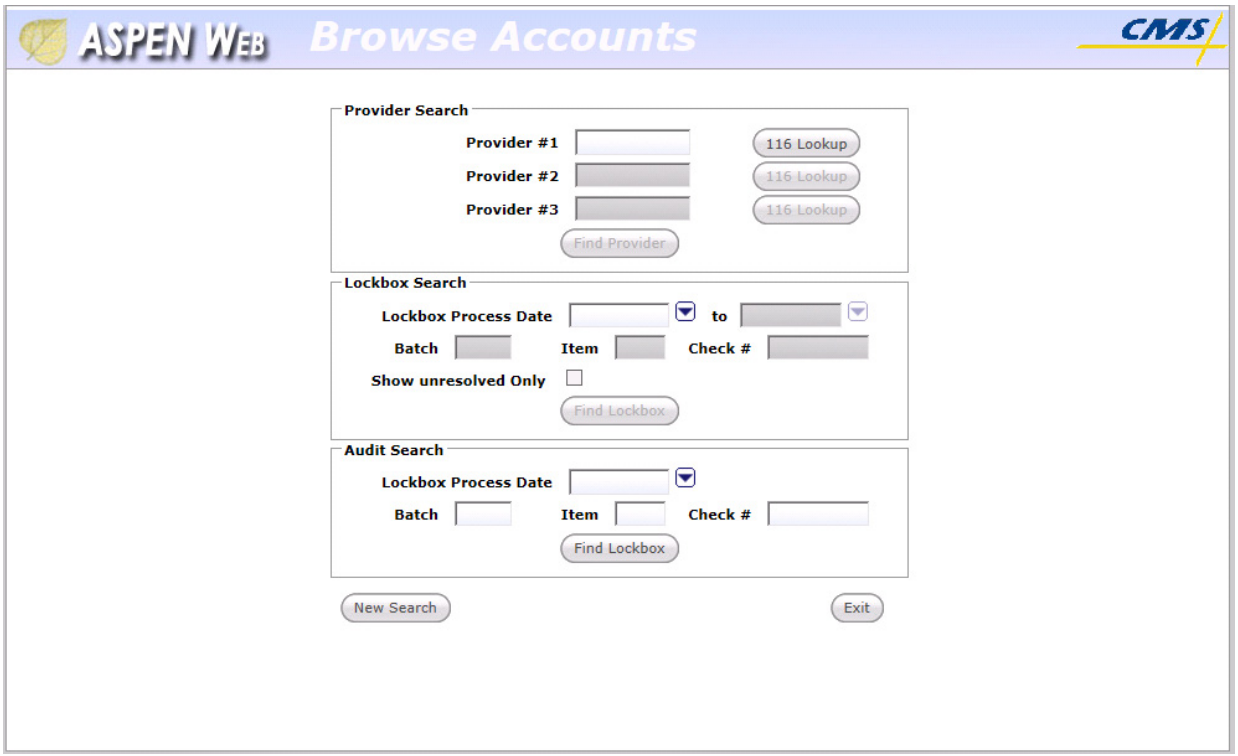


Figure 82: Browse Accounts window

Find Accounting Providers window

This window opens when you click the 116 Lookup button in the Browse Accounts window. It lets you search CLIA 116 forms in the database. It has the same fields as the CLIA 116 Find window.

Fields: "CLIA 116 Find window", on page 387

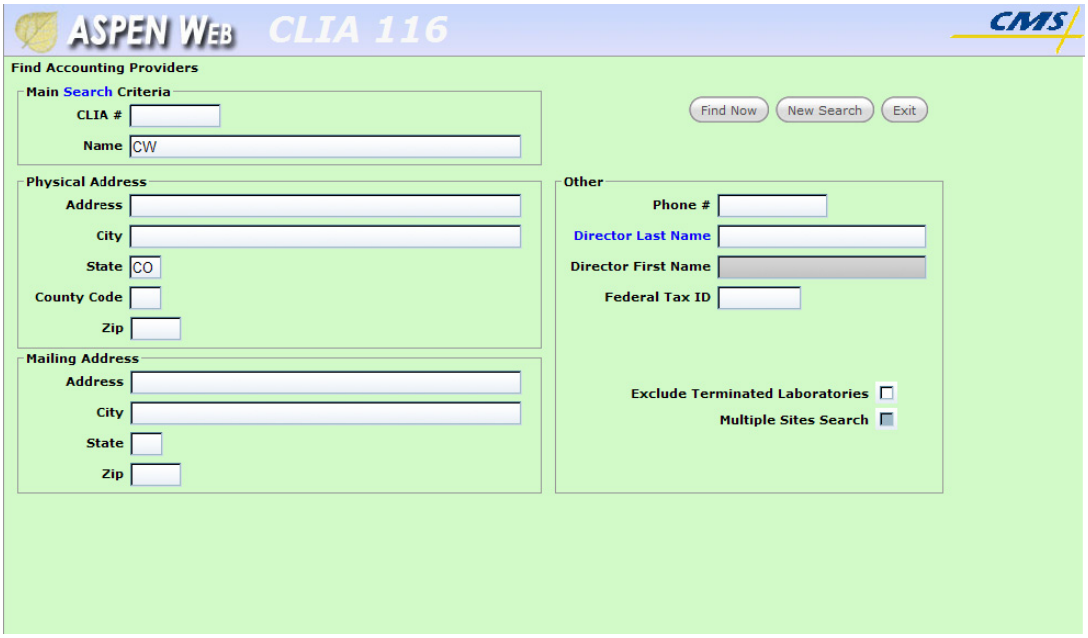


Figure 83: Find Accounting Providers window

Accounting Providers Find Results window

This window displays a list of the laboratories that match the search criteria entered in the Find Accounting Providers window. You select a lab to return its provider number to Browse Accounts. It has the same fields as the CLIA 116 Search Results window.

Fields: "CLIA 116 Search Results window", on page 389

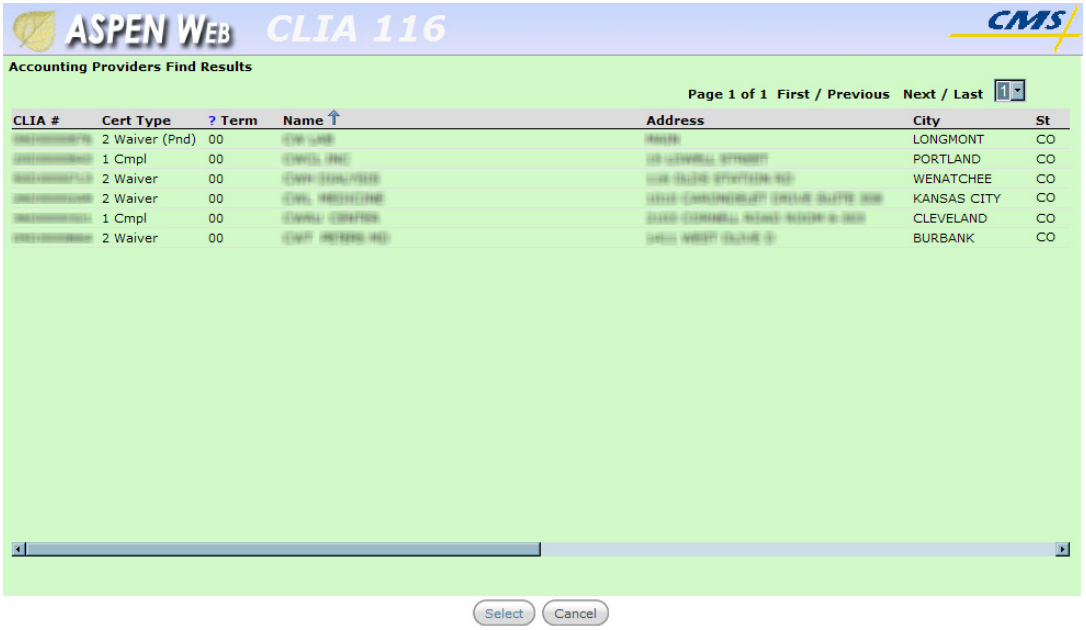


Figure 84: Accounting Providers Find Results window

Certificates and Billing Inquiry window

This window displays the certificate and billing history for up to three labs specified when you search by provider in Browse Accounts. The Certificate Inquiry section displays details about the lab's future (pending), current, and prior certificates. The Billing Inquiry section provides various details about a lab's billing history. All information is read-only.

Note: This window contains information similar, but not identical to that in the CLIA Certificate and Billing Inquiry window in the CLIA 116 web app.

Fields: "CLIA Certificate and Billing Inquiry window", on page 421

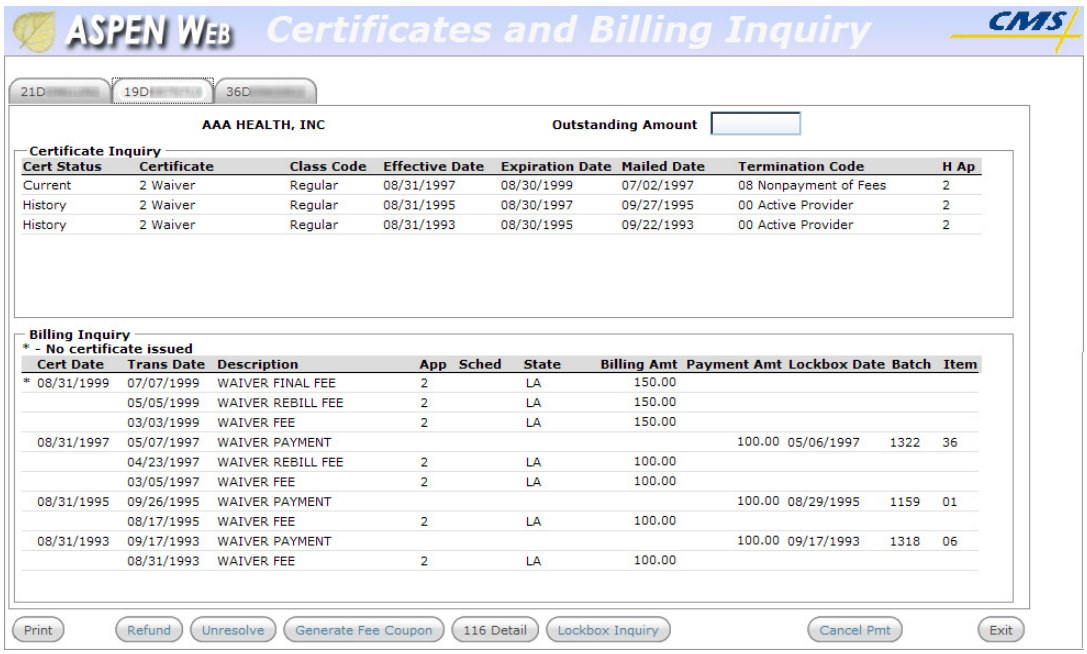


Figure 85: Certificates and Billing Inquiry window opened from Browse Accounts

Inquire By window

Inquire By opens when you select a payment in the Billing Inquiry section of the Certificates and Billing Inquiry window and click the Lockbox Inquiry button. You can choose to search lockbox records by one of the options.

Fields: "Inquire By window", on page 434

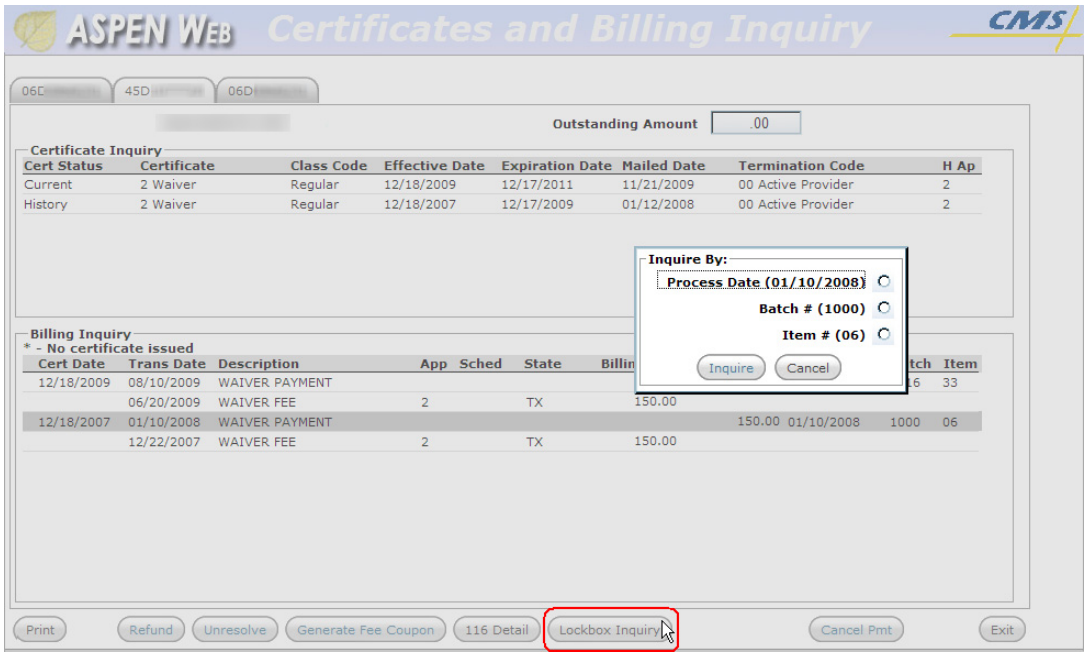
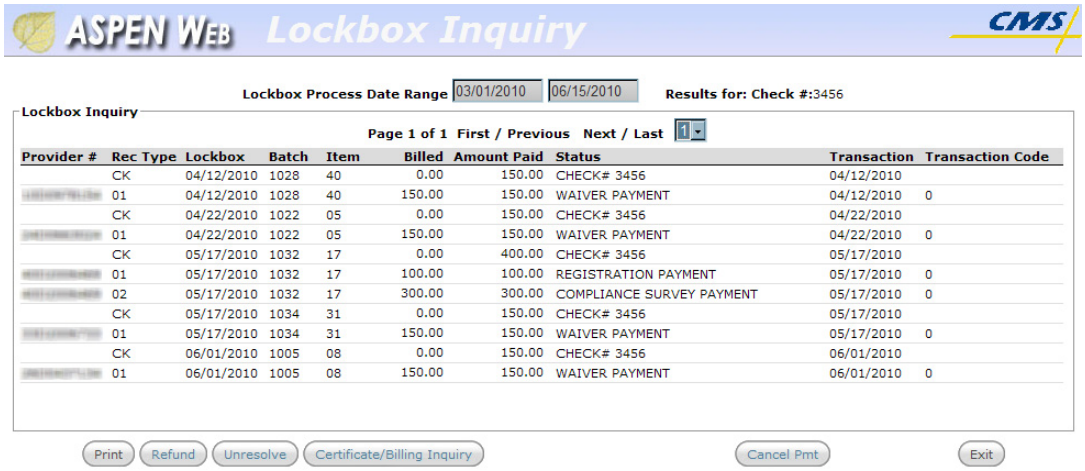


Figure 86: Inquire By window

Lockbox Inquiry window

Fields: "Lockbox Inquiry window", on page 434

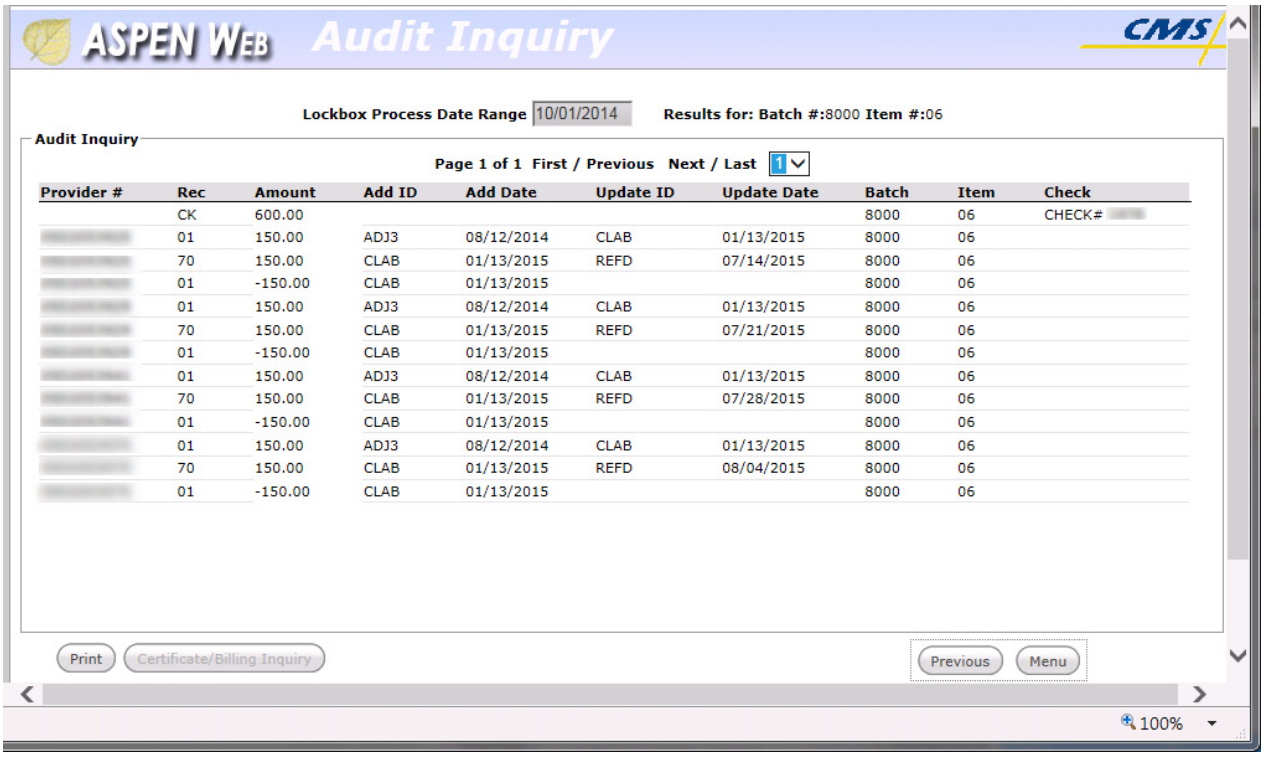


Provider #	Rec Type	Lockbox	Batch	Item	Billed	Amount Paid	Status	Transaction	Transaction Code
	CK	04/12/2010	1028	40	0.00	150.00	CHECK# 3456	04/12/2010	
	01	04/12/2010	1028	40	150.00	150.00	WAIVER PAYMENT	04/12/2010	0
	CK	04/22/2010	1022	05	0.00	150.00	CHECK# 3456	04/22/2010	
	01	04/22/2010	1022	05	150.00	150.00	WAIVER PAYMENT	04/22/2010	0
	CK	05/17/2010	1032	17	0.00	400.00	CHECK# 3456	05/17/2010	
	01	05/17/2010	1032	17	100.00	100.00	REGISTRATION PAYMENT	05/17/2010	0
	02	05/17/2010	1032	17	300.00	300.00	COMPLIANCE SURVEY PAYMENT	05/17/2010	0
	CK	05/17/2010	1034	31	0.00	150.00	CHECK# 3456	05/17/2010	
	01	05/17/2010	1034	31	150.00	150.00	WAIVER PAYMENT	05/17/2010	0
	CK	06/01/2010	1005	08	0.00	150.00	CHECK# 3456	06/01/2010	
	01	06/01/2010	1005	08	150.00	150.00	WAIVER PAYMENT	06/01/2010	0

Figure 87: Lockbox Inquiry window

Audit Inquiry window

Fields: "Audit Inquiry", on page 436



Provider #	Rec	Amount	Add ID	Add Date	Update ID	Update Date	Batch	Item	Check
	CK	600.00					8000	06	CHECK#
	01	150.00	ADJ3	08/12/2014	CLAB	01/13/2015	8000	06	
	70	150.00	CLAB	01/13/2015	REFD	07/14/2015	8000	06	
	01	-150.00	CLAB	01/13/2015			8000	06	
	01	150.00	ADJ3	08/12/2014	CLAB	01/13/2015	8000	06	
	70	150.00	CLAB	01/13/2015	REFD	07/21/2015	8000	06	
	01	-150.00	CLAB	01/13/2015			8000	06	
	01	150.00	ADJ3	08/12/2014	CLAB	01/13/2015	8000	06	
	70	150.00	CLAB	01/13/2015	REFD	07/28/2015	8000	06	
	01	-150.00	CLAB	01/13/2015			8000	06	
	01	150.00	ADJ3	08/12/2014	CLAB	01/13/2015	8000	06	
	70	150.00	CLAB	01/13/2015	REFD	08/04/2015	8000	06	
	01	-150.00	CLAB	01/13/2015			8000	06	

Figure 88: Audit Inquiry window

CLIA Facility Properties

The window specifying facility properties has two possible titles. You use the Define New Facility window to add records *only* for labs of subtype 225 to ACO. When you view or modify an existing provider record for a CLIA lab, the window title is <FacName> Definition where FacName is the name of the lab.

Since the <FacName> Definition window is commonly referred to as Facility Properties (the name of the right-click option used to access it), it is called the Facility Properties window in this procedures guide.

Note: For CLIA lab subtypes 221-224, you *cannot* populate or modify fields in ACO that are updated by the nightly extract from the CLIA 116 web app. Provider information that you optionally add in ACO will not appear in the national CLIA database.

Facility Definition tab

The Facility Definition tab contains basic details about the lab. This tab has four sections:

- Identification
- Description
- Contact Information
- CLIA

Identification

In this section, you provide Federal and state ID numbers for the lab, license information, operating status, and also indicate title/licensure status.

Fields: "Identification", on page 441

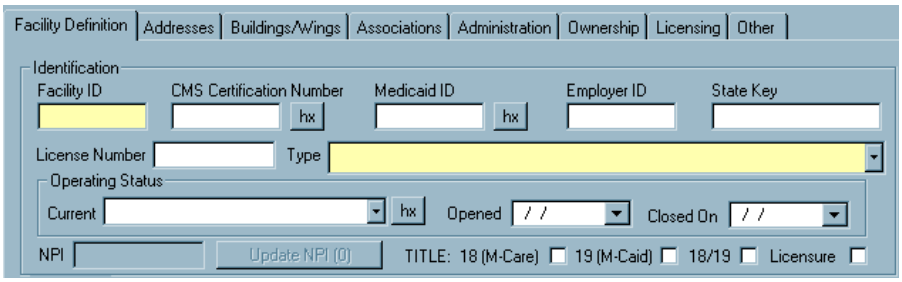


Figure 89: Identification section of the Facility Definition tab

Description

This section contains address and telephone number information for the lab.

Fields: "Description", on page 443

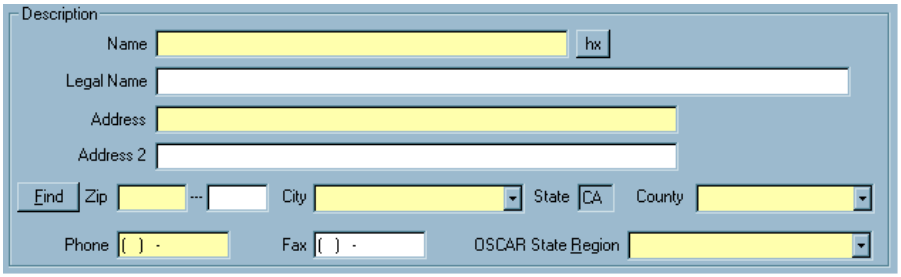


Figure 90: Description section of the Facility Definition tab

Contact Information

Emergency contact and Assessment contact information appears in this segment.

Fields: "Contact Information", on page 444

Figure 91: Contact Information section of Facility Definition tab

CLIA

This section displays CLIA certificate and certification information.

Fields: "CLIA", on page 445

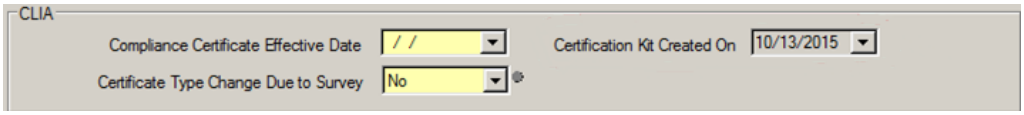


Figure 92: CLIA section of Facility Definition tab

Addresses tab

This tab lets you add, modify, or delete address information for the lab.

Fields: "Addresses tab", on page 445

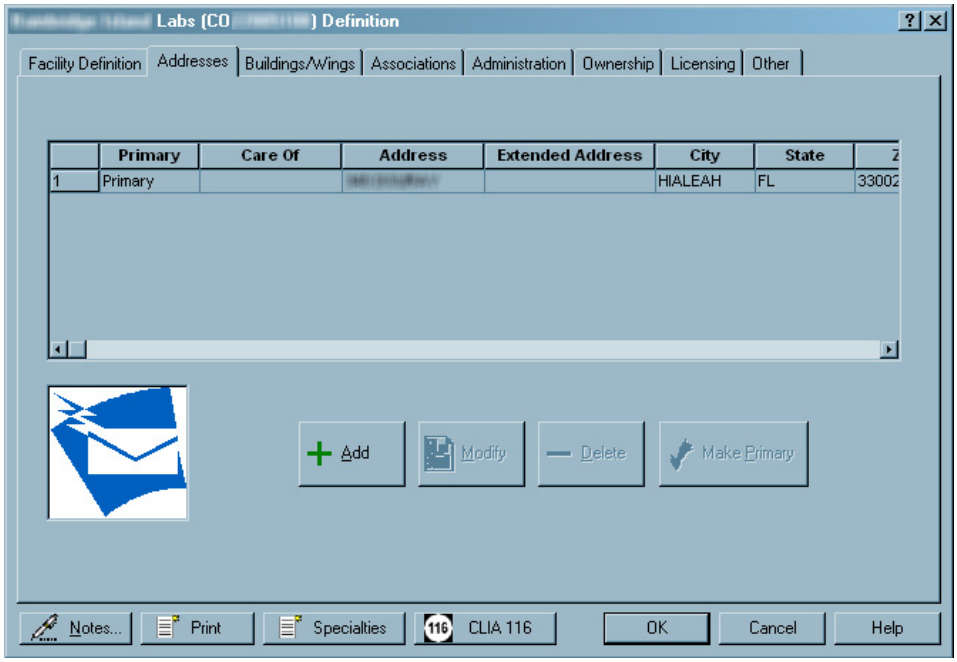


Figure 93: Addresses tab from the Facility Definitions window

Mailing Address window

Select the Add or Modify button on the Addresses tab to add or update an address in this window.

Fields: "Mailing Address window", on page 446

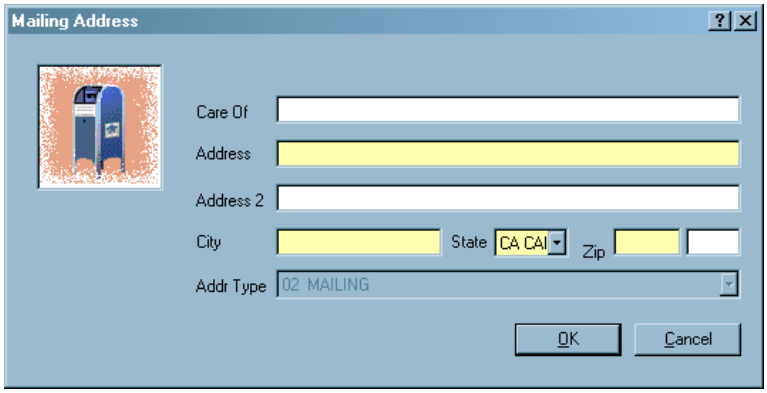


Figure 94: Mailing Address window

Associations tab

This tab displays the assigned agency units, accrediting organizations (AOs), and congressional representatives for the provider. You can select two AOs maximum.

Fields: "Associations tab", on page 446

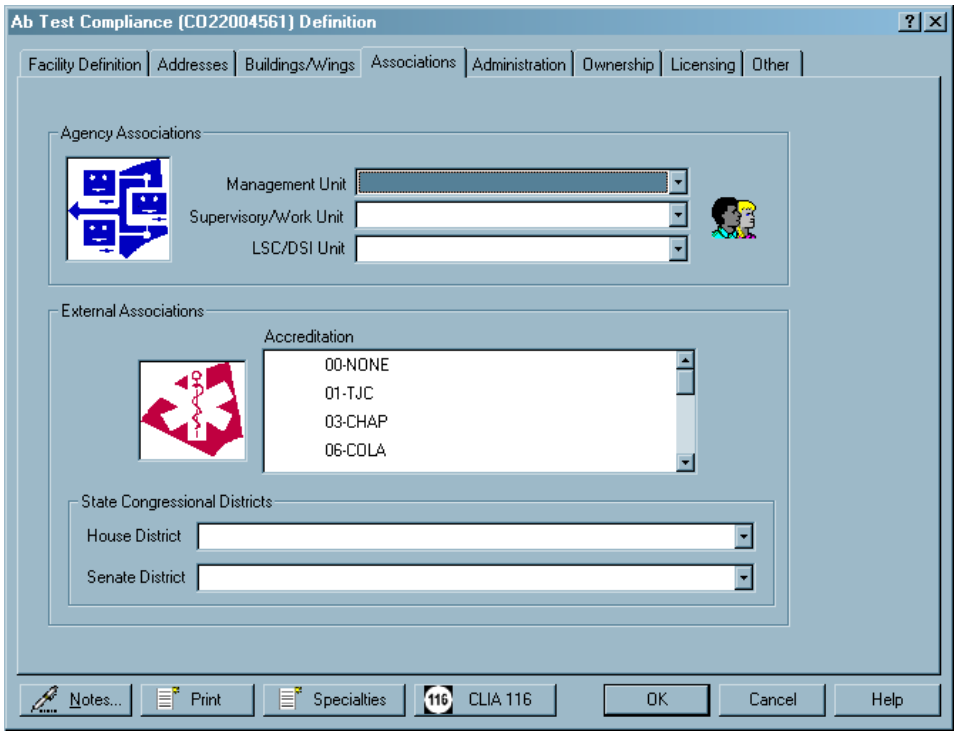


Figure 95: Associations tab

Administration tab

The left pane lets you search for and display CLIA lab directors by name. In the right pane, you assign directors to the lab from the list in the left pane.

The name of the lab director is downloaded to ACO from the CLIA 116 web app and stored in the CLIA section on the Facility Definition tab. You can optionally create lab director records in ACO from the Administration tab, but records created here must be maintained manually.

Fields: "Administration tab", on page 447

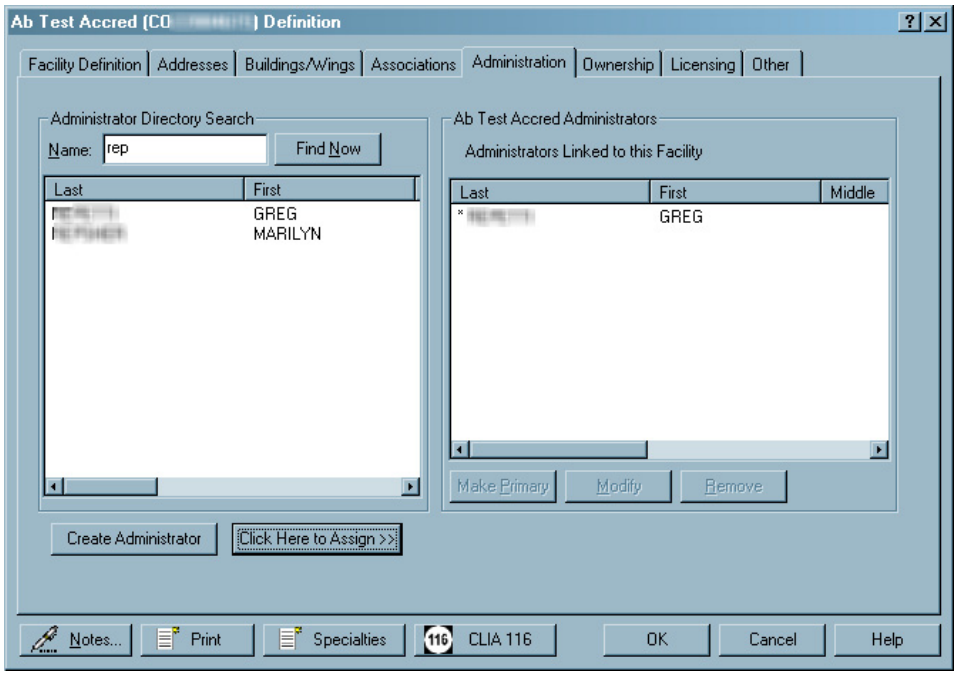


Figure 96: Administration tab

Administrator Information window

Selecting Click Here to Assign an administrator to a lab opens the Administrator Information window.

Fields: "Administrator Information", on page 448

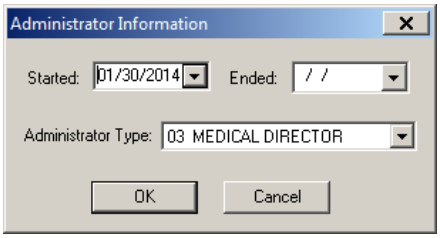


Figure 97: Administrator Information window

Enter Administrator Information

Fields: "Enter Administrator Information", on page 448

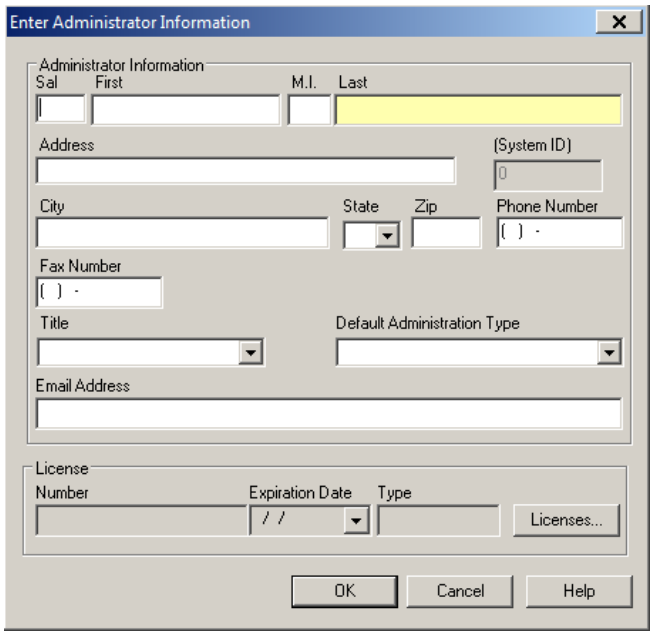


Figure 98: Enter Administrator Information window

Ownership tab

The left pane lets you search for and display owners by name; you can create owner records if necessary. In the right pane, you assign owner companies to the lab from the list in the left pane.

Fields: "Ownership tab", on page 449

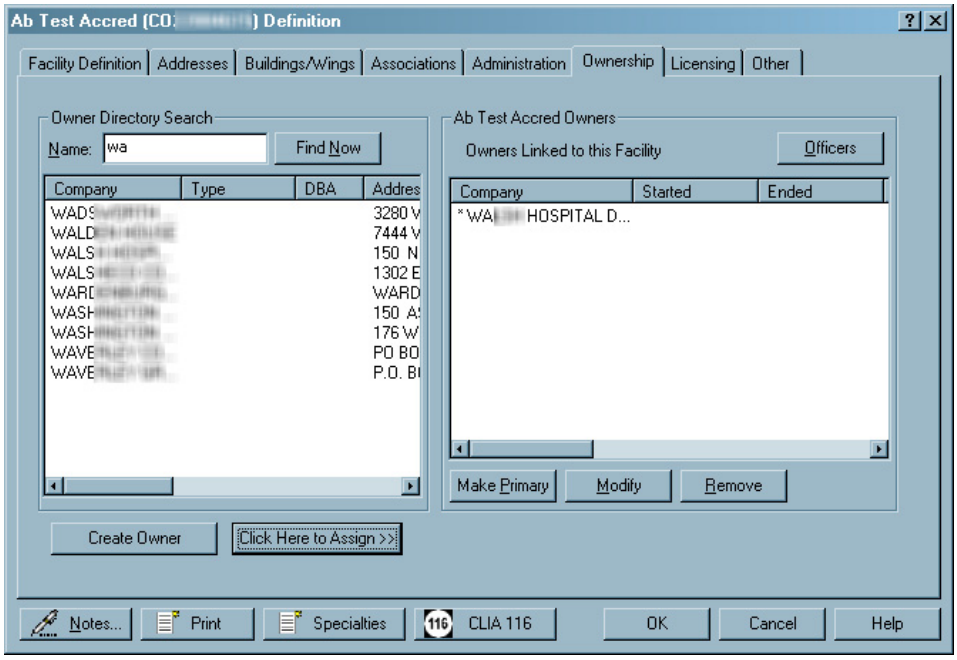


Figure 99: Ownership tab

Owner Properties

Fields: "Owner Properties", on page 450

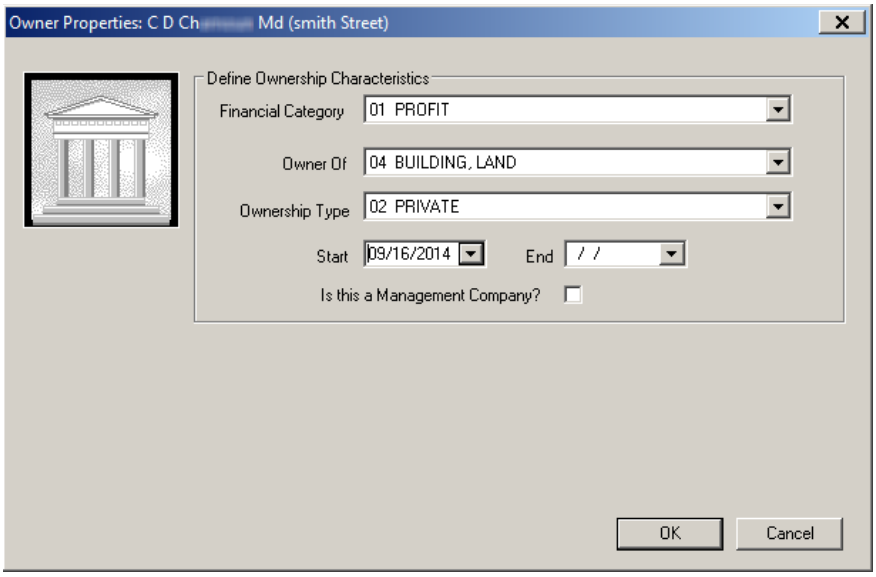


Figure 100: Owner Properties window

Enter Owner Company Information window

Fields: "Enter Owner Company Information", on page 451

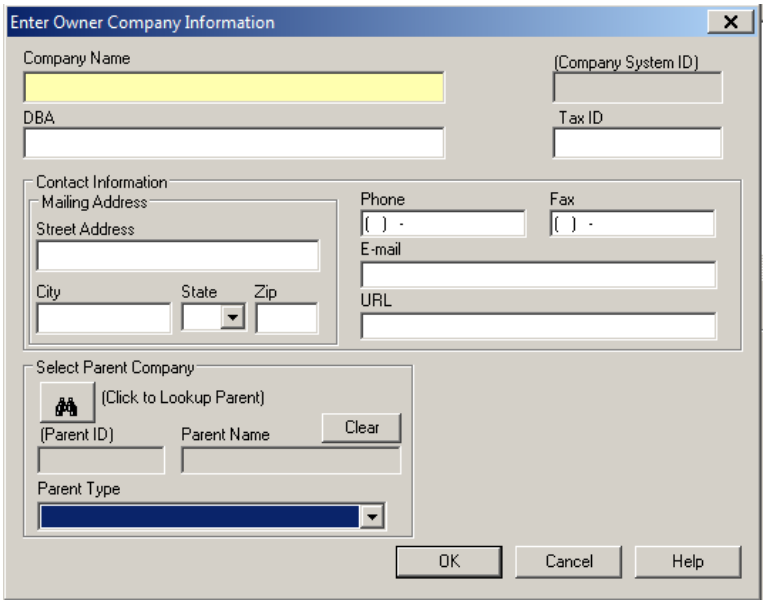


Figure 101: Enter Owner Company Information window

Licensing tab

This tab lets you review and enter licensing information for a specific provider including: license type, issue and effective dates, and continuation status.

Fields: "Licensing tab", on page 452

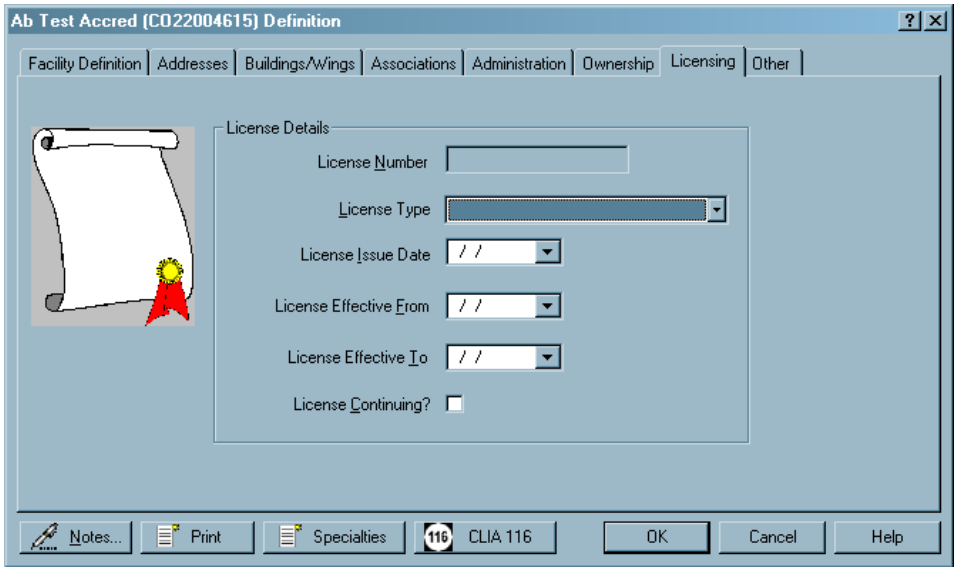


Figure 102: Licensing tab

Other tab

This tab contains miscellaneous information about a provider including geographic location, insurance information, special operating hours, and so on.

Fields: "Other tab", on page 453

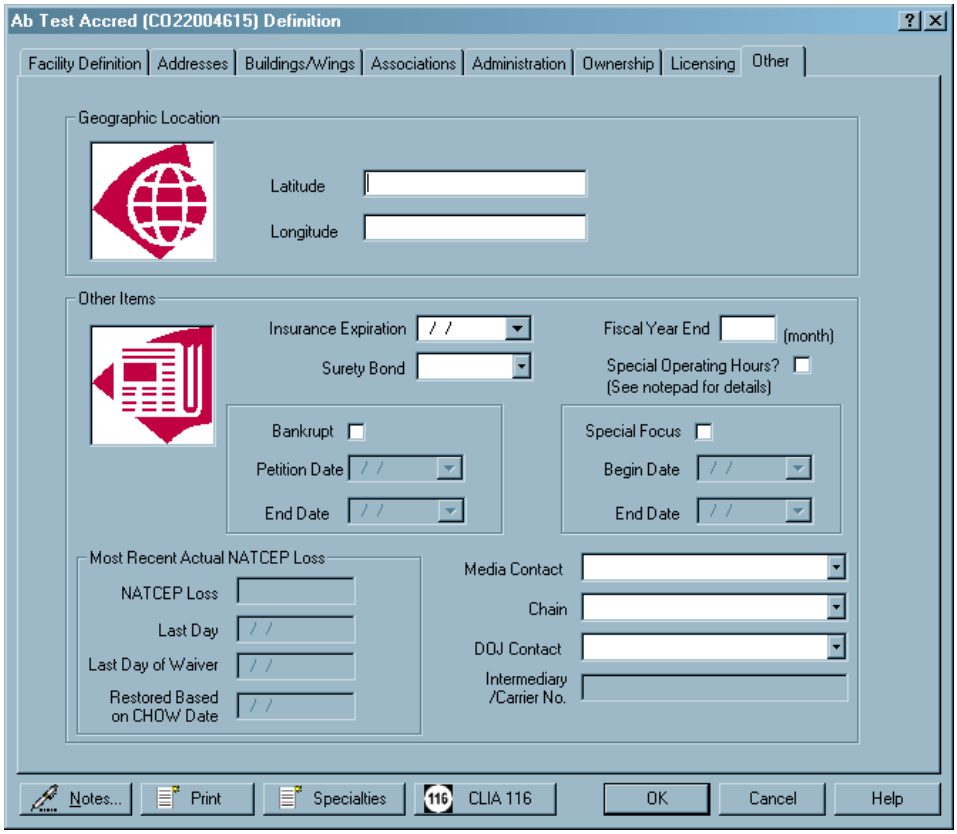


Figure 103: Other tab from the Facility Definition window

CLIA Certification Kits

Certification kits for CLIA labs contain six tabs:

- Certification & Surveys
- Tracking
- Transmittal (CMS-1539)
- Survey (CMS-1557)
- 1557 Specialties
- Upload

Certification & Surveys tab

Every certification kit opens initially to the Certification & Surveys tab. It has five sections:

- Certification Properties
- Citation List
- Survey List
- Special Fields
- CLIA

Certification Properties and Responsible Parties

The Certification Properties section of the Certification & Surveys tab contains basic information about the current certification kit. The Responsible Parties field lists responsible parties assigned to the certification kit.

Fields: "Certification Properties and Responsible Parties", on page 454
Fields: "Responsible Parties", on page 462

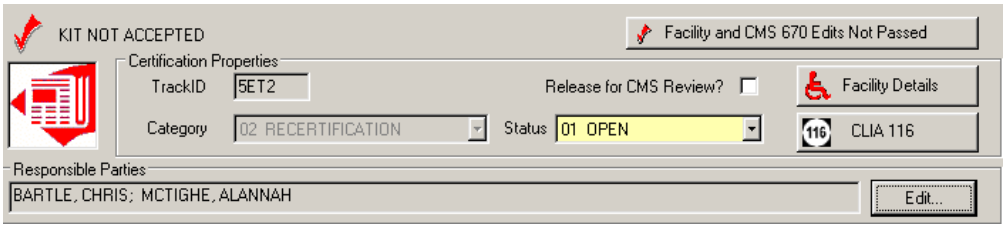
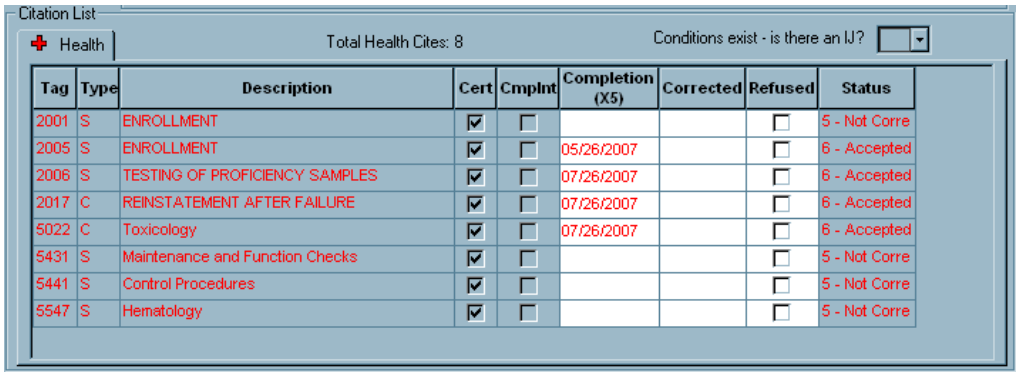


Figure 104: Certification Properties and Responsible Parties

Citation List

The Citation List section lists all of the health tags cited on any survey linked to the certification. The counter keeps track of the total number of cites. You can update information directly in the white columns. Federal tags are red, state tags are blue. The columns displayed vary somewhat according to provider type.

Fields: "Citation List", on page 456



Tag	Type	Description	Cert	Cmplnt	Completion (X5)	Corrected	Refused	Status
2001	S	ENROLLMENT	☑	☐			☐	5 - Not Corre
2005	S	ENROLLMENT	☑	☐	05/26/2007		☐	6 - Accepted
2006	S	TESTING OF PROFICIENCY SAMPLES	☑	☐	07/26/2007		☐	6 - Accepted
2017	C	REINSTATEMENT AFTER FAILURE	☑	☐	07/26/2007		☐	6 - Accepted
5022	C	Toxicology	☑	☐	07/26/2007		☐	6 - Accepted
5431	S	Maintenance and Function Checks	☑	☐			☐	5 - Not Corre
5441	S	Control Procedures	☑	☐			☐	5 - Not Corre
5547	S	Hematology	☑	☐			☐	5 - Not Corre

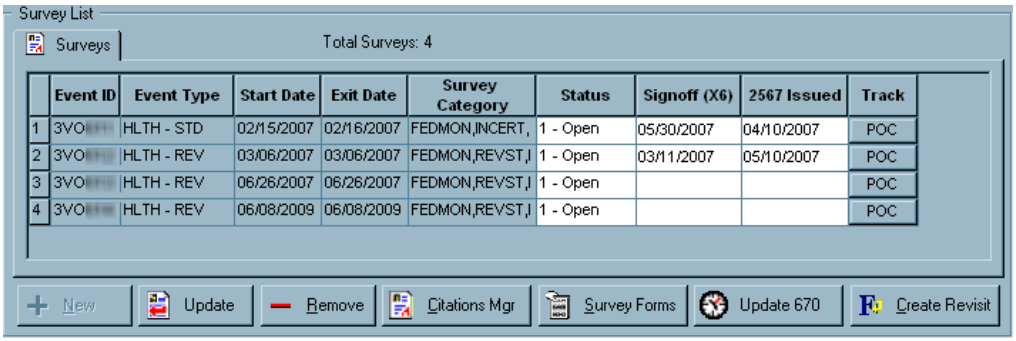
Figure 105: Citation List section with list of tags cited during survey

Survey List

The Survey List displays a one-line summary for each survey and revisit associated with the certification. The columns displayed vary somewhat according to provider type. You can enter information directly into the white columns.

Buttons at the bottom link to standard ACO survey management functions. For example, click Update to open the selected survey in the Survey Properties window so you can update it as needed.

Fields: "Survey List", on page 457



	Event ID	Event Type	Start Date	Exit Date	Survey Category	Status	Signoff (X6)	2567 Issued	Track
1	3VO[illegible]	HLTH - STD	02/15/2007	02/16/2007	FEDMON,INCERT,	1 - Open	05/30/2007	04/10/2007	POC
2	3VO[illegible]	HLTH - REV	03/06/2007	03/06/2007	FEDMON,REVST,I	1 - Open	03/11/2007	05/10/2007	POC
3	3VO[illegible]	HLTH - REV	06/26/2007	06/26/2007	FEDMON,REVST,I	1 - Open			POC
4	3VO[illegible]	HLTH - REV	06/08/2009	06/08/2009	FEDMON,REVST,I	1 - Open			POC

Figure 106: Survey List section

Special Fields

The Special Fields section of the Certification & Surveys tab provides an area for administrative information and instructions.

Fields: "Special Fields", on page 459

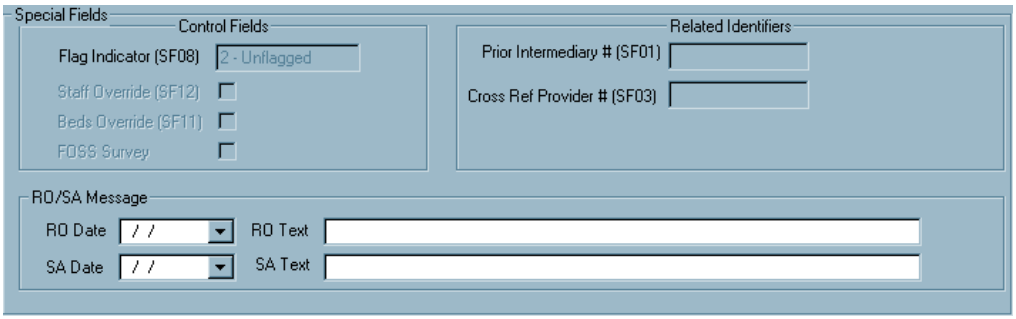


Figure 107: Special Fields section of the Certification and Surveys tab

CLIA

When you open a certification kit for a CLIA lab, the CLIA section appears beneath the Special Fields area. Whether the fields are enabled/required depends on the type of certification kit. Both fields are enabled for a newly created initial certification, as shown below.

Fields: "CLIA", on page 460

Figure 108: CLIA section of the Certification & Surveys tab

Tracking tab

This tab provides a central point for managing and monitoring all aspects of the certification process, both fieldwork and internal office procedures. It includes the following components:

- Certification Summary section
- CLIA Authorization for State Validation Survey (CMS 2802)
- Responsible Parties subtab
- Activities/Action Items subtab
- Processing Steps subtab
- 2567/POC/IDR subtab
- Enforcement subtab
- Notices subtab
- CHOW subtab

Certification Summary

This section at the top of the Tracking tab provides very basic details about the certification.

Fields: "Certification Summary", on page 460

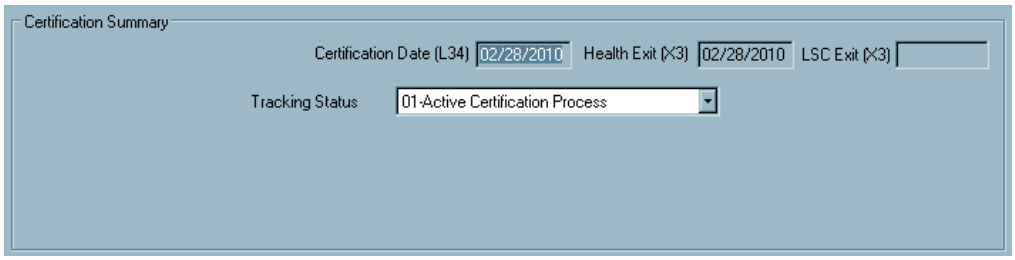


Figure 109: Certification Summary section of the Tracking tab

CLIA Authorization for State Validation Survey (CMS 2802)

This section of the Tracking tab captures RO Approval information for CLIA validation surveys. ACO uses this information to populate the CMS-2802A in validation kits. Only relevant fields are enabled.

Fields: "CLIA Authorization for State Validation Survey (CMS 2802)", on page 461

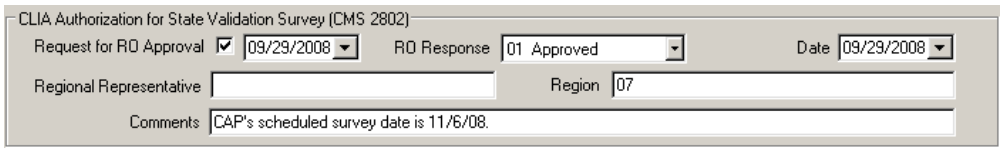


Figure 110: CLIA Authorization for State Validation Survey (CMS 2802) section of the Tracking tab

Responsible Parties

Use this Tracking subtab to designate Responsible Parties for the certification, both SA and RO.

Fields: "Responsible Parties", on page 462

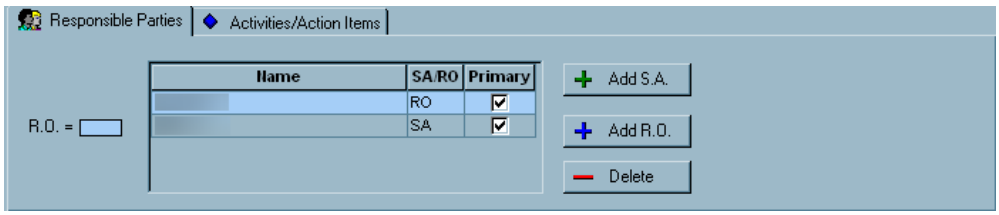


Figure 111: Responsible Parties section of the Tracking tab

Activities/Action Items

On this Tracking subtab, you can assign activities to staff members. Action items are automatically sent to the assigned personnel.

Fields: "Activities/Action Items", on page 462

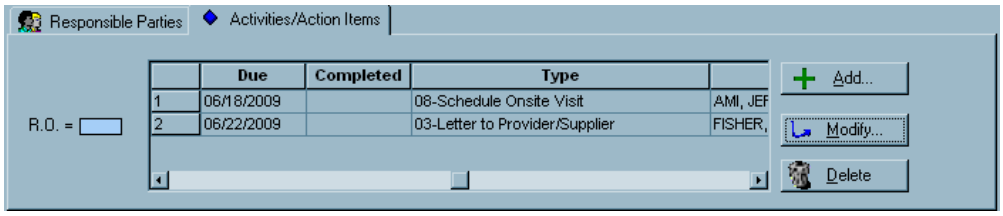


Figure 112: Activities/Action Items section of the Tracking tab

Define Activity window

This window opens when you click Add or select an existing activity and click Modify on the Activities/Action Items subtab on the Tracking tab. When you add an activity, an action item is sent to designated staff members.

Fields: "Define Activity", on page 479

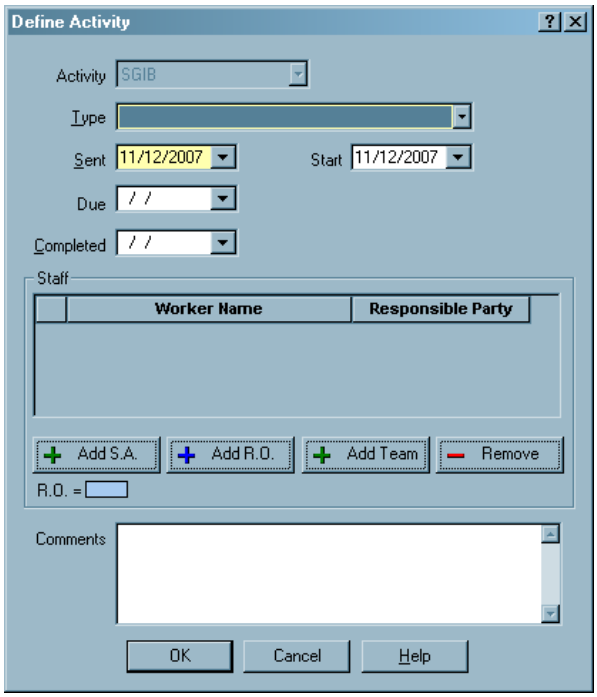


Figure 113: Define Activity window

Processing Steps

This Tracking subtab provides detailed information about individual certification tasks, e.g., Process Due and Complete dates.

Fields: "Processing Steps", on page 464

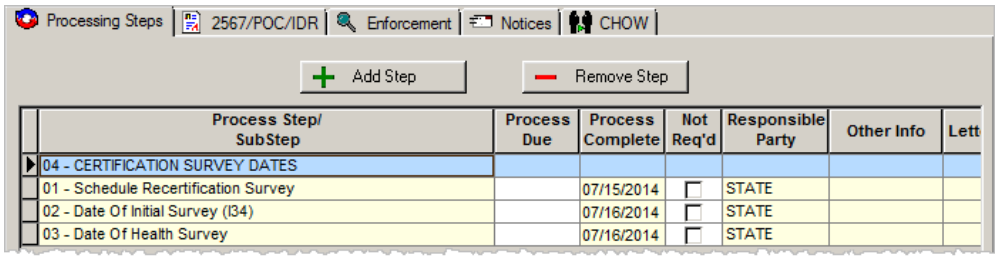


Figure 114: Processing Steps section of the Tracking tab

2567/POC/IDR

This Tracking subtab provides convenient access to dates and details for all SODs and POCs. IDR is not applicable and does not appear in CLIA certification kits.

Fields: "2567/POC/IDR", on page 465

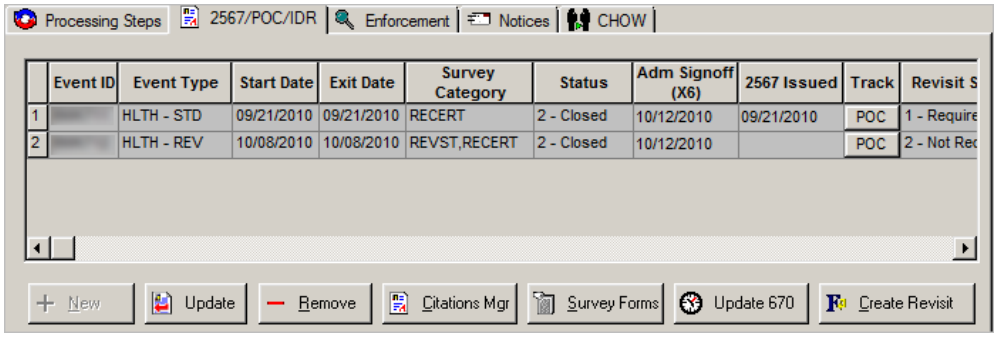


Figure 115: 2567/POC/IDR section of the Tracking tab

Enforcement

This subtab lists enforcement actions associated with a certification process.

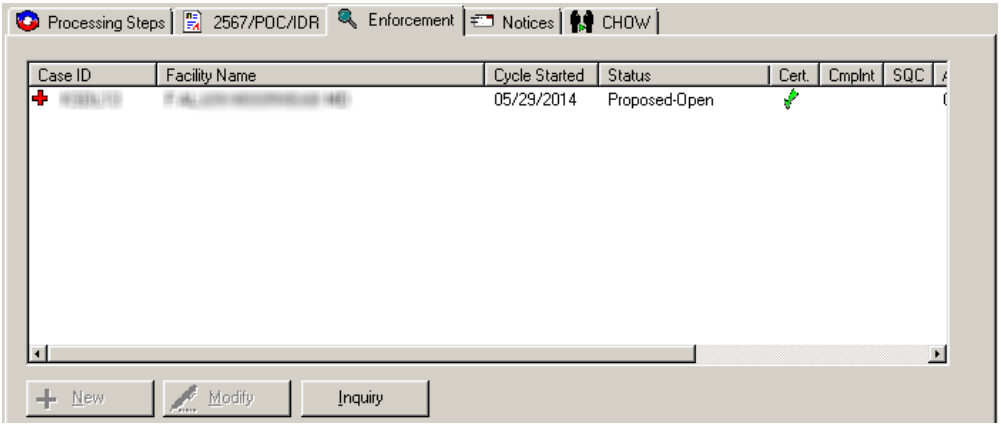


Figure 116: Enforcement section of the Tracking tab

Notices

Use this subtab to print letters and view the letter history associated with the certification process.

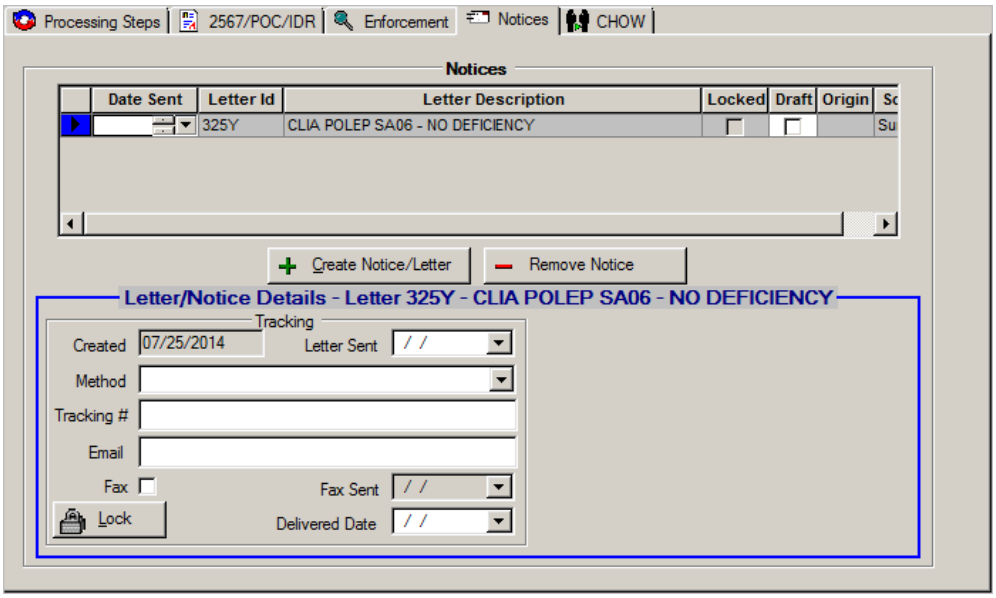


Figure 117: Notices section of the Tracking tab

CHOW

This section is not applicable in CLIA certification kits.

Transmittal (CMS-1539)

The Certification and Transmittal (CMS-1539) form has two parts. Enabled fields vary depending on the mode (ACO or ARO) and the provider type.

CMS-1539 - Part I

Part I of the CMS-1539 contains provider and program participation information to be supplied by State Survey Agency personnel.

Fields: "CMS-1539 Part I", on page 466

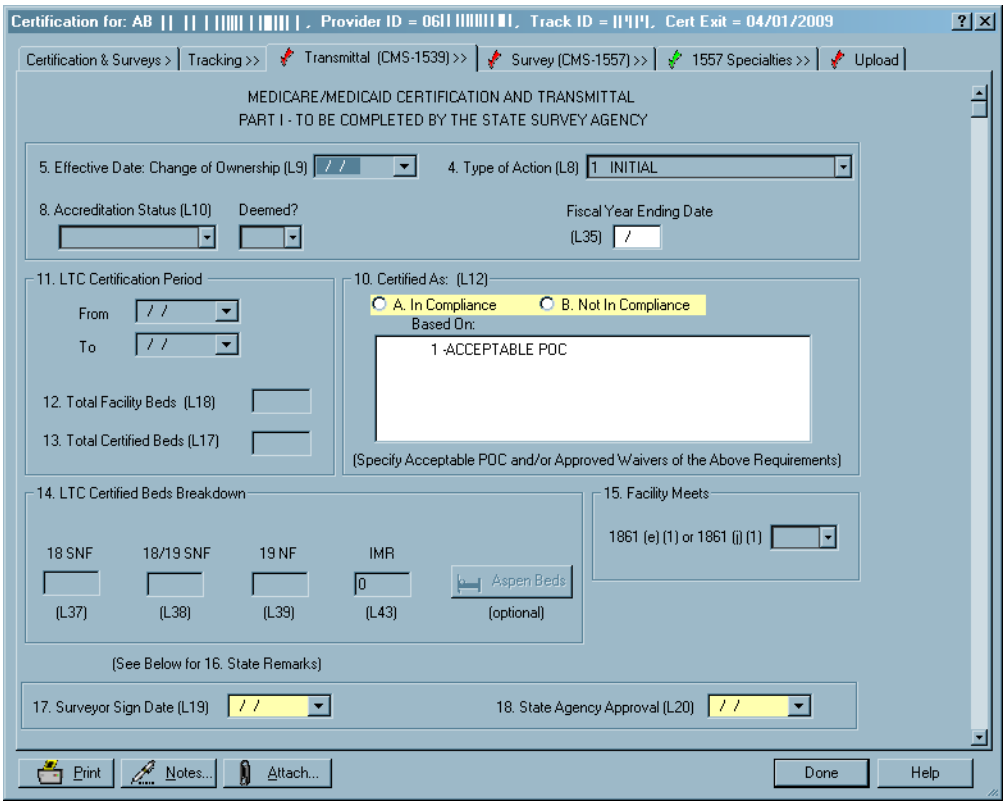


Figure 118: Part 1 of the Transmittal tab

CMS-1539 - Part II

Part II of the CMS-1539 contains administrative details to be completed by Regional Office or Single State Agency personnel.

Fields: "CMS-1539 Part II", on page 468

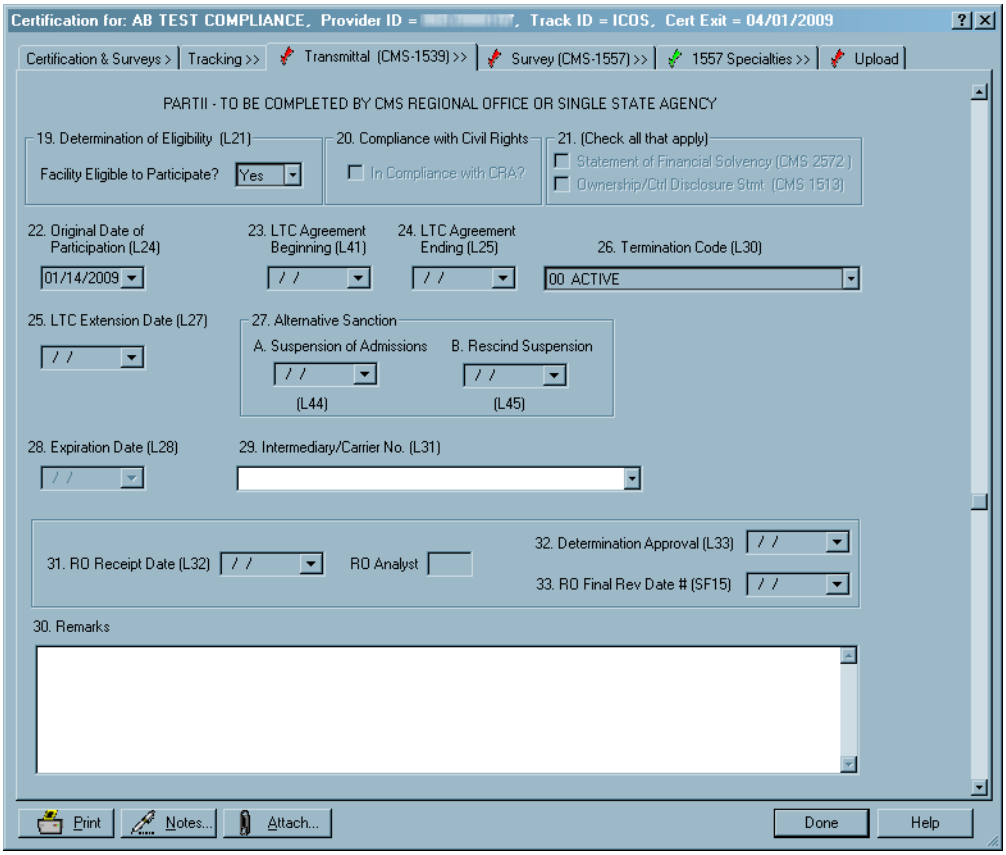


Figure 119: Part 2 of the Transmittal tab

Survey (CMS-1557)

This tab corresponds to the Personnel section of the paper CMS-1557.

Fields: "Survey (CMS-1557)", on page 469

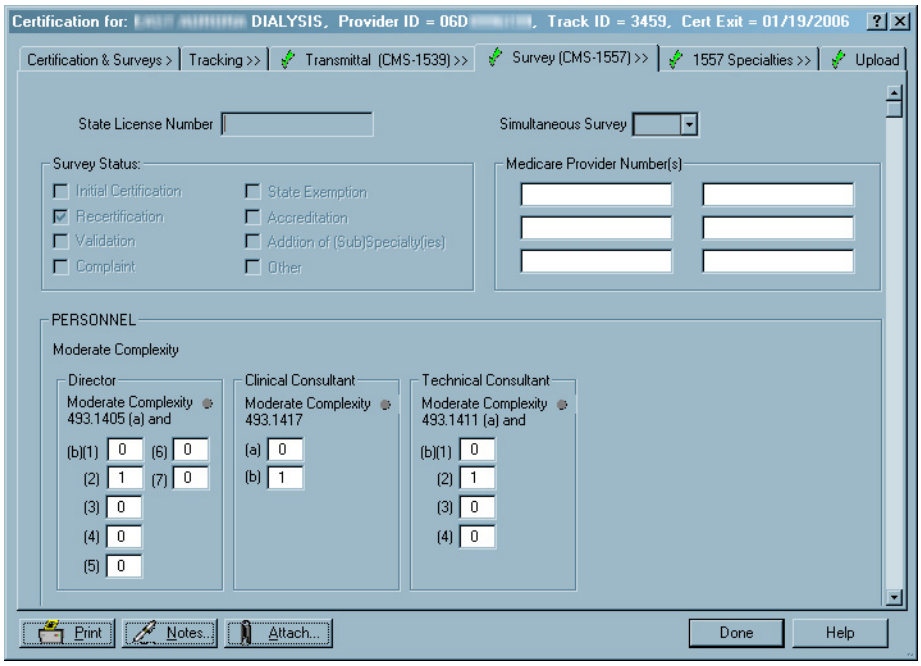


Figure 120: Survey (CMS-1557) tab

1557 Specialties

Use this tab to view, update, delete, or close out survey specialties for Compliance labs and to confirm specialty data for Accredited labs. The 1557 Specialties tab does not appear for certification kits with a Prior status, or for closed labs.

Fields: "1557 Specialties", on page 470

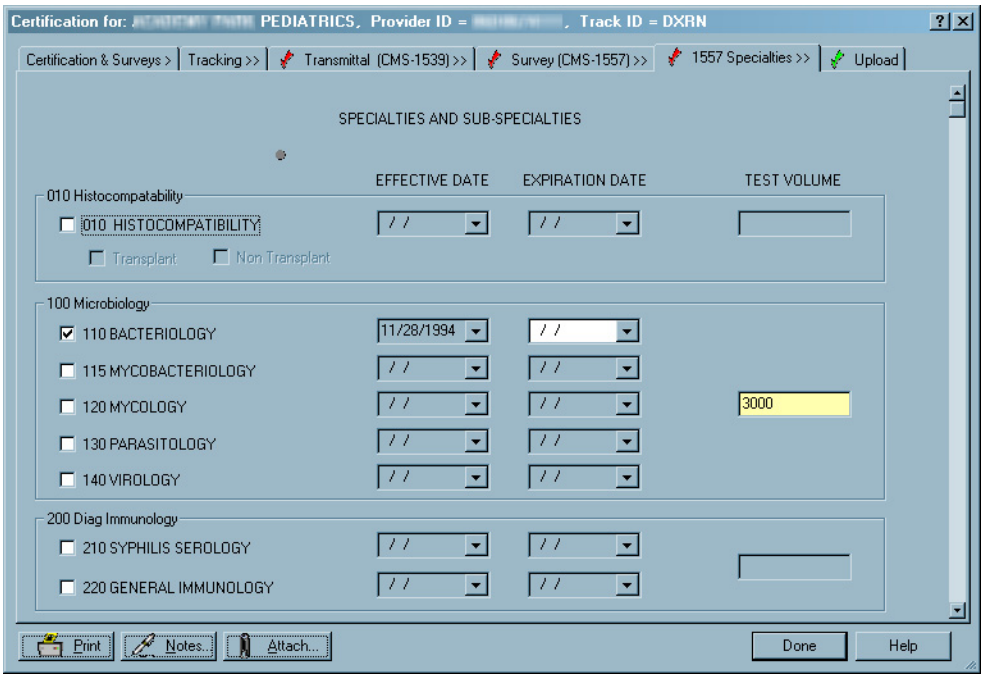


Figure 121: 1557 Specialties tab

Upload tab

When all the information required for upload is entered on a form, the red checkmark on the form's tab changes to green. When all the tabs have green checkmarks and the Facility and CMS-670 Edits button (Certification & Surveys tab) is disabled, the certification kit can be uploaded. The first upload must be manually initiated from the Upload tab. After the first successful upload, certification kits created on or after 07/01/2014 are automatically re-uploaded.

Prior Certification Kit Uploads

The top section of the Upload tab contains action buttons and lists the attempts that have been made to upload the certification kit, with indicators of success or failure.

As in many areas of ACO, you can click a column's heading to sort the list based on that heading. The first sort is by ascending order. Click again to reverse the sort.

Fields: "Upload tab", on page 471

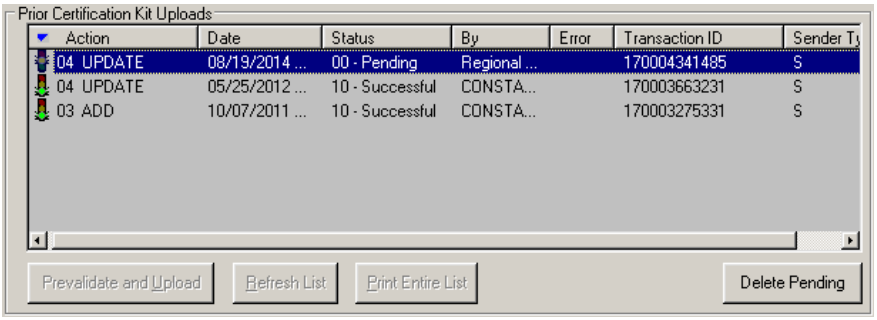


Figure 122: Prior Certification Kit Uploads section of the Upload tab

Upload Transaction Errors

When you click a failed transaction, a lower section opens to provide details about any errors that occurred during either the prevalidation (if manual upload) or the upload.

Fields: "Upload Transaction Errors", on page 472

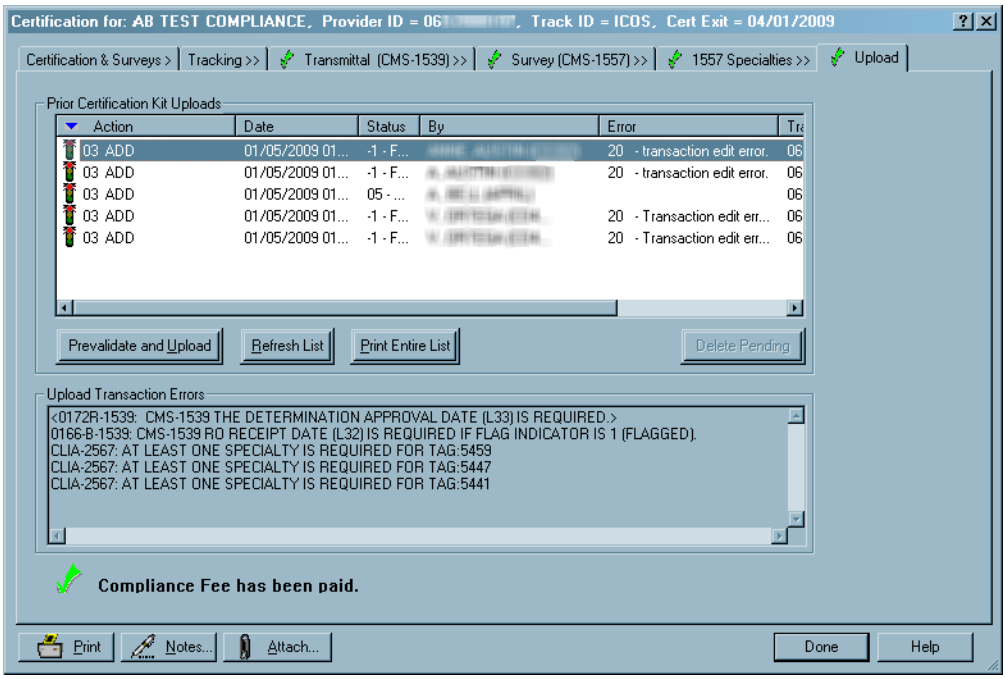


Figure 123: Upload transaction error on the Upload tab

Other Certification Windows

POC Tracking window

The POC Tracking window is available for each survey event listed in the Surveys grid on the Certification & Surveys tab, and in the grid on the 2567/POC/IDR subtab of the Tracking tab. Use it to record the progress of POCs that go through multiple revisions with related correspondence. POC Signoff dates for individual tags are entered in Citation Properties.

Fields: "POC Tracking", on page 473

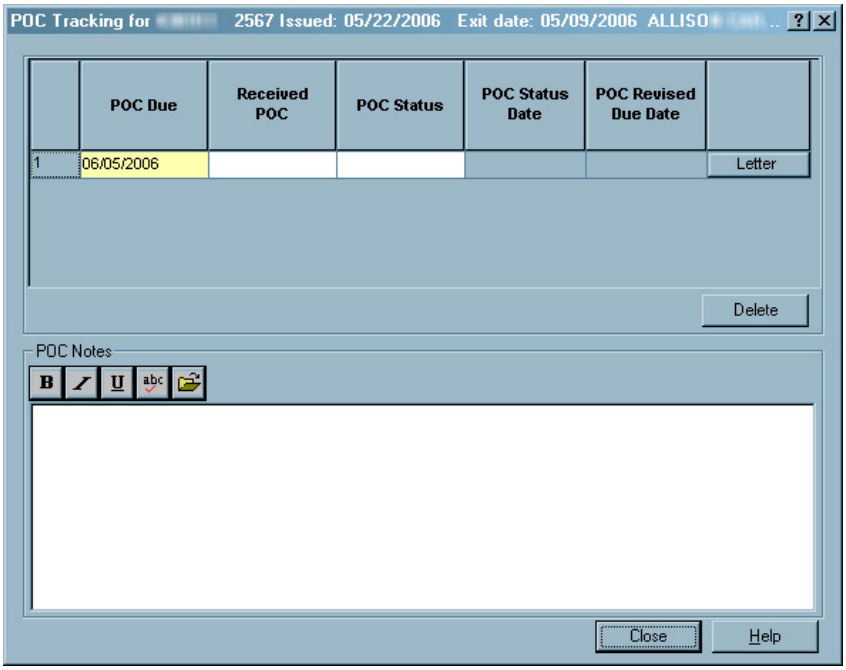


Figure 124: POC Tracking window

Certification Kits window

From the main ACO/ARO menu, select Tracking, then Certifications to see a list of all certification kits. Initial certification are red; recertifications are blue. The list can be filtered by status and date range. The date range filter uses the exit date of the certification kit. You can click a column heading to sort by that column. Double-click a certification to open the kit.

Fields: "Certification Kits (Tracking)", on page 473

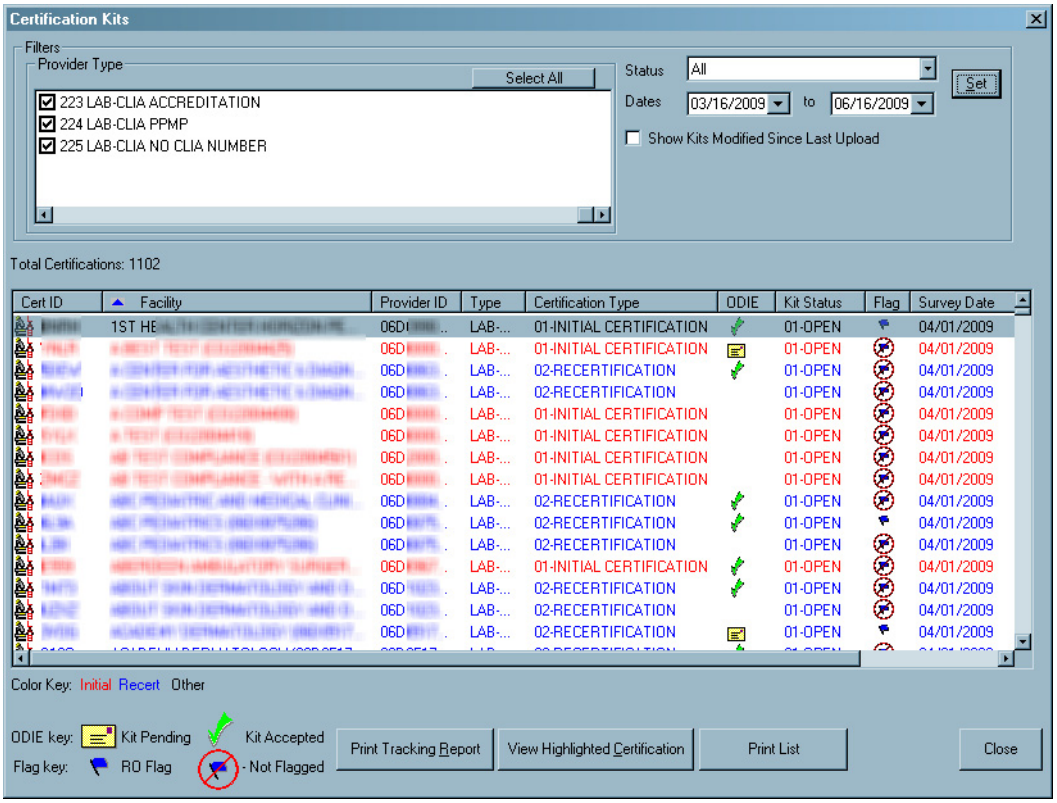


Figure 125: Certification Kits window from the Tracking menu option

Please Specify Transactions window

When you select Transactions from the Tracking menu, this window appears to let you enter a transaction date range and choose which of seven groups of transactions to display.

Fields: "Please Specify Transactions To List", on page 475

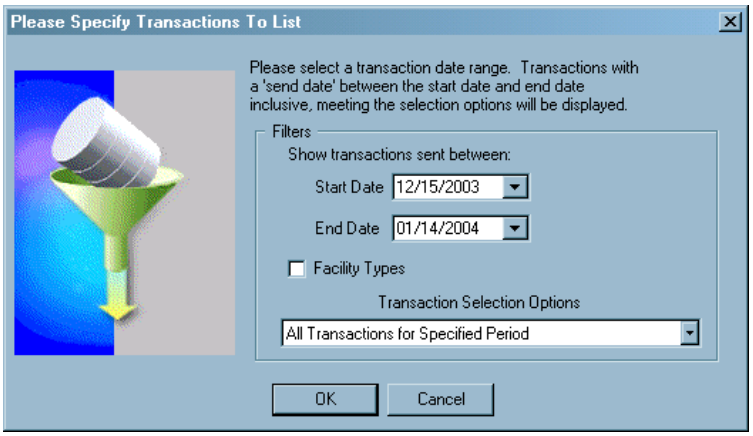


Figure 126: Please Specify Transactions to List window

Transactions window

The Transactions window displays transactions matching the criteria set in the Please Specify Transactions window. Initial certifications are red, recertifications are blue. You can sort this list by any of the column headings. Use the four fields at the top to redefine filtering criteria and sort order; click Refresh List to update the display. Double-click a row or click View Related Certification Kit to display the related certification kit.

Fields: "Transactions", on page 475

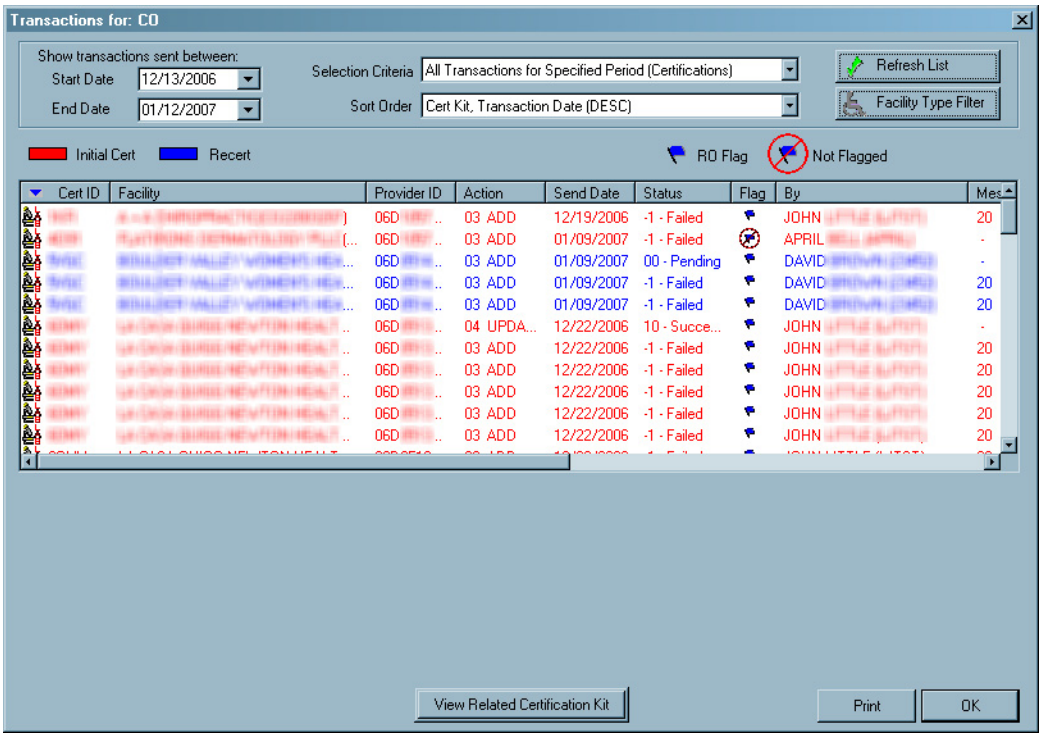


Figure 127: Transactions window

Failed and Overdue Certification Kit Uploads window

The Failed and Overdue Certification Kit Uploads window lists:

- Failed uploads of certification kits
- Certification kits overdue for an upload
- Incomplete certification kits

Fields: "Failed and Overdue Certification Kit Uploads", on page 478

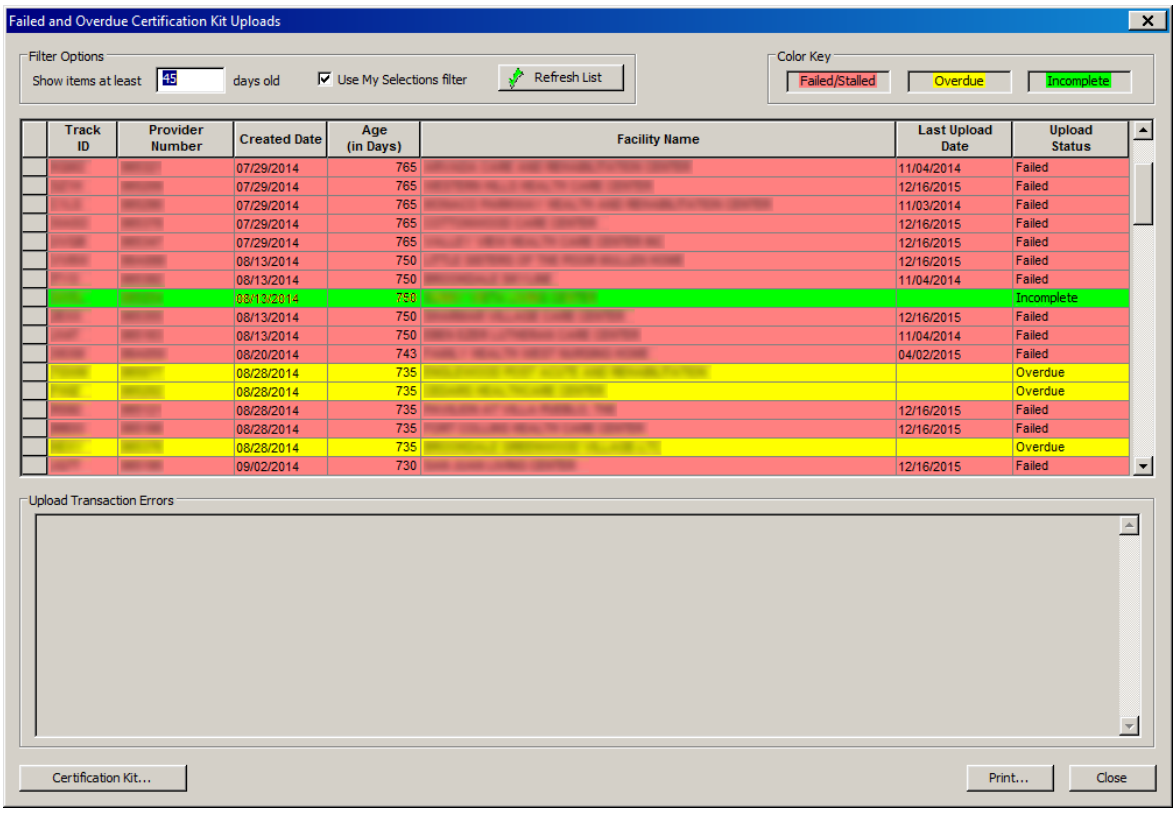


Figure 128: Failed and Overdue Certification Kit Uploads window

Surveys (Merge Surveys) window

Occasionally you may need to merge the information in a survey outside a certification kit with a survey inside the kit. You must have a survey shell already in the kit to receive the information. You cannot merge a standard survey with a revisit or vice versa. Once merged, the survey outside the kit will no longer exist. When applicable, ACO asks if you want to use the Source or the Destination information.

When you right-click a certification kit and select Merge Survey, you will see the following window listing all surveys for the provider not already linked to the certification.

Fields: "Surveys (Merge Surveys)", on page 479

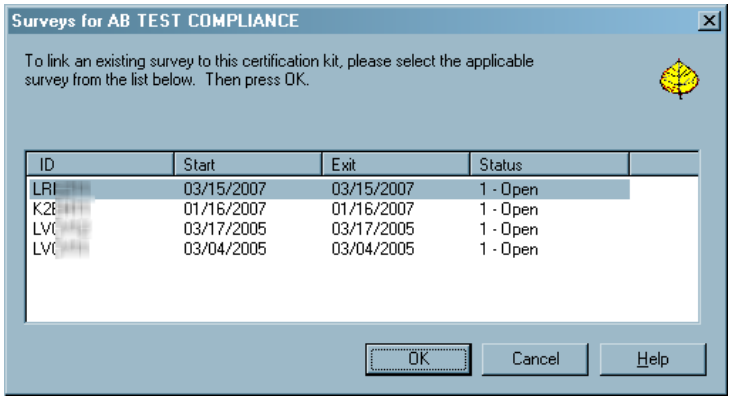


Figure 129: Surveys window

Survey Windows

Create Health Survey/Survey Properties window

When you create a new survey, you enter basic information in this window. You can also view and change information for an existing survey.

Fields: "Create Survey, Survey Properties", on page 481

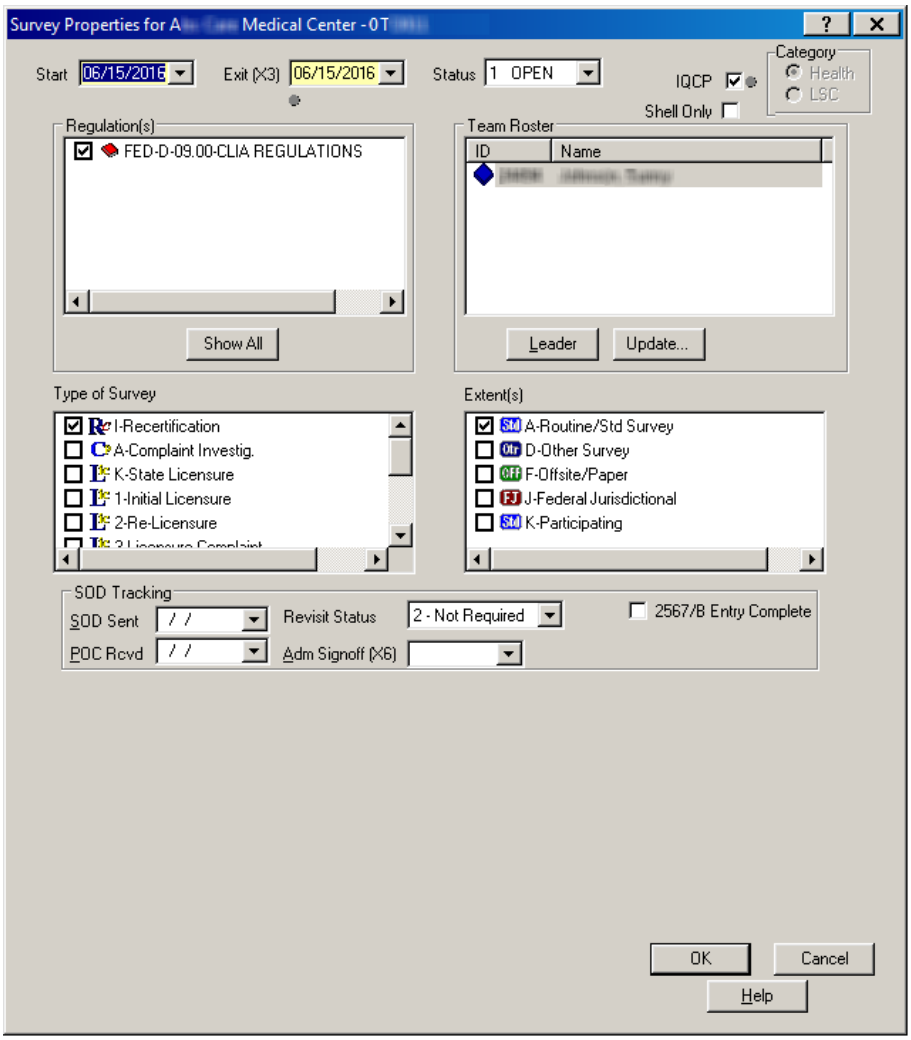


Figure 130: Create Health Survey/Survey Properties window

For special surveys only, there is a Special Survey Tracking section at the bottom of the screen.

Fields: "Special Survey Tracking", on page 485

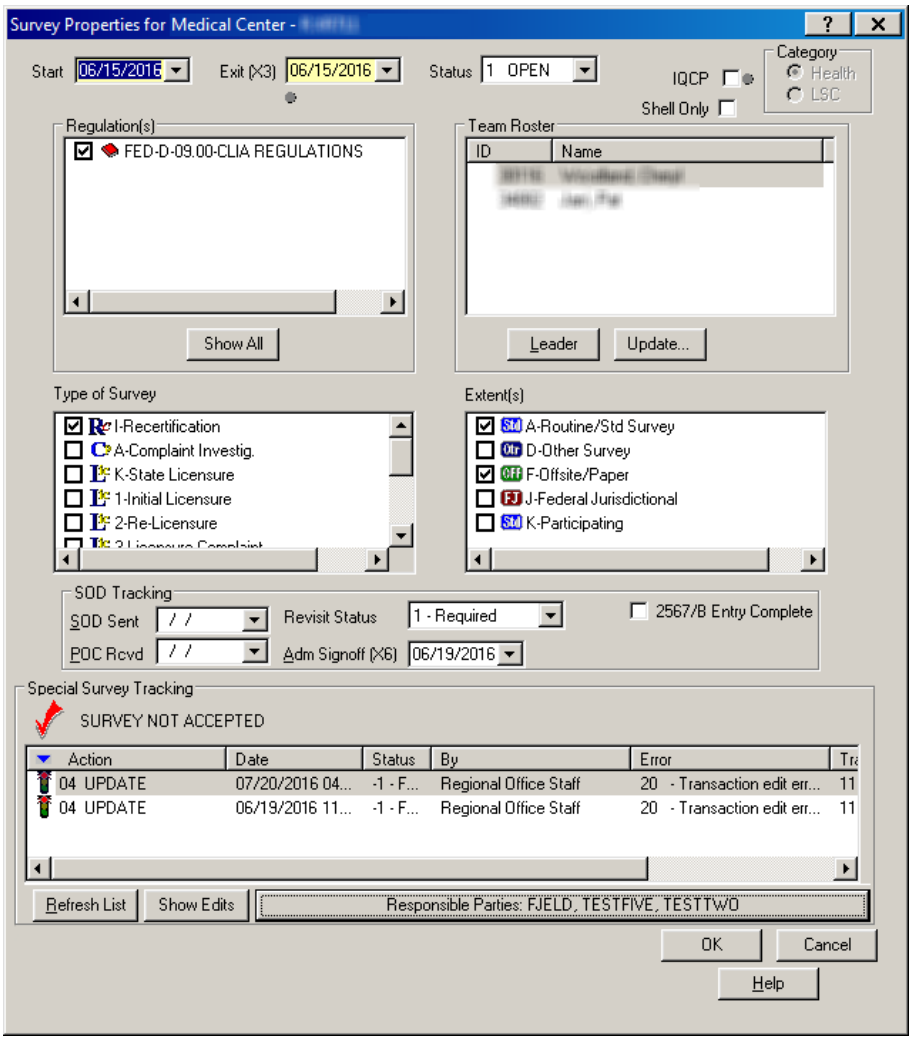


Figure 131: Survey Properties window with Special Survey Tracking section

Citation Manager window

The Citation Manager window lets you enter and modify citations and review the citations entered by other team members, and enter and review remarks. You can view the text or interpretive guidelines of any regulation (tag) and search for any text within the citations, tags, or interpretive guidelines. You can also display and print CMS forms, print customized form letters, and add attachments.

When you add citations to a CLIA lab survey, a 'P' indicates a tag was marked as IQCP. A 'Q' appended to a tag indicates it was flagged for QC exclusion prior to 01/01/16. The Repeat Deficiencies button opens a list of tags cited in previous surveys that match tags cited in the current survey.

Fields: "Citation Manager", on page 486

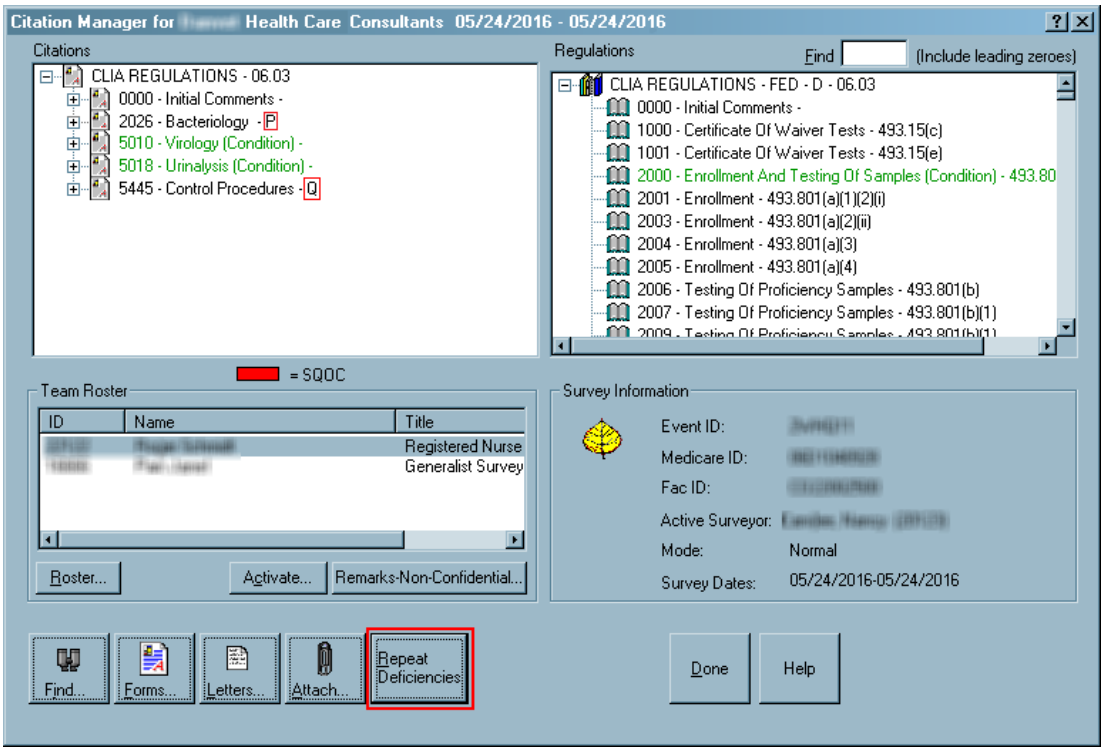


Figure 132: Citation Manager window

Citation Properties window

This window opens whenever you cite a new tag in Citation Manager. You can make changes to citation properties later by right-clicking the tag in Citation Manager and selecting Citation Properties from the menu.

The fields you see vary depending on the properties of the survey. For CLIA labs, the Specialties button is included to let you enter associated specialty information; it is enabled only for tags that require specialty info. The IQCP checkbox appears only for D-tags that are IQCP-eligible. If a tag was marked as QC exclusion prior to 01/01/16, the QC Exclusion checkbox appears.

Fields: "Citation Properties", on page 489

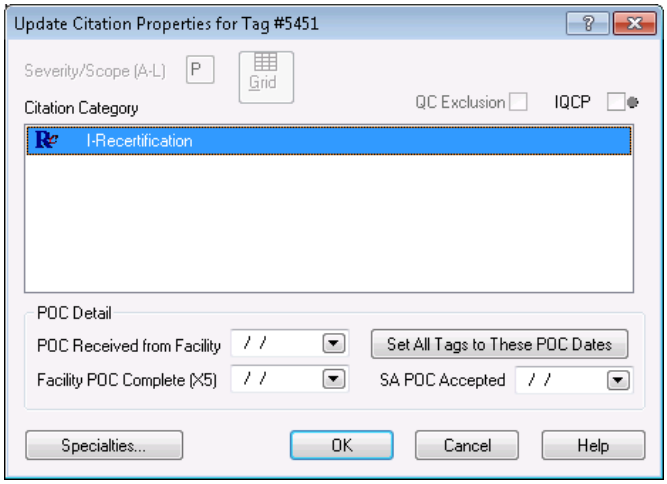


Figure 133: Citation Properties window

The Refused field is included for citations assigned any CLIA special survey type.

Fields: "Citation Properties", on page 489

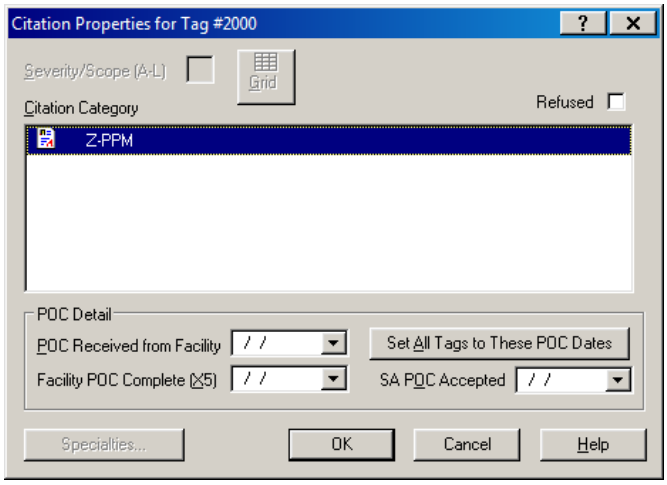


Figure 134: Citation Properties window - CLIA special survey

Repeat Deficiencies window

For CLIA labs, the Citation Manager provides access to a list of repeat deficiencies from previous surveys that used the same regulation set as the current survey. You can view citation text to determine if a tag is cited on the current survey for the same reason it was cited previously. You can also view regulation text and interpretive guidelines for each previously cited tag.

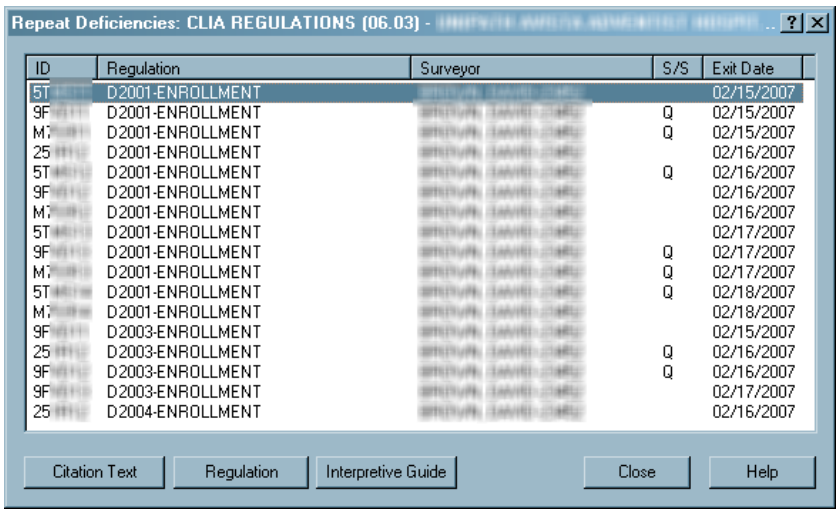


Figure 135: Repeat Deficiencies window

Survey Attachment Documents window

You can attach documents, photographs, or any other relevant files to surveys by clicking Attach in Citation Manager. In addition to attaching files to individual surveys, you can attach files at the provider level by expanding the provider node in Tree view and right-clicking the Attachments node.

Fields: "Survey Attachment Documents", on page 491

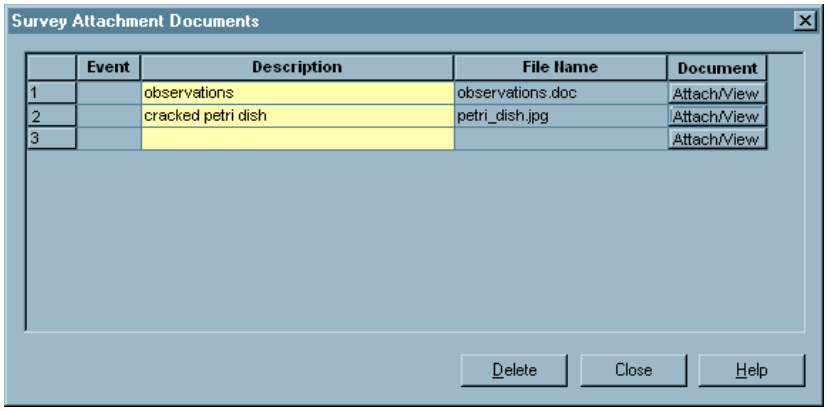


Figure 136: Survey Attachment Documents window

Select Form(s) to Print window

The Select Form(s) to Print window lists standard CMS forms that ACO/ARO can generate. You can generate one or more forms at a time.

Fields: "Select Form(s) to print", on page 491

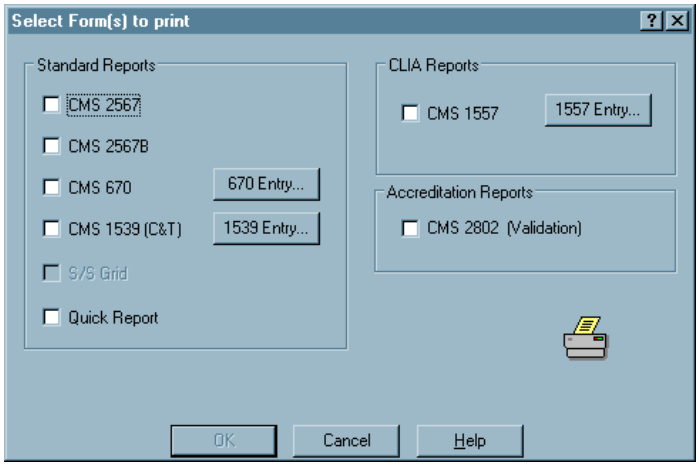


Figure 137: Select Form(s) to Print window

Note: The CMS 2802 (Validation) checkbox is enabled only for validation surveys.

Staff Availability List window

You access this window from the Update button on Survey Properties and Citation Manager windows, and from the Team Roster right-click option for an individual survey. Use it to select the surveyors for the survey team. The list of staff members is filtered by the Work Unit setting in the current My Selections set.

It is also filtered by the Facility Type setting in the current My Selections set and by Allowed Facility Types in the Enter/Update Surveyor window, so that only active surveyors who are eligible to work on currently displayed facility types are included *if and only if*:

Note: "Use facility types of active selection" is selected on the Scheduling tab of My Preferences in AST. It is deselected by default, so you must select it and then click Save Settings. If the "Use facility types" option isn't selected in AST, the list of staff members in the Staff Availability List window is not filtered at all by provider type.

You can add out-of-state and other special surveyors if your state allows it.

A message appears if you select a staff member whose General Staff Type is 02 Clerical/Support in the Enter/Update Surveyor Information window. You can choose whether to go ahead and add that staff member or not.

Fields: "Staff Availability List", on page 493

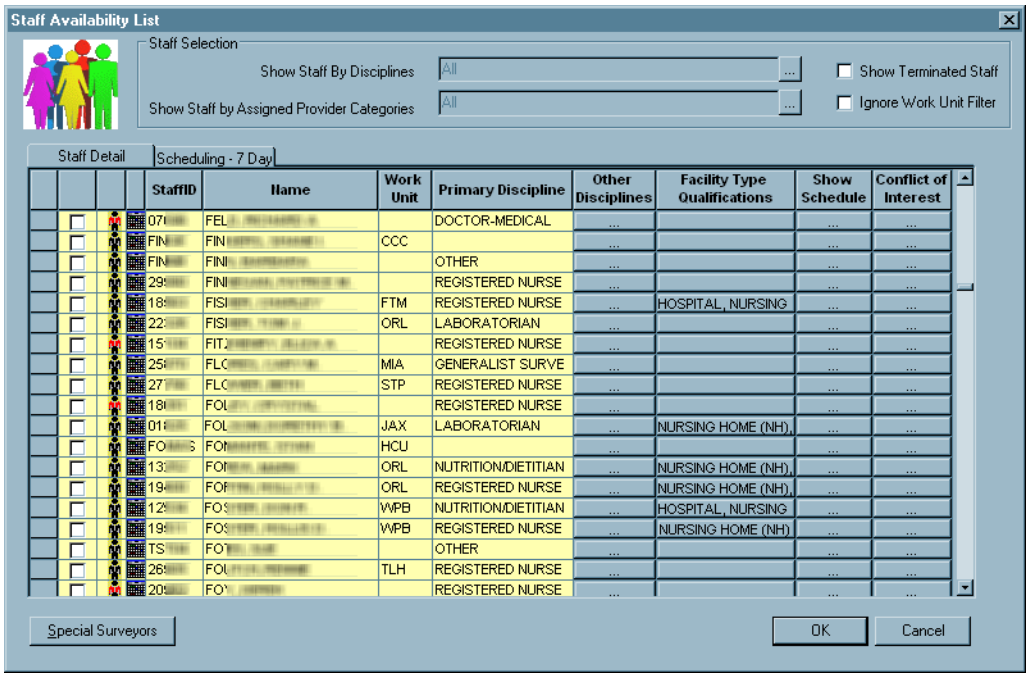
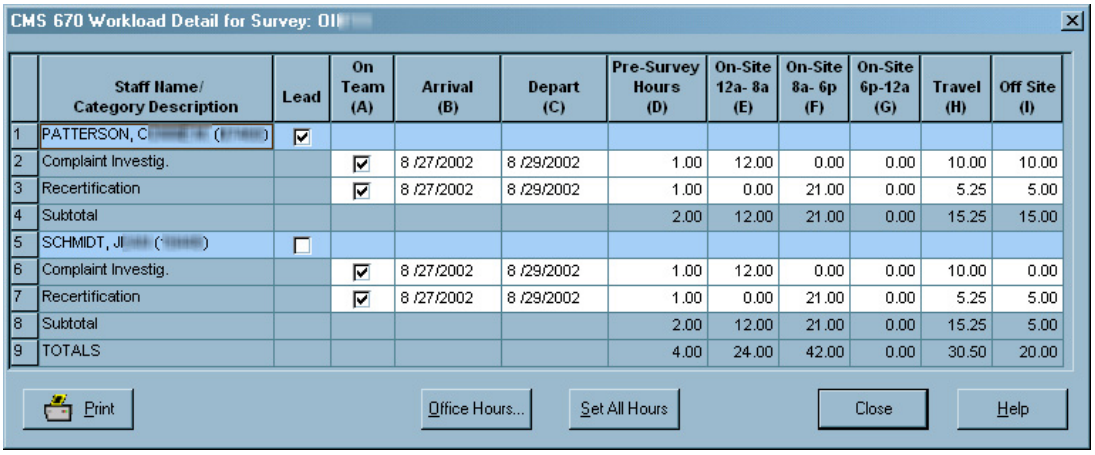


Figure 138: Staff Availability window

CMS 670 Workload Detail window

Enter the time that surveyors spent preparing for and/or conducting a survey—onsite during different shifts, offsite, and traveling. The graphic below shows a combined CMS-670, with hours entered for each surveyor for each survey category. When a certification kit is uploaded, only certification hours are included in the upload.

Fields: "CMS 670 Workload Detail", on page 495



	Staff Name/ Category Description	Lead	On Team (A)	Arrival (B)	Depart (C)	Pre-Survey Hours (D)	On-Site 12a- 8a (E)	On-Site 8a- 6p (F)	On-Site 6p-12a (G)	Travel (H)	Off Site (I)
1	PATTERSON, C	☑									
2	Complaint Investig.		☑	8 /27/2002	8 /29/2002	1.00	12.00	0.00	0.00	10.00	10.00
3	Recertification		☑	8 /27/2002	8 /29/2002	1.00	0.00	21.00	0.00	5.25	5.00
4	Subtotal					2.00	12.00	21.00	0.00	15.25	15.00
5	SCHMIDT, J	☐									
6	Complaint Investig.		☑	8 /27/2002	8 /29/2002	1.00	12.00	0.00	0.00	10.00	0.00
7	Recertification		☑	8 /27/2002	8 /29/2002	1.00	0.00	21.00	0.00	5.25	5.00
8	Subtotal					2.00	12.00	21.00	0.00	15.25	5.00
9	TOTALS					4.00	24.00	42.00	0.00	30.50	20.00

Figure 139: CMS-670 Workload Detail window

Create Followup window

Creates a followup survey (revisit) to the survey where non-compliance was found.

Fields: "Create Followup", on page 497

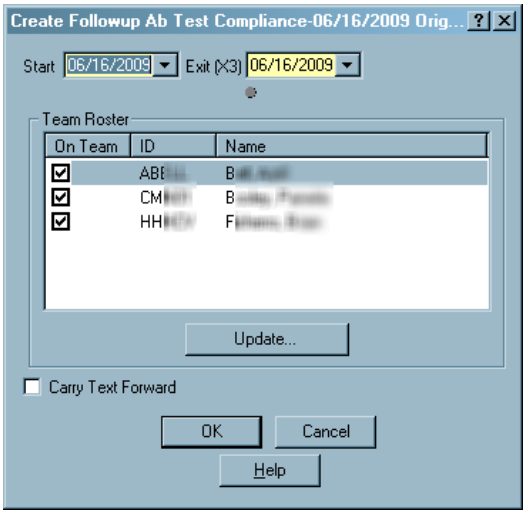


Figure 140: Create Followup Survey window

Failed and Overdue Special Survey Uploads window

The Failed and Overdue Special Survey (SRVY) Uploads window lists:

- Failed special survey uploads
- Special surveys overdue for a SRVY upload
- Incomplete special surveys

Fields: "Failed and Overdue Special Survey Uploads", on page 497

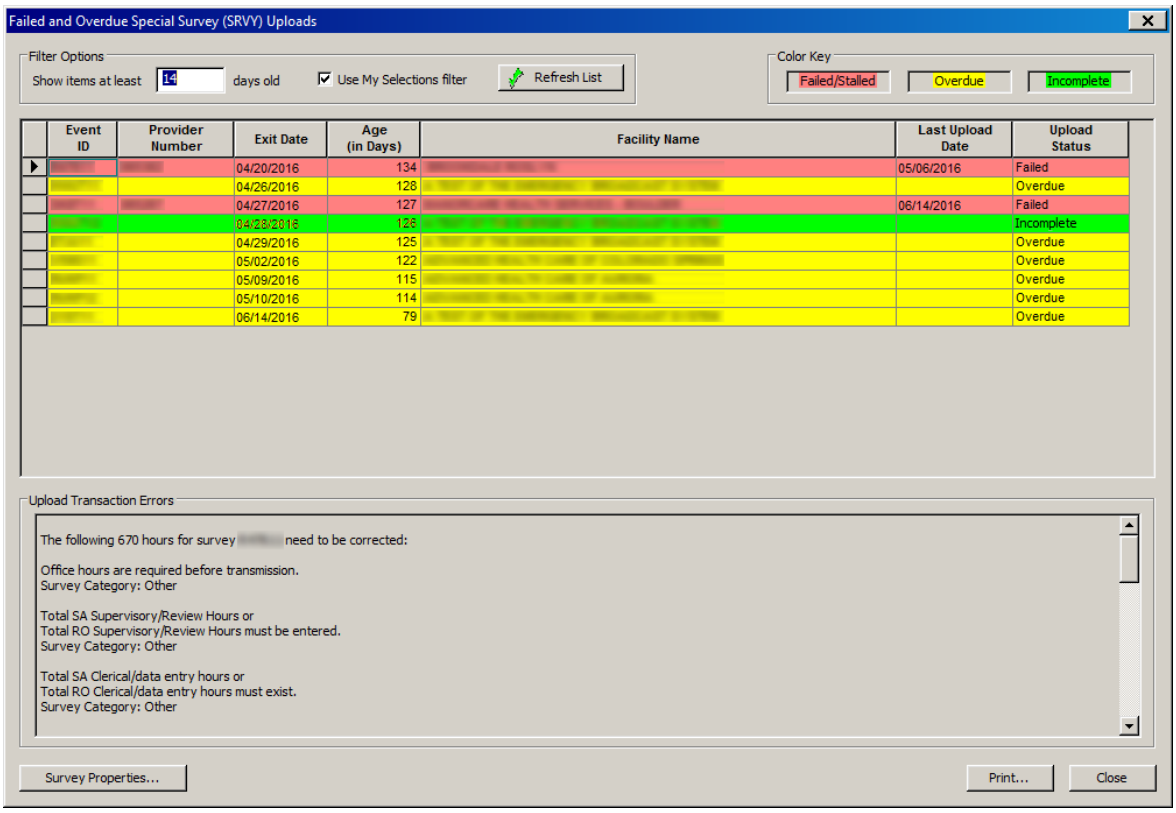


Figure 141: Failed and Overdue Special Survey (SRVY) Uploads window

FMS Tracking window - ARO

The FMS Tracking window, available only in ARO, provides a central point for monitoring all aspects of FMS events. Use this window to track FMS events and as the access point to add, modify, upload, and delete FMS records.

Fields: "FMS Tracking", on page 498

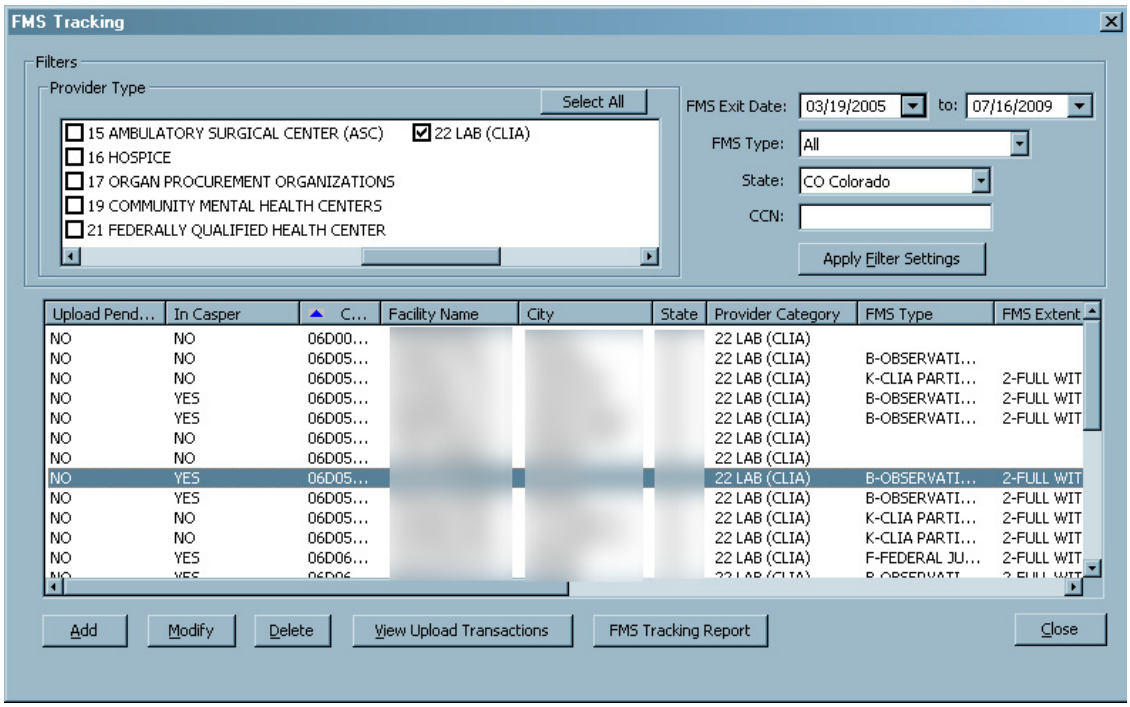


Figure 142: FMS Tracking window

FMS Add/Update window - ARO

The FMS Add/Update window, which is available only in ARO, lets you capture, view, and modify information for individual FMS events.

Fields: "FMS Add/Update", on page 500

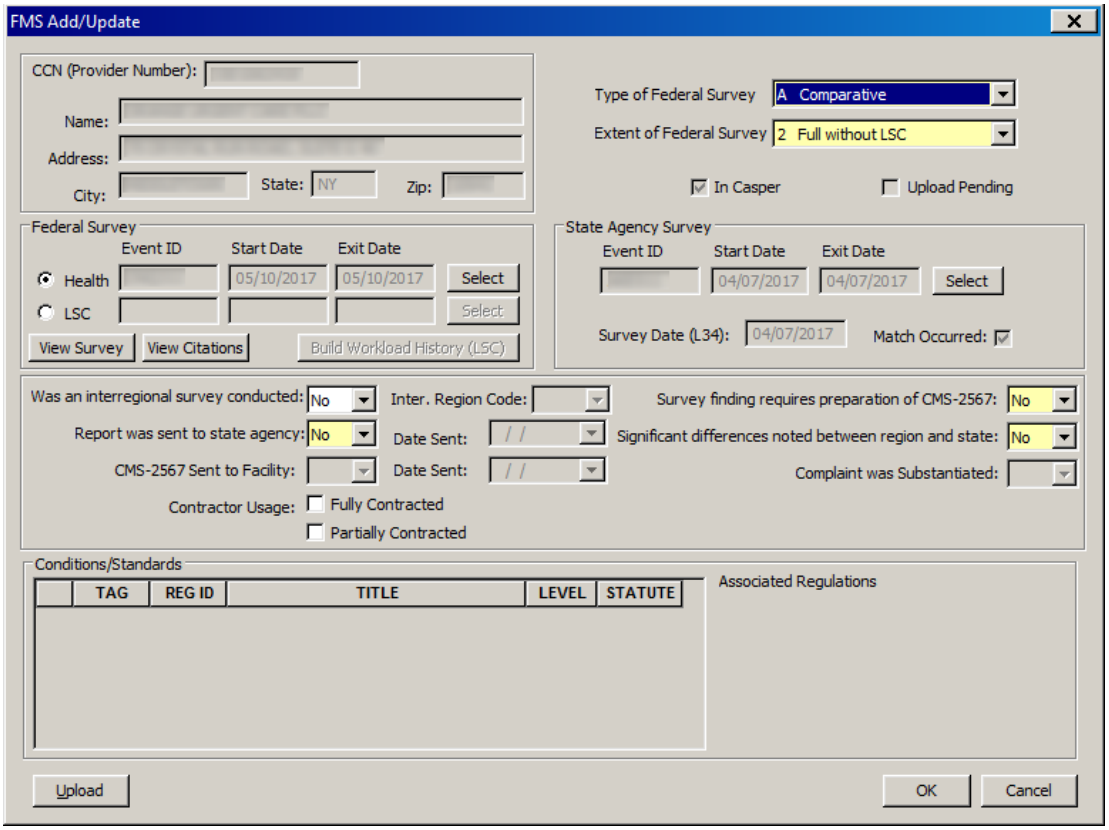


Figure 143: FMS Add/Update window

Data Transfer Windows

Export window

You can export any survey you select to a Transfer Location. From there, surveyors can import the survey into ASE-Q.

TIP: You can export surveys back to ACO/ARO (or ACTS) from ASE-Q. Prompts will ask you to verify any items that differ between source and destination, e.g., extents, when you export from ASE-Q to ACO/ARO or ACTS.

Fields: "Export", on page 503

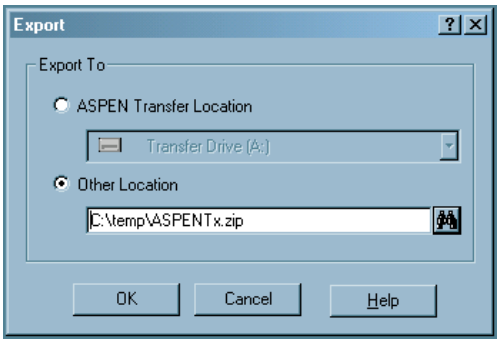


Figure 144: Export window

Survey Export window

Use this window to indicate which survey(s) to export to the specified destination. The title bar indicates the Source of the listed survey(s) and the export Destination, ACO/ACTS and Transfer File respectively in the example below.

Fields: "Survey Export", on page 504

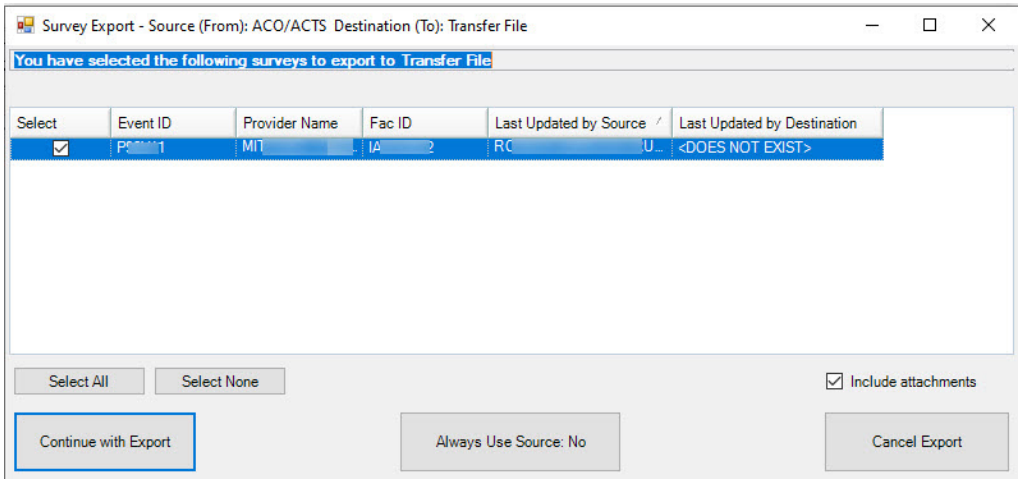


Figure 145: Survey Export window

Import window - ACO/ARO

You can select the Import icon on the ACO/ARO toolbar to import surveys and regulations from a Transfer Location into ACO/ARO. The Import window is used to specify what you are importing and its location.

Fields: "Import - ACO/ARO", on page 504

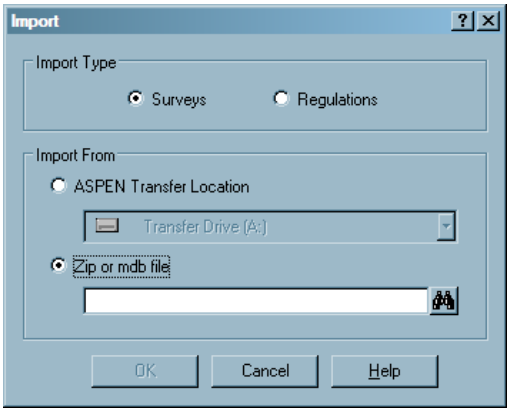


Figure 146: Import window - ACO/ARO

Import window - ASE-Q

You can select the Import icon on the ASE-Q toolbar to import surveys and regulations from a Transfer Location into ASE-Q. The Import window is used to specify what you are importing and its location.

Fields: "Import - ASE-Q", on page 505

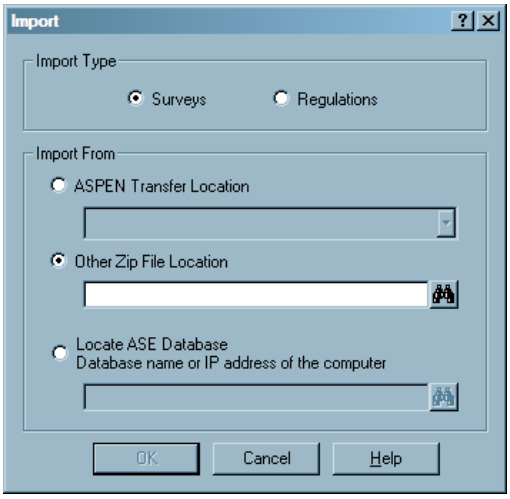


Figure 147: Import Window - ASE-Q

Notices Windows

Notices History

The Notices History window shows letters and notifications that have been sent related to the current certification kit or when you right click on a survey, select Print Letters and click View Letter History. You can also generate new letters and notices from this window.

Fields: "Notices History", on page 505

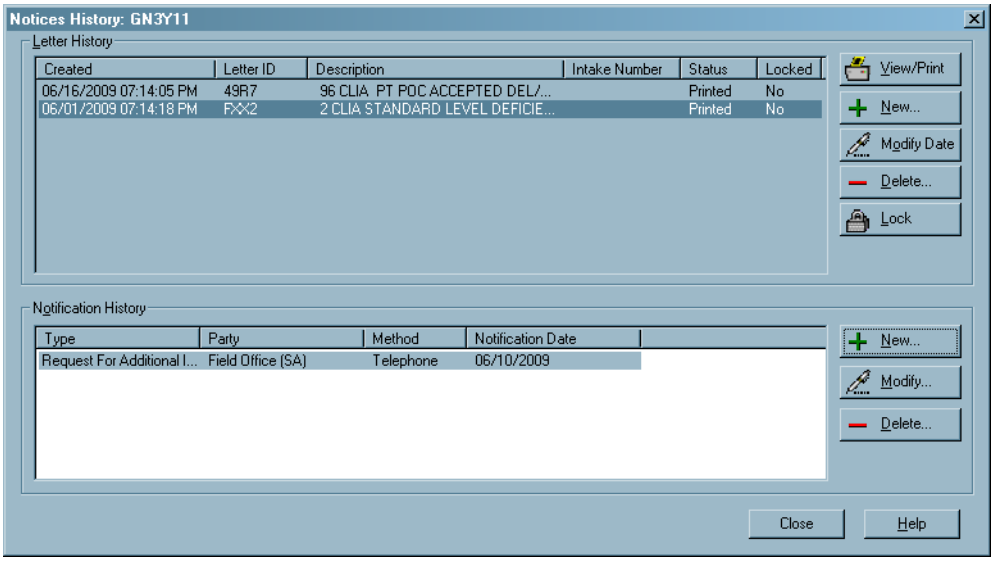


Figure 148: Notices History window

Select Letters and Distribution Lists window

This window opens when you right-click a survey in Tree view, select Print Letters, then Generate New Letter; or click Letters... in the Citation Manager, then click Generate New Letter in the Letter Selection window. The top pane lists the form letters that ACO can generate, and the lower pane lists potential recipients. You select the letter you want to send and its recipient(s), and use Set Action to indicate whether each recipient receives a letter, a copy (CC), or a blind copy (BCC). You can preview the letter before printing it.

TIP: If you open this window from a survey or the Citation Manager, the default display is of Survey letters for the current provider type. Select the Show All checkbox to list all letters.

Fields: "Select Letters and Distribution Lists", on page 506

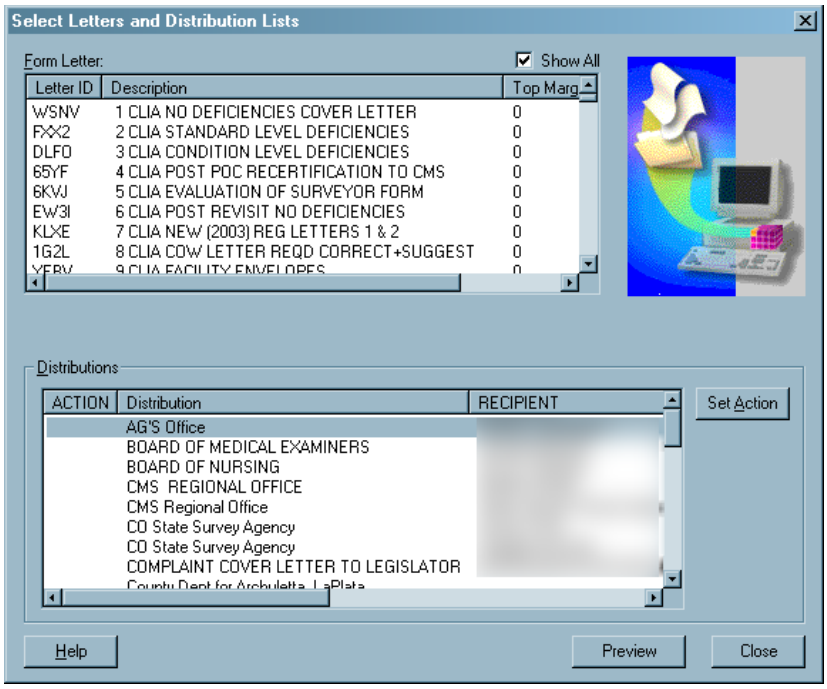


Figure 149: Select Letters and Distribution Lists window

Notification Type window

When you click New in the Notification History section of the Notices History window, you'll be asked to supply details about the notification. All fields are required.

Fields: "Notification Type", on page 507

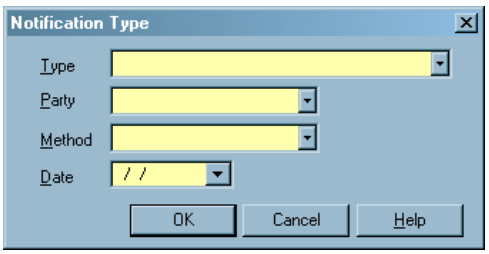


Figure 150: Notification Type window

Letter word processor

This full-featured word processor is used to create and modify the content of:

- New letter templates (WP Ver = New)
- Custom letters generated from new letter templates

Fields: "Letter word processor", on page 507

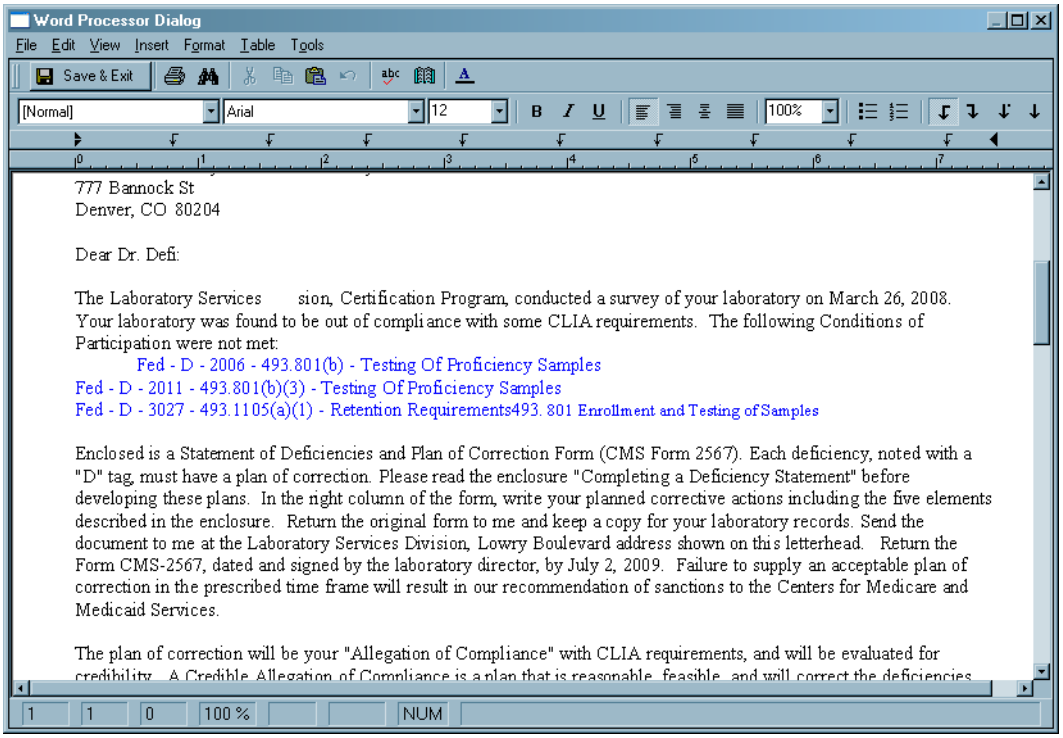


Figure 151: Letter word processor

For letter templates, the window title is Edit Letter Text. For custom letters, the title is Word Processor Dialog.

This word processor includes a variety of formatting options. You can specify margins, create headers and footers, and add logos directly to the letter.

Note: When a user previews a custom letter in this word processor, the Macros field is not displayed.

Other Windows

Find window

The Find window lets you search the database for providers, certifications, surveys, enforcement cases, etc. using the search criterion of your choice. You can choose whether to include closed facilities in the results. The name of the window varies depending on where you open it from.

ARO - When you search for a CLIA lab by CCN (aka CLIA #/number, CLIA provider number, Medicare provider number, provider #/number), Search Results will list all states in which ACO has a record of it having existed. The most current record will be indicated. When you select a lab in the list, you will be switched to the appropriate state database.

Fields: "Find", on page 509

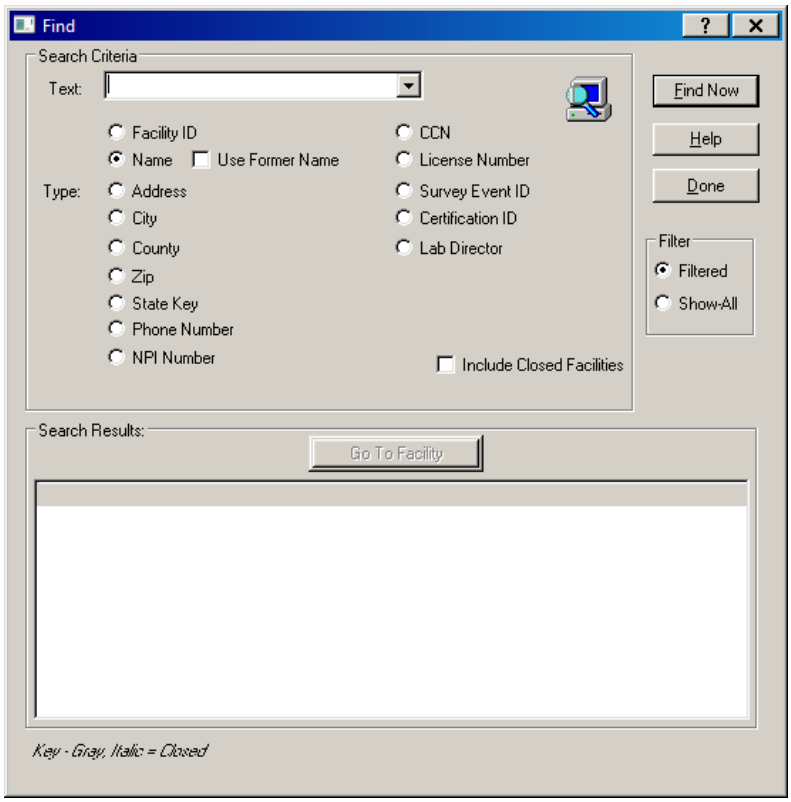


Figure 152: Find window

Action Item Filter Settings window

Use this window to specify filter settings for the display of action items.

Fields: "Action Item Filter Settings", on page 510

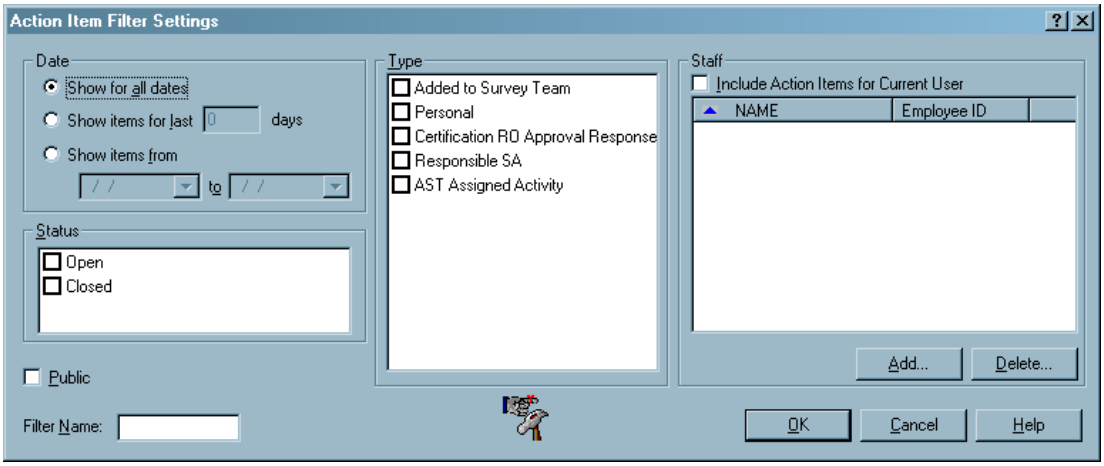


Figure 153: Action Item filter settings window

ASPEN word processor

This word processor has basic formatting features. Use it to:

- Enter supporting text or comments, e.g., citation text, notes.
- Modify content of custom letters generated from old letter templates (WP Ver = Old).

The title of the ASPEN word processor window as well as layout and options vary somewhat depending on what you use it for. The example below is the word processor you see when you click Notes... at the bottom of the Certification window.

Fields: "ASPEN word processor", on page 511

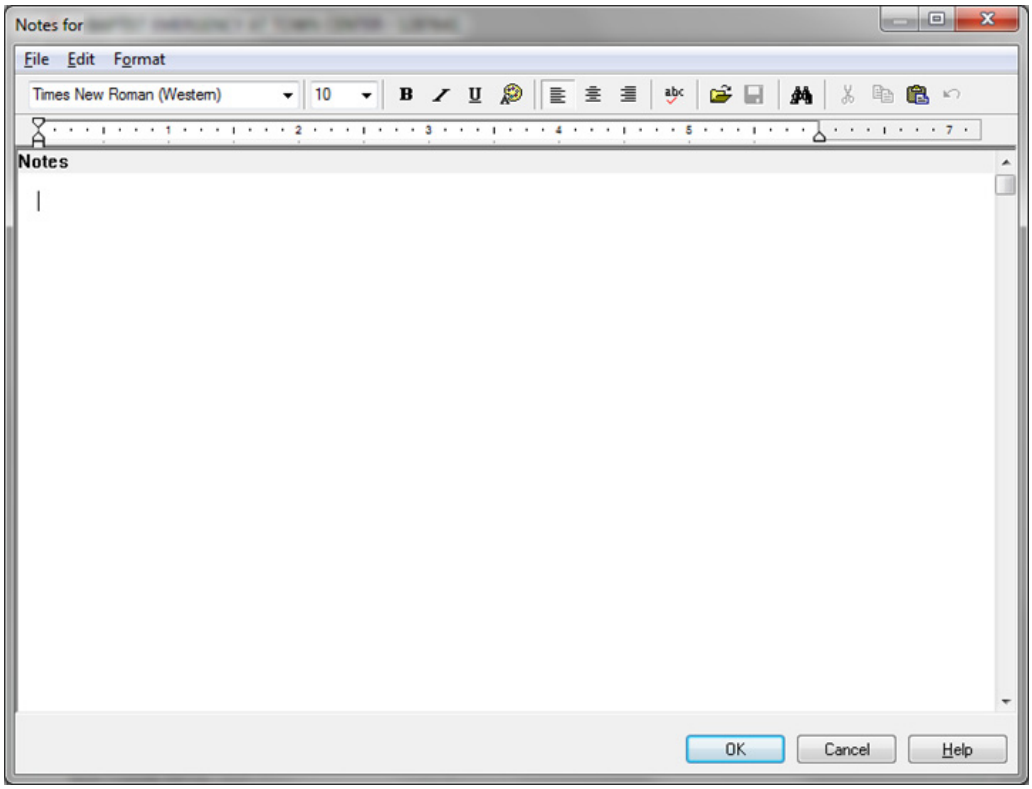


Figure 154: ASPEN word processor

Note: When content is copied and pasted from an external word processor such as Word, RTF formatting is automatically stripped out and the content is pasted as plain text into the ASPEN word processor where you can format it as desired.

You cannot cut text from or paste text into a read-only word processor pane. For example, you cannot cut or paste in the Regulations or Interpretive Guidelines panes of the Citation word processor. You can, however, copy text from a read-only pane and paste it into an editable pane. Editable WP panes are white, read-only are various colors.

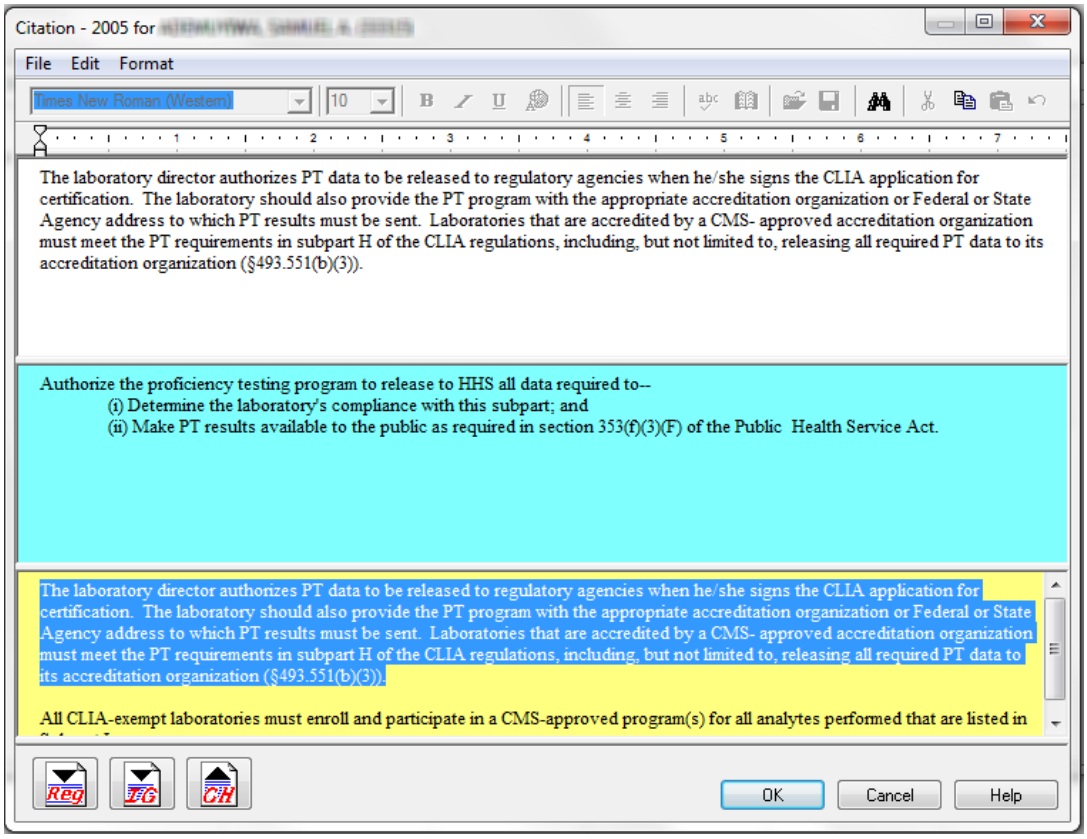


Figure 155: Citation word processor panes

Note: Although an unlimited amount of text can be entered in the word processor, there is a limit of 128K of citation text per tag (approximately 80 printed pages) that can print on the CMS-2567 and related forms.

CLIA Maintenance Windows

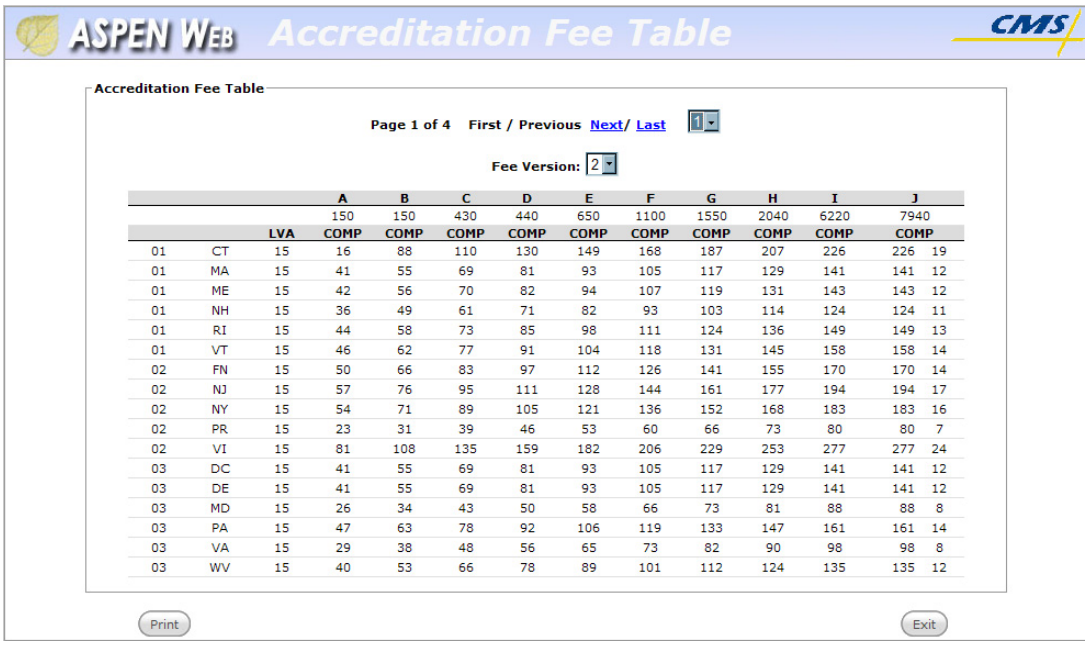
The CLIA Maintenance application provides access to the following items for users with appropriate permissions:

- Accreditation Fee Table
- Compliance/Certificate Fee Table
- State Agency List
- PT Program Maintenance
- PT Analyte Maintenance
- PT Program Analyte Maintenance
- PT Enrollment Inquiry
- PT Score Inquiry
- PT File Upload

Accreditation Fee Table

Central Office personnel can open the Accreditation Fee Table to display a read-only list of all entries in the CLIA State Fee view for the latest version number.

Fields: "Accreditation Fee Table", on page 512



			A	B	C	D	E	F	G	H	I	J	
			150	150	430	440	650	1100	1550	2040	6220	7940	
		LVA	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	
01	CT	15	16	88	110	130	149	168	187	207	226	226	19
01	MA	15	41	55	69	81	93	105	117	129	141	141	12
01	ME	15	42	56	70	82	94	107	119	131	143	143	12
01	NH	15	36	49	61	71	82	93	103	114	124	124	11
01	RI	15	44	58	73	85	98	111	124	136	149	149	13
01	VT	15	46	62	77	91	104	118	131	145	158	158	14
02	FN	15	50	66	83	97	112	126	141	155	170	170	14
02	NJ	15	57	76	95	111	128	144	161	177	194	194	17
02	NY	15	54	71	89	105	121	136	152	168	183	183	16
02	PR	15	23	31	39	46	53	60	66	73	80	80	7
02	VI	15	81	108	135	159	182	206	229	253	277	277	24
03	DC	15	41	55	69	81	93	105	117	129	141	141	12
03	DE	15	41	55	69	81	93	105	117	129	141	141	12
03	MD	15	26	34	43	50	58	66	73	81	88	88	8
03	PA	15	47	63	78	92	106	119	133	147	161	161	14
03	VA	15	29	38	48	56	65	73	82	90	98	98	8
03	WV	15	40	53	66	78	89	101	112	124	135	135	12

Figure 156: Accreditation Fee Table

Compliance/Certificate Fee Table

Central Office personnel can open the Compliance/Certificate Fee Table to review compliance and certificate fee information for the latest version.

Fields: "Compliance/Certificate Fee Table", on page 513

ASPEN WEB Compliance/Certificate Fee Table CMS

Compliance/Certificate Fee Table

Page 1 of 4 First / Previous Next/ Last 1

Fee Version: 2 Cert. Of. Reg: 100 Waiver: 150 Microscopy: 200

			A	B	C	D	E	F	G	H	I	J	
			150	150	430	440	650	1100	1550	2040	6220	7940	
		LVA	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	COMP	
01	CT	300	323	1764	2206	2591	2977	3363	3749	4135	4521	4521	386
01	MA	300	824	1099	1374	1614	1855	2095	2335	2576	2816	2816	240
01	ME	300	838	1118	1397	1642	1887	2131	2376	2620	2865	2865	245
01	NH	300	728	971	1214	1426	1639	1851	2064	2276	2489	2489	212
01	RI	300	872	1162	1453	1707	1962	2216	2470	2725	2979	2979	254
01	VT	300	926	1235	1543	1813	2083	2353	2623	2894	3164	3164	270
02	FN	300	993	1323	1654	1944	2233	2523	2812	3102	3391	3391	289
02	NJ	300	1134	1512	1891	2221	2552	2883	3214	3545	3876	3876	331
02	NY	300	1072	1429	1786	2099	2412	2724	3037	3350	3662	3662	313
02	PR	300	469	625	781	918	1054	1191	1328	1464	1601	1601	137
02	VI	300	1620	2159	2699	3172	3644	4116	4589	5061	5533	5533	472
03	DC	300	828	1104	1380	1621	1863	2104	2346	2587	2829	2829	241
03	DE	300	827	1102	1378	1619	1860	2101	2343	2584	2825	2825	241
03	MD	300	515	687	859	1009	1159	1310	1460	1610	1761	1761	150
03	PA	300	940	1253	1567	1841	2115	2389	2663	2937	3212	3212	274
03	VA	300	576	767	959	1127	1295	1463	1631	1799	1967	1967	168
03	WV	300	793	1057	1321	1553	1784	2015	2246	2477	2709	2709	231

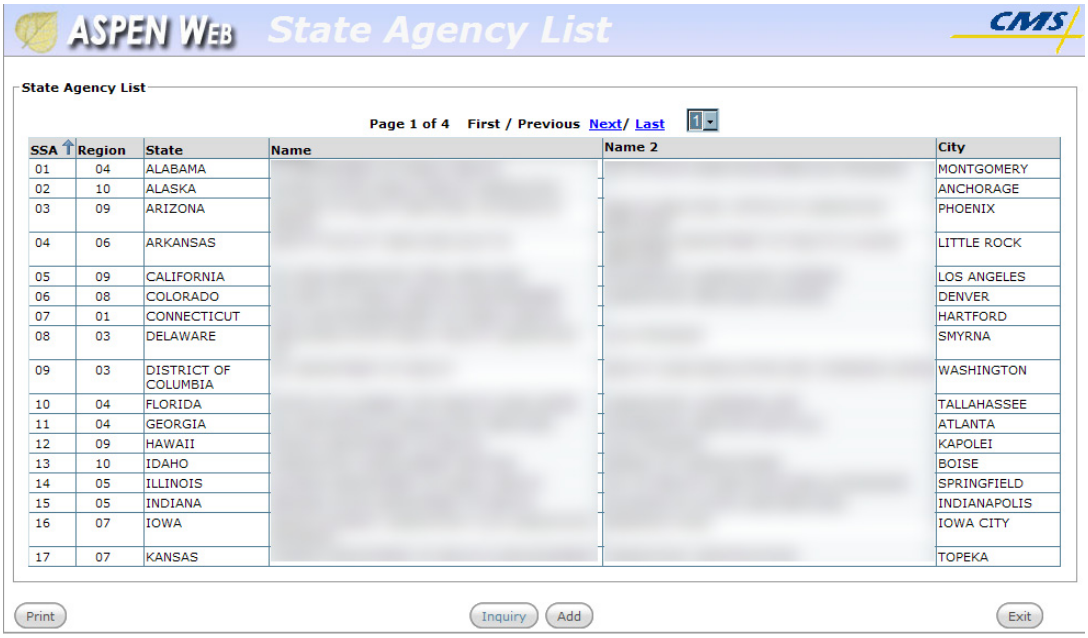
Print Exit

Figure 157: Compliance/Certificate Fee Table

State Agency List

The State Agency List displays state agency information used on correspondence to labs. CO Super Users can update and add records as necessary.

Fields: "State Agency List", on page 514



SSA	Region	State	Name	Name 2	City
01	04	ALABAMA			MONTGOMERY
02	10	ALASKA			ANCHORAGE
03	09	ARIZONA			PHOENIX
04	06	ARKANSAS			LITTLE ROCK
05	09	CALIFORNIA			LOS ANGELES
06	08	COLORADO			DENVER
07	01	CONNECTICUT			HARTFORD
08	03	DELAWARE			SMYRNA
09	03	DISTRICT OF COLUMBIA			WASHINGTON
10	04	FLORIDA			TALLAHASSEE
11	04	GEORGIA			ATLANTA
12	09	HAWAII			KAPOLEI
13	10	IDAHO			BOISE
14	05	ILLINOIS			SPRINGFIELD
15	05	INDIANA			INDIANAPOLIS
16	07	IOWA			IOWA CITY
17	07	KANSAS			TOPEKA

Figure 158: State Agency List

State Agency Address - Update window

The State Agency Address - Add, Update, and Inquiry windows have the same fields, but all fields on the Inquiry window are read-only.

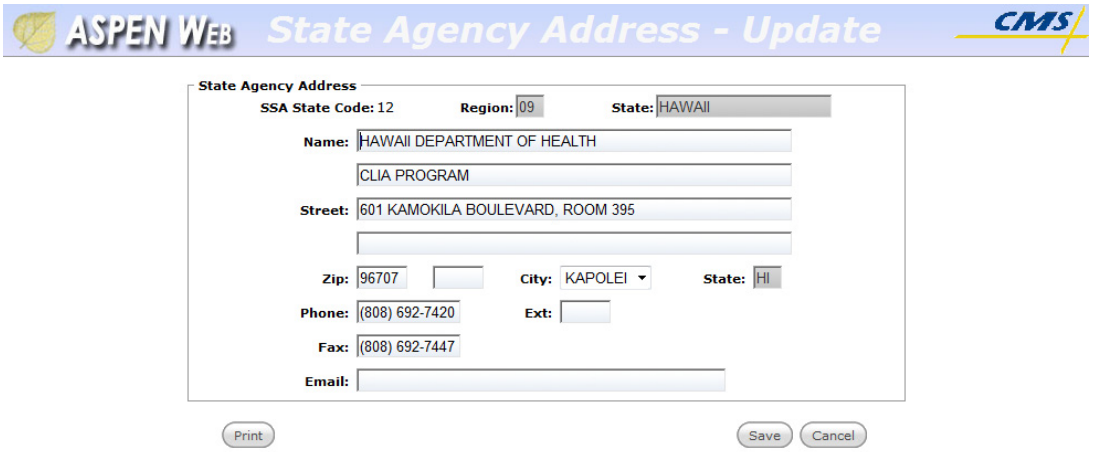


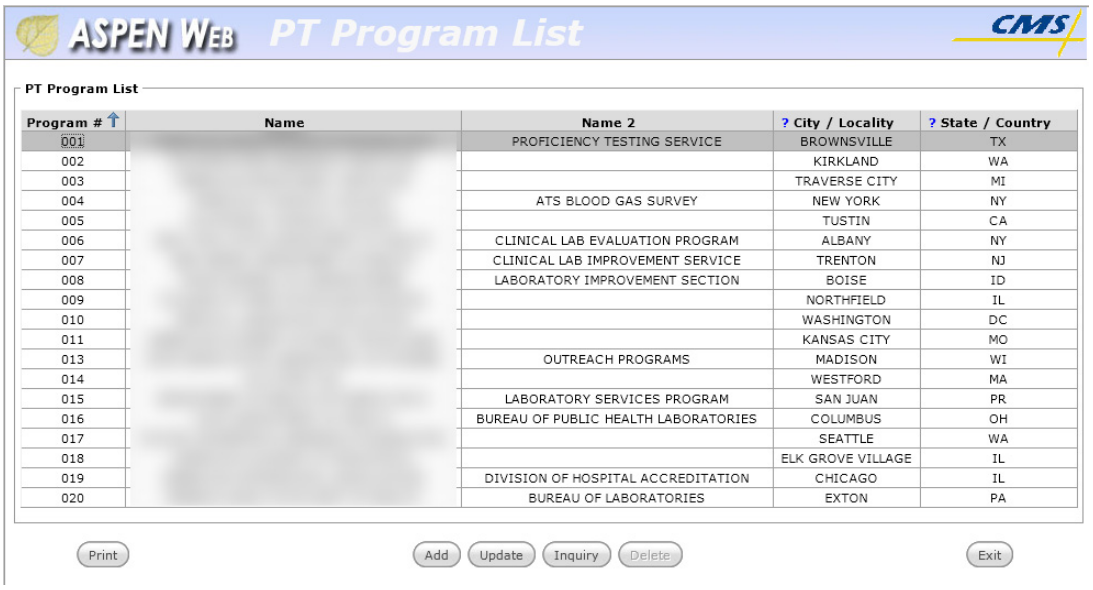
Figure 159: State Agency Address - Update window

PT Program List

The PT Program List displays PT Program name and address information. CO Super Users can update and add records as necessary.

Expired PT Programs are grayed out.

Fields: "PT Program List", on page 516



Program #	Name	Name 2	? City / Locality	? State / Country
001		PROFICIENCY TESTING SERVICE	BROWNSVILLE	TX
002			KIRKLAND	WA
003			TRAVERSE CITY	MI
004		ATS BLOOD GAS SURVEY	NEW YORK	NY
005			TUSTIN	CA
006		CLINICAL LAB EVALUATION PROGRAM	ALBANY	NY
007		CLINICAL LAB IMPROVEMENT SERVICE	TRENTON	NJ
008		LABORATORY IMPROVEMENT SECTION	BOISE	ID
009			NORTHFIELD	IL
010			WASHINGTON	DC
011			KANSAS CITY	MO
013		OUTREACH PROGRAMS	MADISON	WI
014			WESTFORD	MA
015		LABORATORY SERVICES PROGRAM	SAN JUAN	PR
016		BUREAU OF PUBLIC HEALTH LABORATORIES	COLUMBUS	OH
017			SEATTLE	WA
018			ELK GROVE VILLAGE	IL
019		DIVISION OF HOSPITAL ACCREDITATION	CHICAGO	IL
020		BUREAU OF LABORATORIES	EXTON	PA

Figure 160: PT Program List

PT Program Add/Update/Inquiry

The windows for Add, Update, and Inquiry modes all have the same fields. In Inquiry mode, all fields are read-only. In Add/Update mode, required fields are marked with a red asterisk, and all fields are editable except Program # and Last Batch Date fields are read-only.

Fields: "PT Program - Add/Update/Inquiry", on page 517

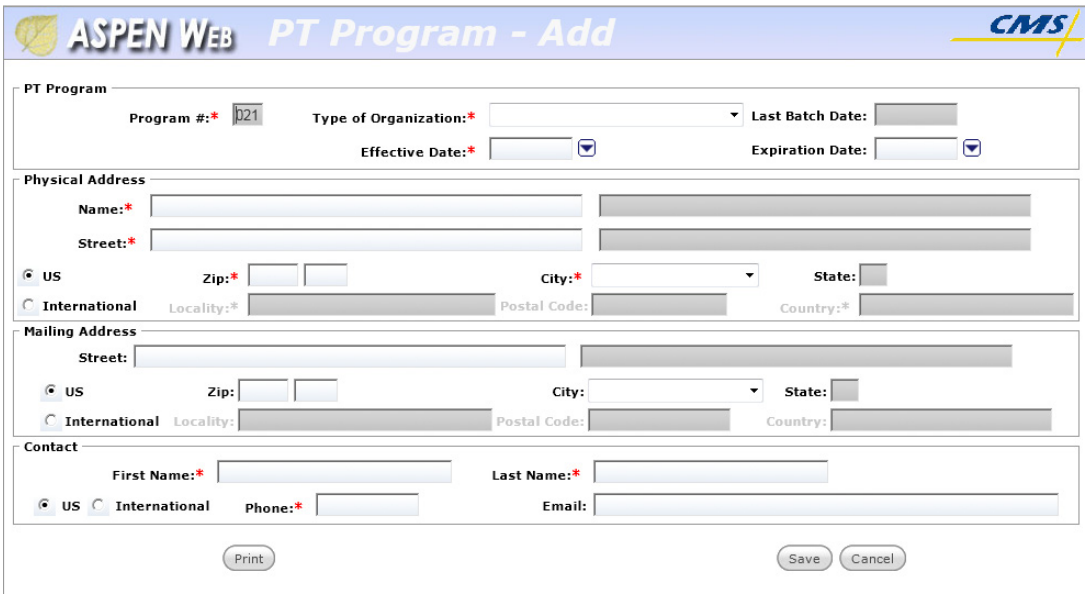
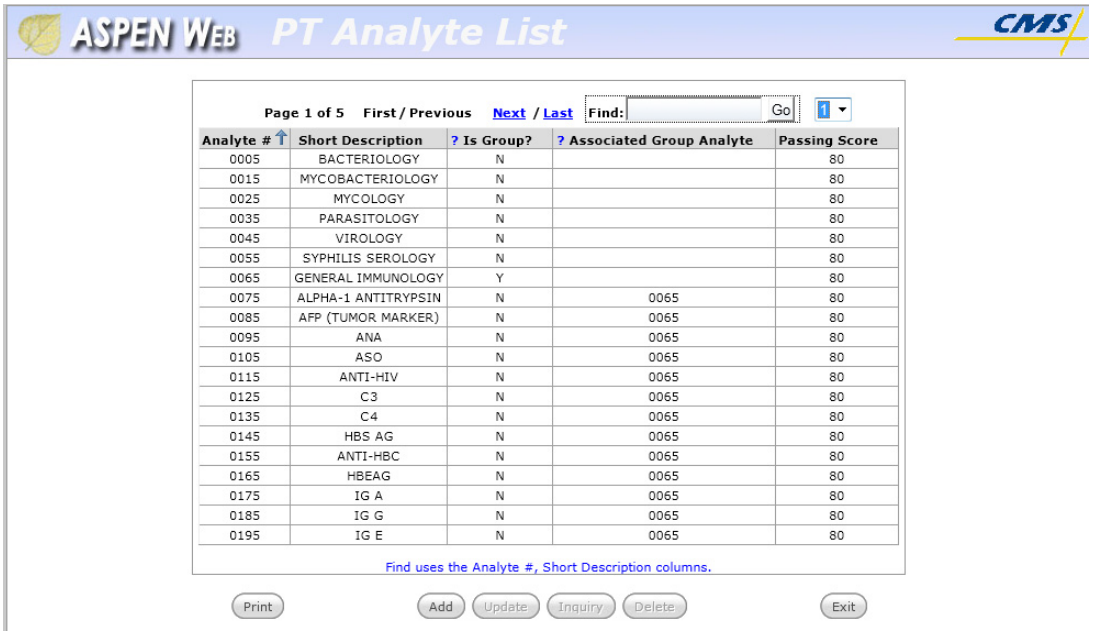


Figure 161: PT Program - Add window

PT Analyte List

The PT Analyte List displays all analytes, with a short description, associated group, if it exists, and passing score.

Fields: "PT Analyte List", on page 519



Analyte #	Short Description	? Is Group?	? Associated Group Analyte	Passing Score
0005	BACTERIOLOGY	N		80
0015	MYCOBACTERIOLOGY	N		80
0025	MYCOLOGY	N		80
0035	PARASITOLOGY	N		80
0045	VIROLOGY	N		80
0055	SYPHILIS SEROLOGY	N		80
0065	GENERAL IMMUNOLOGY	Y		80
0075	ALPHA-1 ANTITRYPSIN	N	0065	80
0085	AFP (TUMOR MARKER)	N	0065	80
0095	ANA	N	0065	80
0105	ASO	N	0065	80
0115	ANTI-HIV	N	0065	80
0125	C3	N	0065	80
0135	C4	N	0065	80
0145	HBS AG	N	0065	80
0155	ANTI-HBC	N	0065	80
0165	HBEAG	N	0065	80
0175	IG A	N	0065	80
0185	IG G	N	0065	80
0195	IG E	N	0065	80

Figure 162: PT Analyte List

PT Analyte Add/Update/Inquiry

The windows for PT Analyte - Add, Update, and Inquiry modes all have the same fields, and required fields are indicated by a red asterisk. In Inquiry mode, all fields are read-only.

Fields: "PT Analyte Add/Update/Inquiry", on page 521

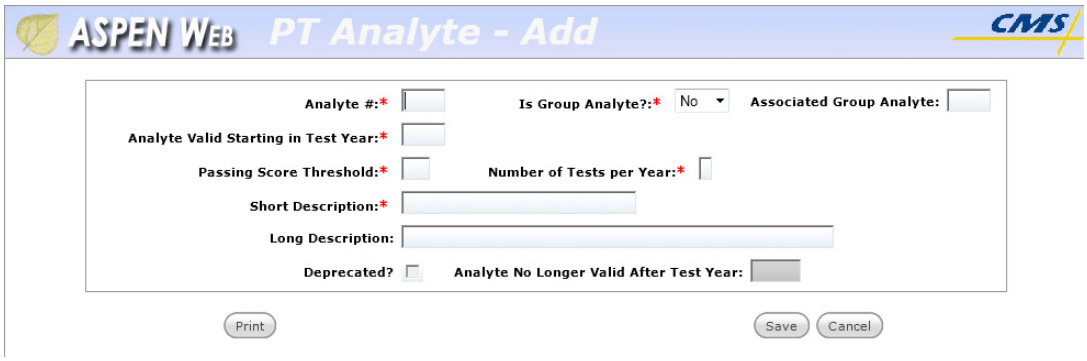


Figure 163: PT Analyte Add window

Program Analyte Search

Selecting PT Program Analyte Maintenance from the ASPEN Web CLIA Maintenance - Select Application window opens the Program Analyte Search window. You can search for approved analytes for a particular program in a given year, or choose the test years to copy program analytes from and to.

Fields: "Program Analyte Search", on page 522

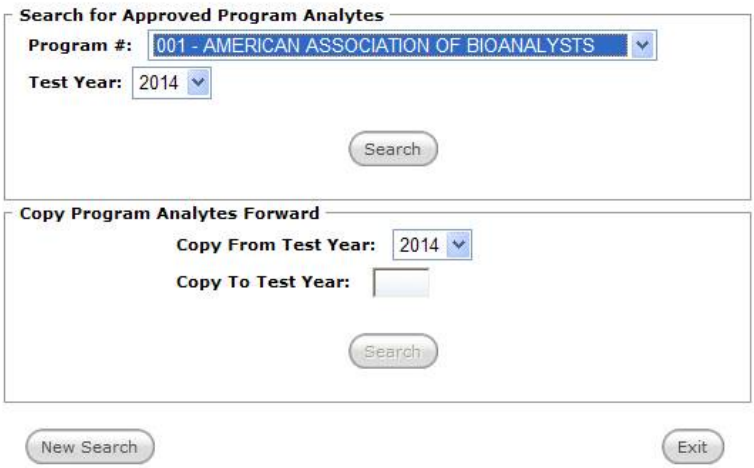


Figure 164: Program Analyte Search window

PT Program Analyte window

Selecting Search for a Program # and Test Year opens the PT Program Analyte window. Analyte Id / Name and Scores are listed for the selected program and test year.

The Score Correct 1-3 columns show a count of corrected scores submitted by the PT program for each routine event.

Fields: "PT Program Analyte", on page 523

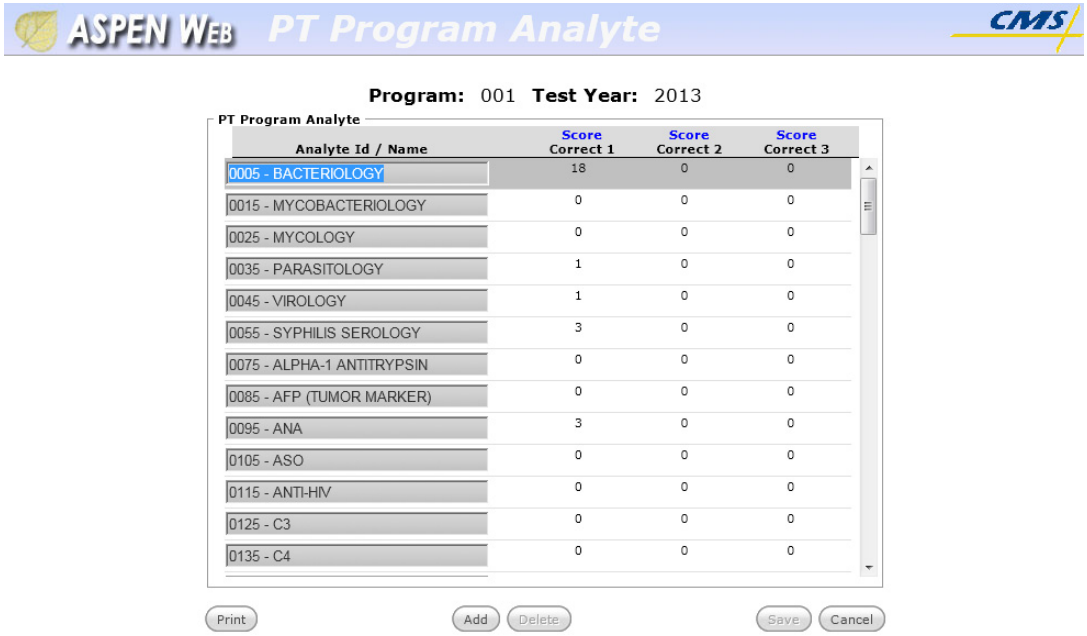


Figure 165: PT Program Analyte window

PT Program Analyte Copy window

The PT Program Analyte Copy window shows all PT Programs that have been approved for analytes on the left side in the Copy From Test Year column, sorted by the PT Program name.

Any matching PT Programs that already have data in the Copy To Test Year show on the right side of the window.

Use this window to chose PT Programs that will have their approved analytes copied forward.

Fields: "PT Program Analyte Copy", on page 524

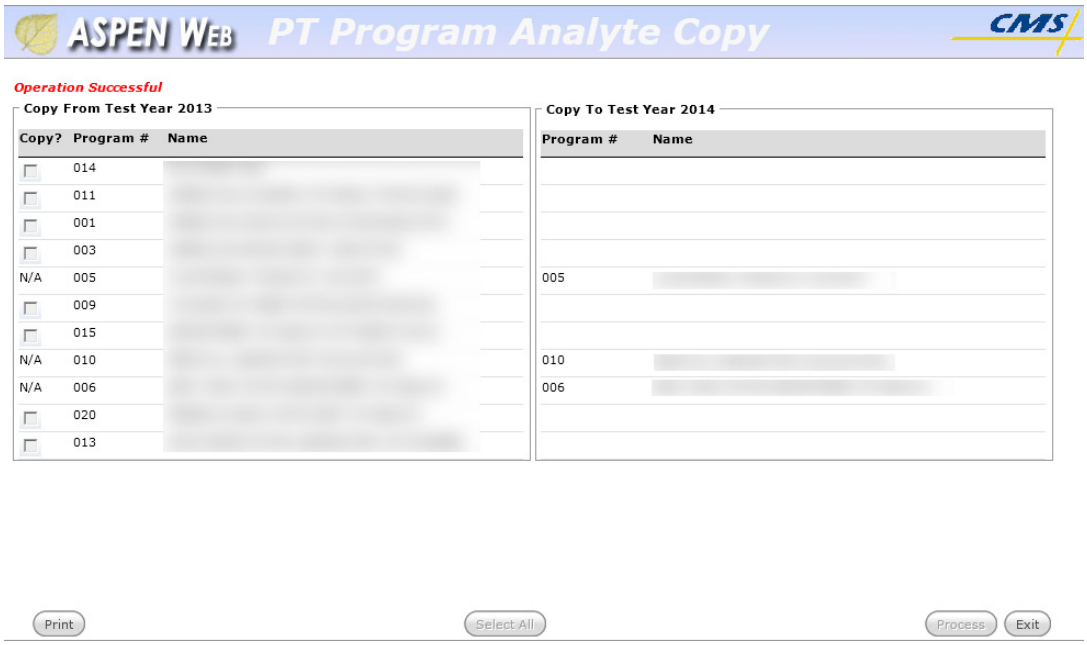


Figure 166: PT Program Analyte Copy window

PT Enrollment Search window

Specify criteria and sort order in the PT Enrollment Search window to display the PT Enrollment List.

Fields: "PT Enrollment Search", on page 525

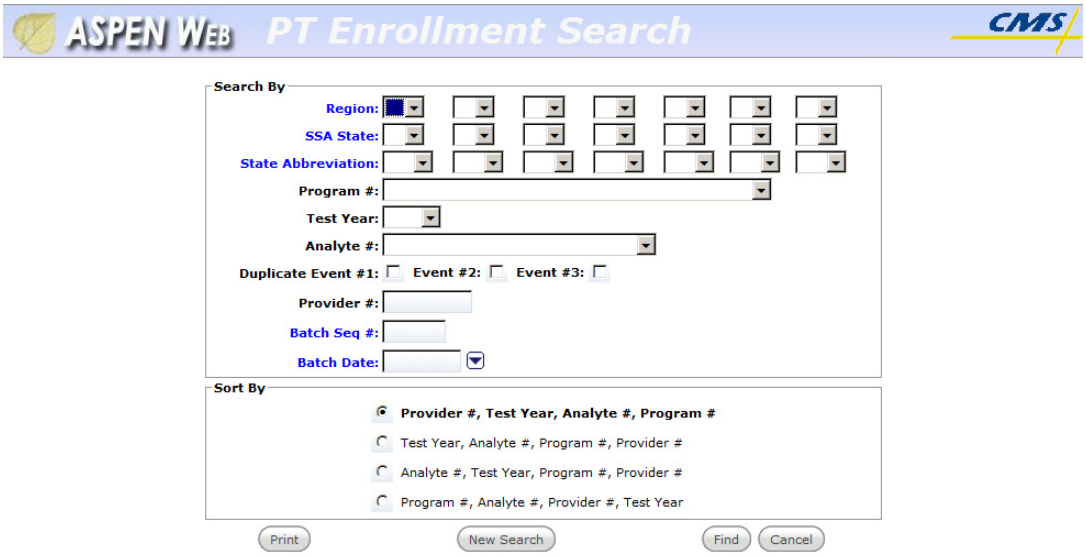


Figure 167: PT Enrollment Search window

PT Enrollment List window

The PT Enrollment List displays enrollment information based on the criteria entered in the PT Enrollment Search window.

Fields: "PT Enrollment List", on page 412

ASPEN WEB PT Enrollment List CMS

More than 5000 records were found for this search of Enrollment records.

PT Enrollment List

Page 1 of 250 First / Previous Next / Last Provider #: Go 1

Provider #	Test Year	Analyte #	Program #	Effective Date	PT Score Submission Dates 1	2	3	Batch Date	Batch Seq #
01D0026	2009	0005	001	01/01/2009	05/08/2009	08/07/2009	12/31/2009	04/28/2009	1
01D0026	2010	0005	001	01/01/2010	05/07/2010	08/06/2010	12/31/2010	04/29/2010	1
01D0026	2011	0005	001	01/01/2011	05/05/2011	08/04/2011	12/29/2011	04/27/2011	1
01D0026	2012	0005	001	01/01/2012	05/11/2012	08/03/2012	12/28/2012	05/09/2012	1
01D0026	2013	0005	001	01/01/2013	05/09/2013	08/02/2013	12/31/2013	04/22/2013	1
01D0026	2009	0005	003	01/01/2009	06/09/2009	09/29/2009		08/03/2010	1
01D0026	2009	0005	003	01/01/2009	06/09/2009	09/29/2009	01/26/2010	05/08/2009	18
01D0026	2010	0005	003	01/01/2010	06/08/2010	09/28/2010	01/25/2011	12/24/2010	8
01D0026	2011	0005	003	01/01/2011	06/07/2011	09/27/2011	01/24/2012	12/23/2011	8
01D0026	2012	0005	003	01/01/2012	06/15/2012	09/25/2012	01/22/2013	12/21/2012	8
01D0026	2013	0005	003	03/04/2013	05/21/2013	09/10/2013	12/31/2013	05/17/2013	8
01D0026	2009	0005	003	01/01/2009	06/09/2009	09/29/2009	01/26/2010	05/08/2009	28
01D0026	2010	0005	003	01/01/2010	06/08/2010	09/28/2010	01/25/2011	12/24/2010	18
01D0026	2011	0005	003	01/01/2011	06/07/2011	09/27/2011	01/24/2012	12/23/2011	19
01D0026	2012	0005	003	01/01/2012	06/15/2012	09/25/2012	01/22/2013	12/21/2012	18
01D0026	2013	0005	003	03/04/2013	05/21/2013	09/10/2013	12/31/2013	05/17/2013	18
01D0026	2009	0005	003	01/01/2009	06/09/2009			08/28/2009	1
01D0026	2009	0005	013	01/01/2009	05/26/2009	09/22/2009	01/05/2010	09/17/2009	1387719
01D0026	2010	0005	013	01/01/2010	05/25/2010	09/28/2010	01/11/2011	05/19/2010	1458756
01D0026	2011	0005	003	11/07/2011			01/24/2012	12/23/2011	30

Print Inquiry Main Menu Search

Figure 168: PT Enrollment List window

PT Address Inquiry

The Inquiry button on the PT Enrollment List opens the PT Address Inquiry window for the selected provider in read-only mode.

ASPEN WEB PT Address Inquiry CMS

Provider Information

Provider #:

Facility Name:

Street:

City:

State:

Zip:

Print Exit

Figure 169: PT Address Inquiry

PT Score Search window

Specify criteria and sort order in the PT Score Search window to display the PT Score List.

Fields: "PT Score Search", on page 528

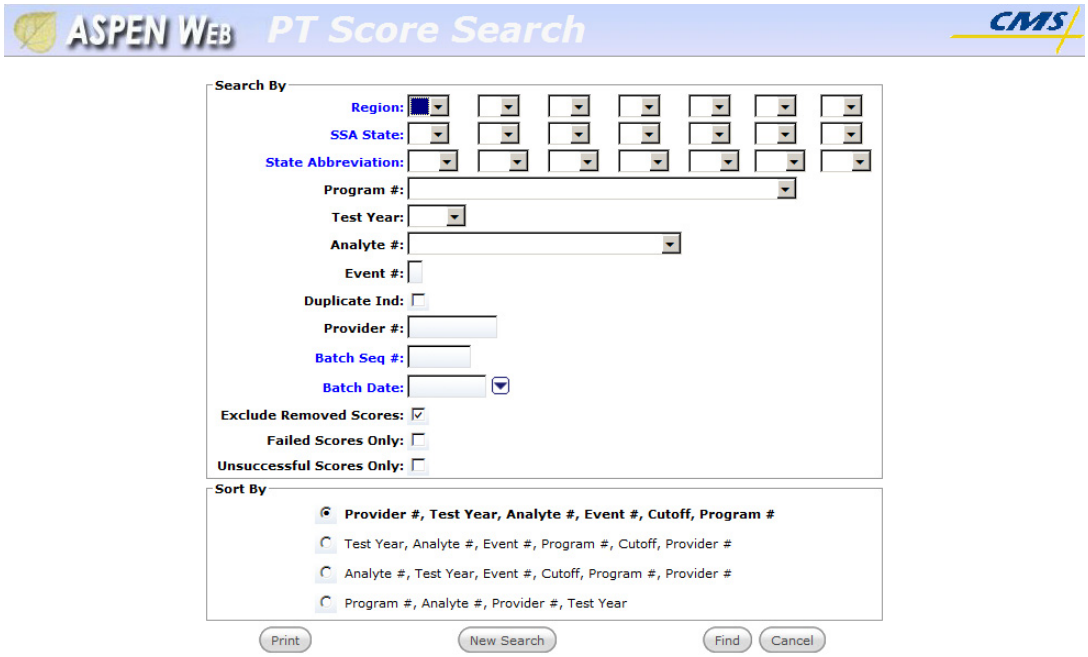


Figure 170: PT Score Search window

PT Score List window

The PT Score List displays score information based on the criteria entered in the PT Score Search window.

Fields: "PT Score List", on page 530

ASPEN WEB PT Score List CMS

More than 5000 records were found for this search of Score records.

PT Score List

Page 1 of 250 First / Previous Next / Last Provider #: Go 1

Provider #	Test Year	Analyte #	Group	Event #	Score Submsn Date	Prog #	Score #	Batch Seq #	Reason Codes	Batch Date	Dup Score	Failed	Unsuccessful	Rmvd Ind
01D002	2013	0005		1	05/09/2013	001	100	12033	, , , ,	04/22/2013		N	N	A
01D002	2013	0005		1	05/21/2013	003	100	87431	, , , ,	04/26/2013		N	N	A
01D002	2013	0005		1	05/21/2013	003	100	87433	, , , ,	04/26/2013		N	N	A
01D002	2013	0005		1	05/21/2013	003	100	87435	, , , ,	04/26/2013	Yes	N	N	A
01D002	2013	0005		1	06/04/2013	013	100	1707665	08, 08, 08, 08, 08	05/30/2013	Yes	N	N	A
01D002	2013	0005		1	05/21/2013	003	100	87436	04, , , ,	04/26/2013		N	N	A
01D002	2013	0005		1	05/21/2013	003	100	87438	04, , , ,	04/26/2013		N	N	A
01D002	2013	0005		1	05/09/2013	001	100	12041	, , , ,	04/22/2013		N	N	A
01D002	2013	0005		1	05/21/2013	003	93	87440	04, , , ,	04/26/2013		N	N	A
01D029	2013	0005		1	05/21/2013	003	100	87442	, , , ,	04/26/2013		N	N	A
01D030	2013	0005		1	05/09/2013	001	100	12066	, , , ,	04/22/2013		N	N	A
01D030	2013	0005		1	05/21/2013	003	100	87448	, , , ,	04/26/2013		N	N	A
01D030	2013	0005		1	05/21/2013	003	100	87450	, , , ,	04/26/2013		N	N	A
01D030	2013	0005		1	05/21/2013	003	100	87451	, , , ,	04/26/2013		N	N	A
01D030	2013	0005		1	05/09/2013	001	100	12079	, , , ,	04/22/2013		N	N	A
01D030	2013	0005		1	04/23/2013	010	100	15828	, , , ,	04/18/2013		N	N	A
01D030	2013	0005		2	07/30/2013	010	100	15033	, , , ,	07/17/2013		N	N	A
01D030	2013	0005		1	05/27/2013	011	87	9304	, , , ,	04/18/2013		N	N	A
01D030	2013	0005		2	08/26/2013	011	40	9136	01, , , ,	07/12/2013		Y	Y	A
01D030	2013	0005		1	05/21/2013	003	100	87456	, , , ,	04/26/2013		N	N	A

Print Main Menu Search

Figure 171: PT Score List window

CLIA Fields and Buttons

For each field or button in a window or section of window, the name is given followed by a description. Function buttons not included within a section are listed under the heading Buttons.

CLIA 116 Web Application Fields

CLIA 116 Find window

Note: Find Affiliated Providers and Find Accounting Providers have the same fields as this window.

Main Search Criteria

CLIA #

All or part of the CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number) of the lab you want to find.

Name

All or part of the name of the lab you want to find.

Physical Address

Address

All or part of the street address where the lab operates. You can use this field in international lab searches.

Note: The CLIA 116 web app searches both the first and second Street fields (Physical Address) in the lab records.

City

All or part of the name of the city where the lab operates. Do not use for international lab searches.

State

Two-character postal code of the state where the lab operates; FN (Foreign) for international labs.

County Code

All or part of the name of the county in which the lab operates. Do not use for international lab searches.

Zip

All or part of the 5-digit Zip code where the lab operates. Do not use for international lab searches.

Mailing Address

Address

All or part of the street address where the lab’s mail is delivered. You can use this field in international lab searches.

Note: The CLIA 116 web app searches both the first and second Street fields (Mailing Address) in the lab records.

City

All or part of the city where the lab’s mail is delivered. Do not use for international lab searches.

State

2-character postal code for the state where the lab’s mail is delivered, or FN (Foreign) for international labs.

Zip

All or part of the 5-digit Zip code where the lab’s mail is delivered. Do not use for international lab searches.

Other

Phone

All or part of the lab’s area code and phone number.

Director Last Name

All or part of the lab director’s last name. If this is the only search criterion specified, the system searches all states.

Director First Name

All or part of the lab director's first name. Not enabled until all or part of the lab director’s last name is entered.

Federal Tax ID

All or part of the lab’s Federal tax identification number.

Exclude Terminated Laboratories

Select the checkbox if you want to exclude terminated laboratories from a search. By default, all matching laboratories are listed, whether they are Active, Pending, or Terminated.

Note: This option is selected and disabled in Find Affiliated Providers because a terminated lab cannot be entered as an affiliated lab.

Multiple Sites Search

Select to search for multiple sites; only the primary site is searched by default. Not enabled until you enter all or part of the laboratory name or physical address. All active multiple sites are returned by the search.

CLIA 116 Find window: Buttons

Find Now

Locates labs matching your search criteria. Pressing Enter will not yield results.

New Search

Clears current search criteria.

Exit

Ends the current CLIA 116 web application session, but does not close the browser. You are returned to the Login window. This option appears when you open the CLIA 116 web app directly in a browser.

In the Find Accounting Providers window, returns to Browse Accounts.

CLIA 116 Search Results window

Note: Affiliated Providers Find Results and Accounting Providers Find Results have the same fields as this window.

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Jump to... box

Jumps directly to the results page you select.

Search Results grid

Click a column title once to sort entries in the Search Results grid in descending order, click twice to sort in ascending order, and click three times to return to the original sort order.

Double-clicking on a row opens the lab record (CLIA 116) in Update mode.

CLIA 116 Search Results window: Buttons

Add

Opens a new lab record in Add mode.

-or-

Select a lab from the list and right-click to open the options menu. Select Add 116 to add a new lab.

Update

Opens 116 record for selected lab in editable Update mode.

-or-

Select a lab from the list and right-click to open the options menu. Select Update 116 to update the lab record.

-or-

Double-click the lab to update the lab record.

Inquiry

Opens a selected lab record in read-only Inquiry mode.

-or-

Select a lab from the list and right-click to open the options menu. Select Inquiry 116 to open the 116 record for the lab in read-only Inquiry mode.

Print

Opens the Report Selection window. If you click Print without selecting a lab, the CLIA 116 Form button will be inactive.

Exit

Returns to the CLIA 116 Find window.

Report Selection window

CLIA 116 Form

Prints data from the selected lab’s record in CMS-116 format.

CLIA Search Results List

Prints the current Search Results list in PDF format. It lists labs in the order they are displayed in the CLIA 116 Search Results window.

Close

Returns to the CLIA 116 Search Results window.

CLIA 116 Form window

Title Bar

Shows the name of the application (CLIA 116) and the mode: Add, Update, or Inquiry.

Header

The shaded area above the tabs is the header. It displays system-generated information about the lab and is always visible. All fields are read-only. You will not see much information in the header for a new lab record until you have entered data and saved the record.

CLIA #

The lab’s assigned CLIA number (ten digits) aka CLIA provider number, CCN, Medicare provider number, provider #/number. It is a sequential number issued by the CLIA system when the lab's application is first saved. A lab always keeps the same number, even if there is a termination or a gap during its certificate period.

The format is <State Code> <D> <sequence #> where the sequence number is a seven-digit sequential number that is unique nationally. State Code is the two-character postal code of the state in which the lab operates. International labs use 99 as their State Code.

Name

The lab’s name.

Most Current Survey

Date of the most recently uploaded certification kit (L34).

116 Complete

Date a new lab record was added, all edit checks passed, and the CLIA # (aka CLIA number, CLIA provider number, CCN, Medicare provider number, provider #/number) generated.

This date represents the lab’s first data entry.

Current

Lab’s current application type.

Pending

Lab’s pending application type.

New

Lab’s new application type.

Survey Pending Date

Exit date of a scheduled certification survey that has not yet been uploaded.

Exp Date

Lab's current certificate expiration date.

Term Code

Current termination code assigned to the lab.

Last Upload

Date the lab record was last successfully uploaded to national.

Enforcement Status

Status and date of most recent enforcement case, if applicable. Status can be one of the following:

- Proposed Open
- Proposed Closed
- Imposed Open
- Imposed Closed

Tabs

The lab record has five tabs:

- Demographics
- Multiple Sites
- Accred Org Info
- Specialties
- Additional Info

The fields on each tab are described separately.

More ...

Fields: "Demographics tab", on page 394
Fields: "Multiple Sites tab", on page 401
Fields: "Accred Org Info tab", on page 404
Fields: "Specialties tab", on page 406
Fields: "Additional Info", on page 410

CLIA 116 Form window: Buttons

Print

Prints a hard (paper) copy of all content on the active tab. Information you must scroll to view in the window is included in the printed version.

Notes

Opens the Notes window. Not enabled for AO and VA users.

When note text is first entered, button label changes to NOTES(*) to indicate there are notes.

Attachments

Opens the Attachments window.

Audit History

Opens the Audit History window.

Certificate/Billing Inquiry

Opens the CLIA Certificate and Billing Inquiry window.

Status Change

Opens the Status Change window.

Termination

Opens the Termination window.

Save

Saves changes to the lab record and exits.

Cancel

Exits the lab record without saving changes.

Demographics tab

General Information

Reason for 116

Select the applicable option. Initial Application is selected by default for new labs.

Required. Must be updated whenever you open a lab record in Update mode.

If Reason for 116 is Initial Application or Survey, be sure to enter or update Application Signature Date on the Additional Info tab.

App Type Requested

Select the applicable option based on the certificate requested by the lab: Compliance, Waiver, Accreditation, or PPMP. Required when adding a new lab.

If you change App Type Requested on a new lab record and have already entered data that is invalid for the new type, you will receive an error message. The invalid data must be replaced or removed before you can change the application type.

You cannot change App Type Requested on an existing lab record; use the Status Change window to change certificate (application) type.

State Agency Received Date

The date the initial application was received in the SA office, usually indicated by a date stamped on the document.

Enabled and required when adding a new lab. Enter a valid date (MM/DD/YYYY). Must be today's date or later; cannot be before 01/01/2006. Read-only in Update/Inquiry mode.

Name

Name of the laboratory. No abbreviations. Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

If the lab’s name starts with “The”, place it at the end of the name following a comma.

Ex: Alpine Medical Group, The

Name, second field

Additional lab name information. Enabled only after data is entered in the first Name field.

No abbreviations. Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

Email Address

Contact email address for the laboratory.

Fed Tax ID

The lab's 9-digit Federal tax identification number, also known as the Employer Identification Number (EIN).

Cannot be an obviously invalid ID number, such as 012345678, 777777777, or 123123123.

Not required for laboratories with an international Physical Address.

Phone

Required except for international labs (State = FN). Phone number for the lab, including area code (domestic labs). International phone numbers are supported. Cannot be all 9's or all 0's. The system will format the number as needed.

Fax

Fax number, including area code. Enter only numeric characters; the system will format the number as needed.

Must be 10 digits long. Cannot be all 9s or all 0s.

Class Code

Lab's classification code.

- 00 Regular - labs covered by the CLIA program
- 05 Exempt - labs exempt from CLIA regulation
- 10 VA - Veterans Affairs labs; similar to exempt labs

A default value is entered based on the type of user adding the new lab record.

Read-only except that qualified users can enter either 00 or 05 for labs operating in the Exempt states of New York and Washington.

Note: You cannot change the code to 05 Exempt if today's date is earlier than the effective date of the current certificate + 1 day.

Director Information

Last Name

The lab director's last name.

First

The lab director's first name. Not enabled until all or part of the lab director's last name is entered.

M.I.

The lab director's middle initial. Single alpha character. Not enabled until all or part of the lab director's last name is entered.

Title

Academic or functional title of the lab director. If you choose 17 Other, enter the applicable title in Other.

Other

Enabled and required only if you select 17 Other for Title. Enter the lab director's title here; 20 characters maximum.

Sal

The lab director's salutation (honorific title, actually): Dr., Ms, etc. It will be used in letters sent to the laboratory.

Physical Address

Specify the physical location of the lab here. If the lab has a mailing address that is different than its physical address, enter it in the Mailing Address section.

Street

Street address of the physical location of the lab where testing is performed. Include floor, suite and/or room, if applicable. Cannot be a post office box number or mail drop address.

Required for all labs. Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

If mail delivery requires the use of ATTN or Attention in the address field, enter here and use the second Street field for the street address.

Street, second field

Additional street address information. Enabled only after data is entered in the first Street field.

Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

US

Selected by default unless State = FN. If selected (automatically or manually), indicates the lab has a domestic (in the United States) physical address and:

- Enables Zip, Zip extension, City. State, County, and State Region
- Disables Locality, Postal Code, and Country

Zip

5-digit Zip code or 9-digit Zip+4 code for the lab. The system generates City, State, County, and State Region based on the Zip code.

Required for domestic labs; disabled for international labs. Must be a valid Zip or Zip+4 code.

City

Name of the city where the lab operates. System-generated based on Zip code. When the Zip code covers more than one city, select the appropriate one from the list.

Required for domestic labs; disabled for international labs.

State

2-character postal code for the state where the lab operates. System-generated based on Zip code for domestic labs; FN (Foreign) for international labs.

County

Name of the county in which the lab operates. System-generated based on Zip code. Select the appropriate county from the list if necessary.

Required for domestic labs; disabled for international labs.

State Region

Name of the region in which the lab operates. System-generated based on Zip code. Select the appropriate county from the list if necessary.

Required for domestic labs; disabled for international labs.

International

Enabled only for CO users with appropriate permissions. If selected (automatically or manually), indicates the lab has an international (outside the United States) physical address and:

- Sets the State code to FN
- Disables Zip, Zip extension, City. State, County, and State Region
- Enables Locality, Postal Code, and Country

Locality

Enabled and required for international labs. Lab’s locality (state, province, region, etc.) Must contain valid alphanumeric characters.

Postal Code

Enabled for international labs; optional. Lab’s postal code. Must contain valid alphanumeric characters.

Country

Enabled and required for international labs. Country in which lab is located. Must contain valid alphanumeric characters.

Mailing Address

If the lab has a mailing address distinct from its physical address, enter it here.

Street

Street address of the location where the lab’s mail is delivered. Include floor, suite and/or room, if applicable. It can be a PO box number or mail drop address.

Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

Street, second field

Additional street address information. Enabled only after data is entered in the first Street field.

Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & -() +

US

Selected by default for all labs. If selected (automatically or manually), indicates the lab has a domestic (in the United States) mailing address and:

- Enables Zip, Zip extension, City. and State
- Disables Locality, Postal Code, and Country

Zip

5-digit Zip code or 9-digit Zip+4 code where the lab's mail is delivered. The system generates City and State based on the Zip code.

Required for domestic mailing addresses; disabled for international mailing addresses. Must be a valid Zip or Zip+4 code.

City

Name of the city where the lab's mail is delivered. System-generated based on Zip code. When the Zip code covers more than one city, select the appropriate one from the list.

Required for domestic mailing addresses; disabled for international mailing addresses.

State

2-character postal code for the state where the lab's mail is delivered. System-generated based on Zip code for domestic mailing addresses; blank and disabled for international mailing addresses.

International

Enabled only for CO users with appropriate permissions. If selected (automatically or manually), indicates the lab has an international (outside the United States) mailing address and:

- Disables Zip, Zip extension, City. and State
- Enables Locality, Postal Code, and Country

Locality

Enabled and required for international mailing addresses. Mailing address locality (state, province, region, etc.) Must contain valid alphanumeric characters.

Postal Code

Enabled for international mailing addresses; optional. Mailing address postal code. Must contain valid alphanumeric characters.

Country

Enabled and required for international mailing addresses. Mailing address country. Must contain valid alphanumeric characters.

Corporate Address

Specify the address of the corporate entity that owns the lab.

Street

Street address of the corporate entity. Include floor, suite and/or room, if applicable. It can be a PO box number or mail drop address.

Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

Street, second field

Additional street address information. Enabled only after data is entered in the first Street field.

Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & -() +

US

Selected by default for all labs. If selected (automatically or manually), indicates the corporate entity has a domestic (in the United States) address and:

- Enables Zip, Zip extension, City. and State
- Disables Locality, Postal Code, and Country

Zip

5-digit Zip code or 9-digit Zip+4 code for the corporate entity. The system generates City and State based on the Zip code.

Required for domestic corporate addresses; disabled for international corporate addresses. Must be a valid Zip or Zip+4 code.

City

Name of the city where the corporate entity is located. System-generated based on Zip code. When the Zip code covers more than one city, select the appropriate one from the list.

Required for domestic corporate addresses; disabled for international corporate addresses.

State

2-character postal code of the state where the corporate entity is located; System-generated based on Zip code for domestic corporate addresses; blank and disabled for international corporate addresses.

International

Enabled only for CO users with appropriate permissions. If selected (automatically or manually), indicates the corporate entity has an international (outside the United States) address and:

- Disables Zip, Zip extension, City. and State
- Enables Locality, Postal Code, and Country

Locality

Enabled and required for international corporate addresses. Corporate entity's locality (state, province, region, etc.) Must contain valid alphanumeric characters.

Postal Code

Enabled for international corporate addresses; optional. Corporate entity's postal code. Must contain valid alphanumeric characters.

Country

Enabled and required for international corporate addresses. Corporate entity's country. Must contain valid alphanumeric characters.

Form Mailing

In this section, you choose the address(es) to which bills and certificates will be sent. Possible options are the same for both fields: Physical, Mail, or Corporate. Available options depend on which addresses have been entered. Physical is always available and selected by default. When you add a Mailing or Corporate address, a message reminds you to check the Form Mailing settings.

Send bills to ...

Required. Select the desired address option.

Send certificate to ...

Required. Select the desired address option.

If you remove the Mailing and/or Corporate Address when one or both Form Mailing fields are set to the removed address type(s), the applicable Form Mailing field(s) are cleared. If only the Physical Address remains, Physical is then automatically selected for the cleared field(s). Otherwise, you are reminded to review the Form Mailing values.

Lab Type

Type of Laboratory

The lab's type. If you select 22 (Practitioner Other) or 29 (Other), enter details in the Other field.

Required for all labs.

Other

Enabled, but not required only if Type of Laboratory is 22 Practitioner Other or 29 Other. Specify the lab type here; 25 alphanumeric characters maximum.

Hours of Laboratory Testing

Use the table to specify the lab's testing schedule.

From/To

For each day of the week the lab is open, enter the time it opens for business and the time it closes for the day as **HH:MM**, and select **am** or **pm**. The system will do some formatting for you.

Ex: Enter 8 and the system formats it as 08:00.

If you enter From hours for a day, To hours for that day are required and vice versa. The hour cannot be greater than 12, minutes cannot be greater than 59, and 0000 is not allowed.

24x7 button

Automatically sets From to 12:00 am, and To to 11:59 pm for each day of the week.

Multiple Sites tab

General Information

Multiple Sites

Required. Defaults to No. Must be Yes if an exception question is marked Yes.

Number of Sites

Total number of sites that share the CLIA number of the primary lab.

Required if Multiple Sites is set to Yes. Must be a number greater than 1; the primary site is counted as 1.

Active Sites Entered

Read-only count of active labs (Status is Active) listed as multiple sites, including the primary site. Automatically increments if you add an active lab (Add button) or change Status in the grid to Active. Auto-decrements if you remove a lab (Remove button) or change Status in the grid to Removed.

Exceptions

Lab with temporary testing sites?

Non-profit, Federal, state or local government lab?

Hospital with several labs at the same address?

Yes/No questions. All default to No. If the answer to any exception question is Yes, the lab's multiple locations can be identified on the Multiple Sites tab. A CMS-116 is not required for each site.

If Multiple Sites is marked Yes, one exception question must be marked Yes, and vice versa.

Multiple Sites list

List of the lab's multiple sites, i.e., labs with the same CLIA number as the primary lab. The additional sites must qualify for a Multiple Sites exception. Information about each lab site is carried in from the Add/Modify Site window. It can include physical address, NPI number, status, and date the current status was set. Read-only except Status.

When the Multiple Sites field is initially marked Yes, the primary (current) lab is automatically entered as the first multiple site.

Multiple Sites tab: Buttons

Active

When selected, displays only active sites (Status is Active) in the Multiple Sites list.

All

When selected, displays all sites in the Multiple Sites list, regardless of status.

Add

Opens the Add Site window. Not enabled if Multiple Sites is marked No.

Modify

Opens the Modify Site window for the selected site.

Remove

Changes the Status of the selected site to Removed and removes it from the Active list. It is included in the list if you select All.

Add/Modify Site window

General Site Information

Name

Name of the additional lab site. No abbreviations. Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

Required. If the site name starts with “The”, place it at the end of the name following a comma.

ID

System-generated sequence number indicating the order in which additional sites were added.

Status

Indicates the status of the additional site: Active, Moved, or Removed; Active is the default. Can also be set directly in the Multiple Sites list. If Status for a site is Moved or Removed, you must display all sites in the Multiple Sites list to see it.

Street

Street address of the additional site. Required. Must contain valid alphanumeric characters: A-Z 0-9 * / , # ' & - ( ) +

Zip

5-digit Zip code or 9-digit Zip+4 code for the additional site. The system generates City, State, and County based on the Zip code.

Required. Must be a valid Zip or Zip+4 code.

City

Name of the city in which the additional site is located. System-generated based on Zip code. When the Zip code covers more than one city, select the appropriate one from the list.

Required. Alpha field. Must match a value in the database table of city names.

State

2-character postal code for the state in which the additional site is located. System-generated based on Zip code. Required. Alpha field. Must be a valid state postal code.

County

Name of the county in which the lab site is located. System-generated based on Zip code. Select the appropriate county from the list if necessary.

Required. County name must match a value in the database table.

Phone

Phone number for the lab site, including area code. Enter only numeric characters; the system will format the number as needed.

Required. Must be 10 digits long. Cannot be all 9's or all 0's.

NPI

National Provider Identifier for the additional lab site. Must be a valid NPI.

Tests Performed/Specialties

Text box in which you can describe the tests performed or specialties of the additional lab site in as much detail as necessary.

Add/Modify Site window: Buttons

Save

Saves the record and adds the site to the Multiple Sites list, or updates information about the site.

Cancel

Exits without saving.

Accred Org Info tab

Letter Sent to Lab

When a Remarks code is entered (see below) and the laboratory has no other AO affiliation (X or Y-match), the CLIA 116 web app sends a letter to the laboratory requesting current CLIA certificate status. This is the date the letter file was created.

The CLIA 116 web app clears this field when:

- An X-match, i.e., an accrediting organization, is added on this tab after the letter is sent.
- A Remarks code (see below) is deleted when a lab changes accreditation affiliation or is terminated, or it (the code) is removed via the AO upload process.

Accrediting Organization Affiliations

This section lists a lab's AO affiliations (X-matches), one per row. Applicable and enabled only for Accredited labs, i.e., App Type Requested on the Demographics tab is Accreditation. Only one AO can accredit each specialty or subspecialty.

Accred Org

Name of the accrediting organization (X-match). Enabled when you select the Add button and a new row is added. You cannot add an AO more than once.

Confirmed

If selected, confirms the AO inspected the lab and found it to be in compliance (Y-match). Enabled for the following user types when they have the necessary permissions: AO, VA, Exempt, CO super users.

Disabled until Accred Org (X-match) is entered. Not selected by default. Once selected and saved, the checkbox is disabled and cannot be cleared.

Confirmed Date

Date the Confirmed checkbox is selected. System-generated, immediately set to today's date when Confirmed is selected.

Disabled until there is a Y-match, i.e., the Confirmed checkbox is selected. Must be later than the current certificate effective date + 1 day.

Since this date is used to create the laboratory's initial Certificate of Accreditation, the following edit checks ensure that overlapping certificates are not created.

- Lab is active.
- Lab has a current 9/3 certificate, and it is at least 2 days past the current certificate effective date.
- Current application type is 3.

Remarks

A selected remark specifies a special condition or problem affecting the AO's accreditation of the lab.

Disabled until Accred Org (X-match) is entered. Defaults to blank.

Remarks Date

Date AO enters as effective for the selected remark.

Disabled until a remark is selected, then a date is required. Defaults to blank. Format is mm/dd/yyyy.

AO Survey Entry

Date of AO's most recent survey of the laboratory.

Disabled until there is a Y-match, i.e., the Confirmed checkbox is selected.

Format is mm/dd/yyyy. Must be later than today and later than 01/01/2001. Cannot be a date in the future.

If this date is more than 12 months after the existing Current date, it becomes the Current date when the lab record is saved, and all other dates switch to the right to the appropriate Prior date slot. If this date is less than 12 months after the existing Current date, it replaces the Current date when the lab record is saved and Prior dates remain the same.

Current, 1st Prior, 2nd Prior, 3rd Prior

Dates of the most recent, then the 1st, 2nd, and 3rd prior surveys of the lab by the AO.

Read-only. Updated by the system as necessary. For example, if the AO Survey Entry date is more than 12 months after the existing Current date, it becomes the Current date when the lab record is saved, and all other dates switch to the right to the appropriate Prior date slot.

Accred Org Info tab: Buttons

Add

Adds a row to the Accrediting Organization Affiliations grid.

Delete

Marks a selected AO for removal from the Accrediting Organizations Affiliations grid by crossing out Accred Org name. All fields in the row are immediately disabled and the row is removed when the lab record is saved. It will not appear the next time the lab record is updated or viewed.

Specialties tab

Schedule Codes

The Schedule Codes section shows system-generated 116 and/or 1557 (survey) schedule codes for Compliance and Accredited laboratories. This section does not appear for Waiver or PPM labs.

116

Shows the billing schedule code for a Compliance or Accredited lab based on self-reported specialties on the lab's CMS-116 form. Read-only, recalculated by the system when 116 specialty and test volume data are updated.

1557

Shows the 1557 billing schedule code for a Compliance or Accredited lab based on survey-verified specialties. Read-only, recalculated by the system when survey specialty and test volume data are updated.

Note: If a status change is in progress, schedule codes are displayed according to CLIA rules.

Specialties tab: Buttons

Schedule Code Chart

Displays the fees by schedule code for Compliance and Accreditation certificates based on the state where the laboratory resides. Also indicates Waiver and PPM fees.

Specialty Source

Indicates the source of the specialties entered. You can switch between 116 and Survey as needed.

116 Specialties

When selected, 116 sub-specialties fields are displayed in the Sub-specialty grid and populated as appropriate. 116 specialties are those the lab has included on the CMS-116. Default view except for AO users.

CO, RO, SA, VA, and Exempt state users can enter 116 specialty information.

Survey Specialties

When selected, survey sub-specialties fields are displayed in the Sub-specialty grid and populated as appropriate. The survey specialties are those entered on the 1557 Specialties tab in the ACO certification kit. Default view for AO users only.

CO super users can update survey specialties for Accredited labs only. VA and Exempt state users can update survey specialties for VA and exempt labs respectively.

Specialty History

When selected, displays survey specialty history for a Compliance or Accredited lab in an unlabeled section below Total Annual test volume.

Last Update Date

Displays the latest date that specialties (116 or survey depending on selected source) were updated for the lab based on the date in the ASPEN Specialty table. Read-only.

Total Annual test volume

All Waived Tests

Shows the approximate number of Waived tests performed annually.

Required and must be greater than 0 if the application type is Waiver and State Agency Received Date is later than 01/19/2008, optional otherwise.

Optional if the application type is Compliance, Accreditation, or PPMP.

Note: For a status change to application type 2 Waiver, you must enter waived test volume regardless of State Agency Received Date.

All PPM Tests

Shows the approximate number of PPM tests performed annually.

Required and must be greater than 0 if the application type is PPMP and State Agency Received Date is later than 01/19/2008, optional otherwise.

Note: For a status change to application type 4 PPMP, you must enter PPM test volume regardless of State Agency Received Date.

Optional if the application type is Compliance or Accreditation; disabled if Waiver.

No Testing

When selected, indicates the lab does not conduct the corresponding tests.

Disabled if a test volume greater than zero is required. If enabled and Waived or PPM test volume is not required, then select the corresponding No Testing option.

If No Testing is selected after a test volume is entered, the volume number in the corresponding entry field changes to zero and the field is disabled, regardless of application type.

Sub-specialty grid

The data you see depends on the selected specialty source. If a status change is in progress, specialty data is displayed according to CLIA rules.

If specialty source is 116 ...

For Accredited and Compliance labs, at least one 116 sub-specialty and associated test volume is required. If a lab is downgrading its certificate to Waiver or PPM, this requirement does not apply. User type and permissions determine if you can view or update 116 specialties.

For Compliance labs, you can select applicable sub-specialties and enter test volume for specialties. For Accredited labs, you also indicate the AO that accredits each sub-specialty.

If specialty source is survey ...

Survey specialty data is entered from ACO. User type and permissions determine if you can view or update survey specialties. You cannot enter survey specialties in new lab records.

For Compliance labs, specialty data includes sub-specialties and their effective and expiration dates, and test volume for specialties. For Accredited labs, the AO that accredits each sub-specialty is also shown and test volume is given for each AO at the bottom.

Accrediting Org

For Accredited labs, the AO that accredits the sub-specialty. Enabled for 116 and survey specialties, depending on user class and permissions, for labs with an application or pending application of type 3 and at least one X-match, i.e., AO entered on the Accred Org Info tab.

Effective Date, Expiration Date

Effective and expiration (closeout) dates for the survey sub-specialty. Displayed for Accredited and Compliance labs. Enabled depending on user class and permissions.

When you add a survey sub-specialty, the Effective Date must be greater than the Expiration Date of the last matching closed sub-specialty to prevent overlapping specialty dates.

Test Volume

116 specialties, Compliance labs - number of tests performed annually for the specialty, i.e., total number of tests for all selected sub-specialties in the specialty group.

116 specialties, Accredited - number of tests performed annually for the specialty, which represents the AO test volume for the specialty.

Survey specialties, Compliance labs - number of tests performed annually for the specialty, i.e., total number of tests for all selected sub-specialties in the specialty group.

Survey specialties, Accredited labs - annual test volume for each AO, i.e., the number of tests performed annually for each AO that accredits the lab’s specialties.

<AO> Test Volume

Accredited labs only, survey specialties only. Number of tests performed annually for each listed AO. Displayed above Total Annual Test Volume at the bottom of the tab. CO super users can update all AO test volume fields. AO users can update only the test volume field for their AO

Total Annual Test Volume

System-generated sum of Test Volume numbers. For Compliance labs, it is the total of all the specialty test volume fields. For Accredited labs, it is the sum of the individual AO test volume fields.

If a status change is in progress ...

If a status change is being processed, specialty data is displayed according to the following rules:

- From app type 2 or 4 to app type 2 or 4: no 116 or 1557 schedule codes or specialty data.
- From app type 2 or 4 to app type 1 or 3: show 116 schedule code and data, no 1557 schedule code or survey specialty data.
- From app type 1 or 3 to app type 1 or 3: show 116 and 1557 schedule codes and specialty data.
- From app type 1 or 3 to app type 2 or 4: no 116 schedule code or specialty data, show 1557 schedule code and survey specialty data.
- From Registration to app type 2 or 4: no 116 or 1557 schedule codes or specialty data (if either is present).
- From Registration to app type 1 or 3: show 116 schedule code and specialty data, no 1557 schedule code or survey specialty data (status change not allowed if survey specialty data is present).

Additional Info

Director Affiliations with Other Laboratories

Director Affiliations grid

Lists director affiliations with provider # (aka CLIA #/number, CLIA provider number, CCN, Medicare provider number, provider number), lab name, application type, termination code, and lab director name for each.

Insert Affiliated Lab button

In the text field, enter the CLIA number (aka CLIA #, CLIA provider number, CCN, Medicare provider number, provider #/number) of an additional lab the director is affiliated with, then click this button to add it to the list of director affiliations.

There is no limit on the number of affiliations you can enter, but only 8 are uploaded. There is currently no edit check to confirm that the affiliated lab you select actually has the same director.

An individual can serve as the director for up to five PPM, Compliance, or Accredited labs, and an unlimited number of Waiver labs.

Find

Opens the Find Affiliated Providers window. Use to search for an affiliated lab if you do not know the lab’s CLIA number. Select the lab from the search results to add it to the list of director affiliations.

Delete

Marks the selected director affiliation for removal after confirmation. The entry is crossed out for the rest of the session, then removed when you save and close the lab record.

Other

Type of Control

Type of organization that operates the lab.

Required. If you choose 03 Other or 09 Other Government, enter the applicable control type in Other.

Other

Enabled and required only if you select 03 Other or 09 Other Government for Type of Control. Specify the type of organization that operates the lab; 25 alphanumeric characters maximum.

Application Signature Date

Date the application was received.

Required if the Reason for 116 on the Demographics tab is Initial Application or Survey, and State Agency Received Date is on or after 01/19/2008.

Must be later than 08/31/1992 and on or before the current date. When this field is updated, the previous value is audited by the system.

Cross Reference Provider Number

CLIA number (aka CLIA #, CLIA provider number, CCN, Medicare provider number, provider #/number) previously assigned to a lab holding a multiple site certificate.

Required when the termination code for that lab is 13 Multiple to Single Site Certificate. Must be a valid CLIA provider number of an active or terminated lab, but cannot be the same as the current provider number.

CLIA Medicare Number

The Medicare provider number (six or ten digits) assigned to the laboratory. For Histocompatiblity labs, the Medicare provider number is SSHLNN, where SS is the state code and NN is a sequence number.

Federal Jurisdiction

Enabled only for RO users with full access. Select Yes if the lab is in the Federal Jurisdiction program; No or blank if not.

CASPER Certification Add Date

Date the certification kit was successfully uploaded to CASPER (national reporting system).

Certification Transaction Date

Date the kit passed ASPEN upload edits and an upload transaction was created.

Certification Approval Entered Date

Determination Approval date (L33) entered by the RO on the Transmittal (CMS-1539) tab.

Certification Review

Indicates whether or not the certification kit is flagged for RO review.

Cyto PT Enrollment

This section has details about Cyto PT enrollment for Compliance and Accredited labs that are approved for cytology testing (630 specialty code).

Letter Sent Date

Date of last letter sent to laboratory performing cytology testing (630) requesting enrollment status in one of the CMS-approved cytology proficiency testing organizations.

Read-only. Set by national batch jobs that generate the letters.

Enrollment Status

Cyto PT (Proficiency Testing) enrollment status of the lab corresponding to each Letter Sent Date. Status for 2005-2007 is historical data from the OSCAR/CLIA system. CO users can select the status once national batch jobs set Year.

Year

Year associated with each Enrollment Status. Read-only. Set by national batch jobs when they generate Cyto PT letters.

PT Info tab

PT Enrollment List

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Page number box

Jumps directly to the results page you select.

Search Results grid

Test Year

Calendar year in which the indicated proficiency testing takes place. Data is available for the previous five calendar years.

Analyte #

Number associated with the indicated analyte. To see the master list of analytes, see the PT Analyte List in PT Analyte Maintenance.

Program #

Number associated with the PT program that submitted the indicated enrollment record. To see a list of the PT programs see the PT Program List in PT Program Maintenance.

Effective Date

Date the laboratory enrolled in the PT program for the indicated analyte/event.

PT Score Submission Date (1, 2, 3)

Date the PT program must submit scores to CMS. It is sixty days after the date the laboratories must submit their values to the PT program for the indicated analyte/event.

Batch Date

Unique date contained in the header of a PT program file uploaded to the CLIA PT data system.

Batch Seq #

One up number for each record in the PT program file uploaded to the CLIA PT data system.

PT Score List

All

Radio button displays all scores.

Failed/Unsuccessful

Radio button displays only failed or unsuccessful scores.

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Page number box

Jumps directly to the results page you select.

Search Results grid

Test Year

Calendar year in which the indicated proficiency testing takes place. Data is available for the previous five calendar years.

Analyte

Number associated with the indicated analyte. To see the master list of analytes see the PT Analyte List in PT Analyte Maintenance.

Group

A Y indicates that the analyte is a group code, meaning there are other analytes listed under that group code. For example: analyte number 0065 General Immunology contains many analytes such as 0075 Alpha-1 Antitrypsin, 0085 AFP (Tumor Marker), 0095 ANA, etc. To see the master list of analytes see the PT Analyte List in PT Analyte Maintenance.

Event

PT event number: 0=Non-routine, 1=Event # 1, 2=Event # 2, 3=Event # 3.

Score Submission Date

Date the PT program must submit scores to CMS. It is sixty days after the date the laboratories must submit their values to the PT program for the indicated analyte/event.

Program

Number associated with the PT program that submitted the indicated enrollment record. To see a list of the PT programs see the PT Program List in PT Program Maintenance.

Score #

Percentage of correct responses the indicated PT program gave the laboratory for the indicated analyte/event.

0: 0 TO 19 SCORE

20: 20 TO 39 SCORE

40: 40 TO 59 SCORE

60: 60 TO 79 SCORE

80: 80 TO 99 SCORE

100: SCORE OF 100

Batch Seq #

One up number for each record in the PT program file uploaded to the CLIA PT data system.

Reason Codes

Values assigned to reason statements that are submitted by the PT programs with score records, to explain scores of 0% or 100% assigned by the PT program that have not resulted from actual values submitted by the laboratory.

Batch Date

Unique date contained in the header of a PT program file uploaded to the CLIA PT data system.

Dup Score

A value of Y indicates that more than one PT program submitted results for this score. Further information can be obtained by running CASPER report #0158D.

Failed

A value of Y indicates that the individual score for the indicated analyte/event fell below the passing value.

Unsuccessful

A value of Y indicates that the score is the second failing score in the last two consecutive events, or in the last three events.

Rmvd Ind

A value of A indicates that the indicated score is an active record. A value of R indicates that the score record has been removed from the PT data system due to issues with the enrollment record.

Notes

Note text must contain valid characters, A-Z 0-9 * / , # ' & - ( ) +

Notes are saved immediately; you don't have to save the lab record. When note text is first saved, the Notes button label changes to NOTES(*) to indicate there are notes.

Text Boxes

State User

Text box in which SA users can enter notes.

Regional Office User

Text box in which RO users can enter notes.

Central Office User

Text box in which Central Office users can enter notes.

Notes: Buttons

Save

Saves the note text and exits.

Cancel

Exits without saving.

Attachments

Attachments are associated with the lab record. Users with the correct permissions can open previously stored attachments and add new attachments. Attachments will not save changes. If you need to change an attachment, you need to remove it from the database, change the source file, then re-attach the source file.

Attachments grid

Entry Name

Descriptive name for the attachment. Initially, this is the only active field. After entering a name, you can specify the file to be attached.

Must contain valid characters, A-Z 0-9 * / , # ' & - ( ) +

No abbreviations.

File Name

Automatically populated after you use the Browse function to locate the file you want to attach, or enter a filename in the Attach field.

Attach

Becomes active after you enter a name in the Entry Name field and press the Tab key. Enter the filename of the attachment here, or click Browse to locate the file you want to attach.

Browse

Lets you locate the file you want to attach. File Name is automatically populated when you select the file in search results.

View

Opens the selected attachment.

Date Attached

Automatically populated with today's date after you use the Browse function to locate the file you want to attach, or enter a filename in the Attach field.

Attachments grid: Buttons

Add

Adds a row in the Attachment grid.

The attachment is saved immediately; you don't have to save the lab record. When the first attachment to the lab record is saved, the Attachments button label changes to ATTACHMENTS(*) to indicate there is at least one attachment.

Remove

Marks the attachment for removal; Entry Name and File Name are crossed out. The attachment is deleted when you close the Attachments window.

Close

Saves attachment information and exits the Attachments window.

Audit History window

All fields are system-generated and read-only.

Header

CLIA #

Lab's CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number).

Name

Name of the lab.

MSA Update Dt

Date the lab record was most recently updated. Set to the current date and time when any of the following are updated:

- EIN
- Facility Name
- Facility 2 Name
- Physical Address information
- Type of Laboratory
- Current certificate information

The Medicaid state agency (MSA) is notified of these updates through Report 91. Used by the MSA to determine if pertinent CLIA information, such as certificate type and certificate effective/expiration dates, has changed and if MSA needs to update its system.

Note: The date shown in Report 91 is not the same date used to generate Report 91.

Last Updated

Date the lab record was most recently updated.

Added On

Date the lab record was added.

Added By

Name or ID of the user who added the lab record.

Audited Fields

Physical Address

Displays changes to the lab's physical address data, including:

Date of Change

User ID

Address 1

Address 2

City

State

Zip Code

Ext County

Mailing Address

Displays changes to the lab's mailing address data, including:

Date of Change

User ID

Address 1

Address 2

City

State

Zip Code

Facility Name

Displays changes to the lab's name, including:

Date of Change

User ID

Name 1

Name 2

Telephone

Displays changes to the lab telephone number, including:

Date of Change

User ID

Phone #

Lab Class

Displays changes to lab's classification, including:

Date of Change

User ID

Current and Pending Lab Class

Director Name

Displays changes to the director name, including:

Date of Change

User ID

Last Name

First Name

Middle Name

AO Information

Displays changes to AO data, including:

Date of Change

User ID

Accreditation Code

Confirmed

Confirmed Date

Remarks

Remarks Date

AO Survey Dates

Displays changes to AO survey dates, including:

Date of Change

User ID

Accreditation Code

AO Survey Date

Application Signature Date

Displays changes to the application signature date, including:

Date of Change

User ID

Application Signature Date

Termination Information

Displays changes to termination data, including:

Date of Change

User ID

CLIA Termination Code

Expiration Date

Pending Expiration Date

Pending Termination Code

Application Information

Displays changes to application data, including:

Date of Change

User ID

Effective Date

New Effective Date

New Type Code

Pending Effective Date

Pending Type Code

Current Application Code

Letter Sent to Lab

Displays changes to letter data, including:

Date of Change

User ID

Letter Sent Date

Federal Tax ID

Displays changes to the lab Federal tax ID, including:

Date of Change

User ID

Tax ID

Close button

Exits the Audit History window.

CLIA Certificate and Billing Inquiry window

General Information

CLIA #

The lab's CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number). Read-only.

Name

Name of the lab. Read-only.

Enforcement Action Extension

Enabled only for RO and CO users with full access. Select Yes to extend the expiration date of the current certificate for a laboratory with an enforcement status of Imposed-Open. The date the indicator was set is automatically entered.

Note: The flag indicates an extension is in place, but the certificate expiration date (Exp Date) displayed on the CLIA 116 screen does not change.

The laboratory must meet the following criteria:

- It is not exempt or VA.
- 30 days or less are left in the current certificate cycle.
- No status changes are in process.
- It is active (not terminated).

When the Enforcement Action Extension indicator is set:

- The laboratory's specialty values are frozen.
- The CWF/MSA date will be extended.
- Status changes and termination are prevented.
- The lab will not be processed by the batch billing jobs.
- The lab will not be processed by the AO Upload job.
- Another fee is not generated.
- Payments continue to be applied to the laboratory.

When the enforcement action is resolved, the flag can be removed only through a PCR and then normal 2 year cycles will continue.

Certificate Inquiry

CWF Date

Common Working File Date for the lab. It is the lab's current certificate expiration date plus six months. This date is sent to CWF and MSA files as the specialty expiration date.

Note: Do not provide this date to the laboratories, as it leads them to believe they have an extra six months on their current certificate.

Compliance Certificate Effective Date

Effective date for a Compliance certificate, i.e., the date the laboratory was determined to be in compliance with program requirements. This date is increased by two years for each Compliance certificate issued after registration.

Last Survey Date

Date the lab was last surveyed.

Last AO Inspection Date

Date the lab was last inspected by an accrediting organization.

Certificate Inquiry grid

Displays up to nine historical certificates, plus one current and one pending certificate, for a total of eleven. All fields are read-only.

Cert Status

Status of the certificate.

Certificate

The certificate type: 1 Compliance, 2 Waiver, 3 Accreditation, 4 Microscopy - PPMP, or 9 Registration. Although not displayed in the grid, Registration has two subtypes: 1 Compliance and 3 Accreditation, depending on application type.

Class Code

Lab’s classification code: Regular, Exempt, or VA.

Effective Date

The certificate's effective date.

Expiration Date

The certificate's expiration date.

Mailed Date

Date the certificate was mailed to the lab/owner.

Termination Code

The lab’s termination code.

H Ap

Application type code for current and historical certificates. Taken together, entries in the column provide a history of application types for a lab.

Miscellaneous Billing Information

Generate Replacement Certificate

Indicates that a replacement certificate should be generated. Defaults to blank; can be updated to Yes by SA, RO, and CO users with appropriate permissions.

If set to Yes, a request is sent to CMS for a replacement certificate for the lab. When CMS mails the replacement certificate, a new Mailed Date is inserted.

Override Adjustment Edits

Indicates whether adjustment edits should be overridden. Defaults to No; can be updated to Yes by CO super user only.

Override Adjustment Date

Date that Override Adjustment Edits was set to Yes. Entered when the batch job is run. Read-only.

Outstanding Balance

Outstanding balance due from the lab. Read-only.

Billing Inquiry grid

Lab’s billing and payment history. All fields are read-only.

Cert Date

Date the certificate was issued.

Trans Date

Date the billing transaction was recorded.

Description

Short text description of the billing activity.

App

Numeric ID of the application type.

Sched

The lab's schedule code.

State

State where the lab is located.

Billing Amt

Amount billed to the lab.

Payment Amt

Amount paid by the lab.

Lockbox Date

Date the payment was entered by the bank vendor, i.e., date the lockbox batch job was run.

Batch

Lockbox batch job number.

Item

Lockbox item number.

CLIA Certificate and Billing Inquiry window: Buttons

Print

Prints all certificate and billing information for the lab including information not currently visible in the window, which you must scroll to view.

Save

Saves any changes and exits.

Cancel

Exits without saving.

Status Change window

Laboratory Information

All fields are read-only.

CLIA #

The lab's CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number).

Compliance Certificate Effective Date

Effective date of a Compliance certificate, i.e., the date the laboratory was determined to be in compliance with program requirements.

Enforcement Status

Lab's current enforcement status, if applicable. Status can be one of the following:

- Proposed Open
- Proposed Closed
- Imposed Open
- Imposed Closed

Exp Date

Current expiration date of the lab's certificate.

Term Code

Current termination code assigned to the lab.

ASPEN Pending Survey

Pending survey date from ACO.

***Last Uploaded Survey**

Date of the last successful survey upload to national.

Application/Certificate grid

Information about the lab's Pending, Current, and First Prior applications and certificates including:

Application Type: 1 Compliance, 2 Waiver, 3 Accreditation, or 4 PPMP.

Certificate Type: 1 Compliance, 2 Waiver, 3 Accreditation,
4 Microscopy - PPMP, or 9 Registration. Although not displayed in the grid, Registration has two subtypes: 1 Compliance and 3 Accreditation, depending on application type.

Eff Date: effective date of certificate

Exp Date: expiration date of certificate

Term Code: termination code for lab

Status Change

Is this a correction?

Enabled only if today's date is within 6 months of the current certificate effective date. Select Yes if you are correcting the certificate. Corrected certificates maintain the same Effective Date as the original certificate.

Note: If you select Yes and corrections are not allowed, you will receive a message.

Select No if you are not correcting the certificate, but rather beginning a new certificate cycle.

New App Type

Lab’s new CLIA application type.

Required for status changes. Cannot be the same as the current application type, unless a pending application type is present and different than the current application type.

New Eff Date

New effective date of certificate.

Depending on the situation, this field is:

- Automatically set and disabled.
- Enabled and required.
- Disabled if a status change is not allowed.

When this date is automatically set, it is read-only. A message tells you: “The New Effective date has been set to the [date origin]” where the [date origin] is the name of the field from which the date was derived.

When this field is enabled, you must enter a date within the range specified by the system. The acceptable range of dates is based on changes, corrections, and the new application type.

Status Change: Buttons

Cert/Billing

Opens the Cert/Billing Inquiry window.

Save

Saves changes and exits.

Cancel

Exits without saving.

Termination window

Laboratory Information

All fields are read-only.

General Information

CLIA #

The lab's CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number).

Compliance Certificate Effective Date

Effective date of a Compliance certificate, i.e., the date the laboratory was determined to be in compliance with program requirements.

Enforcement Status

Lab's current enforcement status, if applicable. Status can be one of the following:

- Proposed Open
- Proposed Closed
- Imposed Open
- Imposed Closed

Exp Date

Current expiration date of the lab's certificate.

Term Code

Current termination code assigned to the lab.

ASPEN Pending Survey

Pending survey date from ACO.

***Last Uploaded Survey**

Date of the last successful survey upload to national.

Application/Certificate grid

Information about the lab's Pending, Current, and First Prior applications and certificates including:

Application Type

1 Compliance, 2 Waiver, 3 Accreditation, or 4 PPMP.

Certificate Type

1 Compliance, 2 Waiver, 3 Accreditation, 4 Microscopy - PPMP, or 9 Registration. Although not displayed in the grid, Registration has two subtypes: 1 Compliance and 3 Accreditation, depending on application type.

Eff Date

Effective date of certificate.

Exp Date

Expiration date of certificate.

Term Code

Termination code for lab.

Termination/Reactivation

Term Code

Termination code for the lab. Only qualified Central Office or Billing Contractors can select 08 Non-Payment of Fees and only qualified RO and CO users can select 80 (Awaiting State Approval), 33 (Accreditation not Confirmed), and 99 (Do Not Reactivate Without Checking with RO).

Termination Date

Must be greater than the current certificate effective date plus one day, and less than or equal to the current certificate expiration date. For Compliance and Accredited labs, cannot be prior to the effective date of any specialties. Cannot be more than six months in the future.

Gap?

Indicates if there will be a gap in the certificate cycle, or if a certificate will be issued as if the lab was never terminated.

If a lab requests reactivation before 6 months have lapsed since the current certificate expiration date, this question must be answered. The lab may or may not be reactivated with a gap in the certificate cycle, depending on circumstances.

If a lab requests reactivation after 6 months have elapsed, there must be a gap in the certificate cycle. The question is answered Yes, and the field is disabled. Gap Effective Date is set to today’s date.

Gap Eff Date

Effective date of reactivation with a gap. Enabled when the answer to “Gap?” is Yes. Automatically set to today’s date when “Gap?” is set to Yes by the system. Term Code for the pending certificate is set to 00 and the pending effective date is set to this date.

Must not be more than 6 months after today’s date.

Gap App Type

Application type for reactivation with a gap. The lab may choose to return with a different application type.

Termination/Reactivation: Buttons

Cert/Billing

Opens the CLIA Certificate and Billing Inquiry window.

Save

Saves changes and exits.

Cancel

Exits without saving changes.

Browse Accounts Fields

Browse Accounts window

Provider Search

Provider #1 - 3

Enter up to 3 valid CLIA provider numbers.

116 Lookup button

Click to open the Find Accounting Providers window to locate a lab if you don’t know its provider number.

Find Provider button

Click to initiate search and open Certificates and Billing Inquiry window with certificate and billing information for the specified CLIA providers.

Lockbox Search

Lockbox Process Date ... to

Single lockbox process date or a range. If you specify a date range, the search pulls all Lockbox data in the range, inclusive of the dates entered.

When you enter a Lockbox Process Date range, you must also enter a Check # and/or select Show unresolved Only.

Batch

Batch job number within the lockbox file.

Item

Item (accounting record) number within the batch.

Check #

Check number in the accounting record.

Show unresolved Only

Limits the search to unresolved accounting records.

Find Lockbox button

Click to initiate search for accounting history records matching the specified lockbox criteria and open Audit Inquiry window displaying the matching records.

Audit Search

Lockbox Process Date

Date the lockbox file was processed.

Batch

Batch job number within the lockbox file.

Item

Item (accounting record) number within the batch.

Check #

Check number in the accounting record.

Find Lockbox button

Click to initiate search for accounting records matching the specified lockbox criteria and open Lockbox Inquiry window displaying the matching records.

Browse Accounts window: Buttons

New Search

Clears the current search criteria.

Exit

Returns to the Select Application window.

Find Accounting Providers window

See Fields: "CLIA 116 Find window", on page 387.

Accounting Providers Find Results window

See Fields: "CLIA 116 Search Results window", on page 389.

Certificates and Billing Inquiry window

General Information

CLIA # on tab

The lab’s CLIA number (aka CLIA provider number, CCN, Medicare provider number, provider #/number). Up to three tabs, one for each provider.

Name of lab

Lab’s name is at the top of the tab.

Outstanding Amount

Balance of outstanding fee, if any.

Certificate Inquiry grid

Displays up to nine historical certificates, plus one current and one pending certificate, for a total of eleven. All fields are read-only.

Cert Status

Status of the certificate.

Certificate

The certificate type: 1 Compliance, 2 Waiver, 3 Accreditation, 4 Microscopy - PPMP, or 9 Registration. Although not displayed in the grid, Registration has two subtypes: 1 Compliance and 3 Accreditation, depending on application type.

Class Code

Lab’s classification code: Regular, Exempt, or VA.

Effective Date

The certificate's effective date.

Expiration Date

The certificate's expiration date.

Mailed Date

Date the certificate was mailed to the lab/owner.

Termination Code

The lab’s termination code.

H Ap

Application type code for current and historical certificates. Taken together, entries in the column provide a history of application types for a lab.

Billing Inquiry grid

Lab’s billing and payment history. All fields are read-only.

Cert Date

Date the certificate was issued.

Trans Date

Date the billing transaction was recorded.

Description

Short text description of the billing activity.

App

Numeric ID of the application type.

Sched

The lab's schedule code.

State

State where the lab is located.

Billing Amt

Amount billed to the lab.

Payment Amt

Amount paid by the lab.

Lockbox Date

Date the payment was entered by the bank vendor, i.e., date the lockbox batch job was run.

Batch

Lockbox batch job number.

Item

Lockbox item number.

Certificates and Billing Inquiry window: Buttons

Print

Prints all certificate and billing information for the lab on the active tab including information not currently visible in the window, which you must scroll to view.

Refund

Creates a Refund record, i.e., moves money associated with the selected record (row) in Billing Inquiry to Refund. Enabled only for users with appropriate permissions and if the lab and billing record meet the following conditions:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Billing record is for either full or partial payment.
- Record type is 01, 02, 04, 05, or 06.
- Certificate date associated with the payment to be moved is for the most current cycle: pending, if present; otherwise current.

Unresolve

Creates an Unresolved record, i.e., moves money associated with the selected record (row) in Billing Inquiry to Unresolved. Enabled only for users with appropriate permissions and if the lab and billing record meet the following conditions:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Billing record is for either full or partial payment.
- Record type is 01, 02, 04, 05, 06, or 70.
- Certificate date associated with the payment to be moved is for the most current cycle: pending, if present; otherwise current.

Generate Fee Coupon

Generates a replacement fee coupon if the current laboratory is active or terminated with termination code 08 (Non-Payment of Fees), non-exempt, and has an outstanding fee. Enabled only for users with appropriate permissions.

116 Detail

Opens the CLIA 116 for the current lab in read-only Inquiry mode.

Lockbox Inquiry

Accesses the Lockbox Inquiry window after you enter search criteria in the Inquire By window.

Cancel Pmt

Cancels payment for a Paid record selected in Billing Inquiry if:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Record type is 01, 02, 04, 05, or 06.

Enabled only for users with appropriate permissions.

Exit

Returns to the Browse Accounts window.

Inquire By window

The values shown for the lockbox criteria are copied from the selected payment record in the Billing Inquiry section of the Certificates and Billing Inquiry window. You can choose to search lockbox records by one option only.

Process Date

Select to open the Lockbox Inquiry window and show all records associated with the process date.

Batch #

Select to open the Lockbox Inquiry window and show all records associated with the process date and batch number.

Item #

Select to open the Lockbox Inquiry window and show all records associated the process date, batch number, and item number.

Lockbox Inquiry window

Specified search criteria are shown at the top.

Lockbox Inquiry

Provider #

Lab’s provider number (aka CLIA #/number, CLIA provider number, CCN, Medicare provider number).

Rec Type

Accounting type code for paid bills, CK for lockbox check records, 70 for refunds, 80 for unresolved records.

Lockbox

Date the lockbox file was processed.

Batch

Lockbox batch job number.

Item

Lockbox item (accounting record) number within the batch.

Billed

For paid fee records, amount the lab was billed; 0.00 otherwise.

Amount Paid

For paid fee records, amount the lab paid on the fee. Otherwise, check amount, unresolved amount, or refund amount–as applicable.

Status

Billing status/category description.

Transaction

Lockbox process date, payment status date, audit date, or add date depending on record type, audit code, payment status code, and payment amount.

Transaction Code

Lockbox transaction code.

Lockbox Inquiry window: Buttons

Print

Prints the contents on all pages of the Lockbox Inquiry window in PDF format.

Refund

Creates a Refund record, i.e., moves money associated with the selected record (row) in Billing Inquiry to Refund. Enabled only for users with appropriate permissions and if the lab and billing record meet the following conditions:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Billing record is for either full or partial payment.
- Record type is 01, 02, 04, 05, 06, or 70.
- Certificate date associated with the payment to be moved is for the most current cycle: pending, if present; otherwise current.

Unresolve

Creates an Unresolved record, i.e., moves money associated with the selected record (row) in Billing Inquiry to Unresolved. Enabled only for users with appropriate permissions and if the lab and billing record meet the following conditions:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Billing record is for either full or partial payment.
- Record type is 01, 02, 04, 05, 06, or 70.
- Certificate date associated with the payment to be moved is for the most current cycle: pending, if present; otherwise current.

Certificate/Billing Inquiry

When Lockbox Inquiry is accessed from Browse Accounts, this button opens the Certificates and Billing Inquiry window.

When Lockbox Inquiry is accessed from the Certificates and Billing Inquiry window, this button is disabled; click Exit to return to the Certificates and Billing Inquiry window.

Cancel Pmt

Cancels payment for a Paid record selected in Billing Inquiry if:

- Class code for lab is Regular (CLIA); can't be exempt or VA.
- Lab is active or terminated.
- Record type is 01, 02, 04, 05, or 06.

Enabled only for users with appropriate permissions.

Exit

Returns to the previous window.

Audit Inquiry window

Specified search criteria are shown at the top.

Audit Inquiry

Provider #

Lab’s provider number (aka CLIA #/number, CLIA provider number, CCN, Medicare provider number).

Rec

Accounting type code for paid bills, CK for lockbox check records, 70 for refunds, 80 for unresolved records.

Amount

For paid fee records, amount the lab paid on the fee. Otherwise, check amount, unresolved amount, or refund amount–as applicable.

Add ID

ID of individual or batch job that added the record.

Add Date

Date record was added

Update ID

ID of individual or batch job that updated the record.

Update Date

Date record was updated

Batch

Lockbox batch job number.

Item

Lockbox item (accounting record) number within the batch.

Check

Check number.

Audit Inquiry window: Buttons

Print

Prints a hard (paper) copy of the displayed accounting audit trail.

Certificate/Billing Inquiry

Always disabled.

Previous

Returns to the previous window.

Menu

Returns to the ASPEN Web CLIA Maintenance - Select Application window.

Other ASPEN Web CLIA Fields

Login window

User ID

Your assigned national system user ID.

Password

Your national system user password.

Login button

Logs you in and opens the Select Application window.

System Information window

Qies System Notes

Displays messages posted about system status. CO users can enter notes; read-only for all others.

Failed Upload Transactions

Lists failed CLIA transactions from the previous night's cycle.

Trans #

ID number of the transaction.

Trans Category

Transaction category: CLIA, ENF (Enforcement), or ODIE.

CLIA #

Lab’s assigned provider number (aka CLIA number, CLIA provider number, CCN, Medicare provider number, provider #).

Trans Date

Date of the transaction.

Trans Status

Transaction status: -1, 00, 05, 10, or 15

Trans Type

Transaction type code: 00, 01, 03, 04, or 05.

Trans Description

One-word description of the transaction type: Add, Delete, Add, Update, Prior.

Current User Information

Name

National system login name of current user.

Type

Current user type:

01 Regional Office

02 Central Office

04 Accrediting Organization

05 Veterans Administration

06 Billing Contractor

07 Lockbox User

Security Role

Security level or role within Type assigned to current user.

Type	Role
01, 20	FA Full Access RO Read-Only
02	FA Full Access RO Read-Only SU Super User
04	01 TJC 02 AOA 03 AABB 04 CAP 05 COLA 07 ASHI
05, 06, 07	Not Applicable

State

State Agency user's state.

Region

Regional Office user's region number.

Batch Jobs

Date From

Start date of date range filter.

To Date

End date of date range filter.

Find button

Click to update the list of audit files according to the specified date range.

Calculated Run Date

Date job was calculated to run.

Actual Run Date

Date job actually ran.

Job Name

Name of the batch billing job.

Job Status

Run status of the job.

View Audit Messages/View button

Click the View button to open the audit file for the job in a text editor.

Other System Information

Database

Database the current user is accessing.

Other ASPEN Web CLIA Fields: Buttons

Print

Prints the contents of the System Information window.

Done

Returns to the Select Application window.

CLIA Facility Properties Fields

For CLIA lab subtypes 221-224, you cannot populate or modify fields in the <FacName> Definition window that are updated by the nightly extract from the CLIA 116 web app. Provider information that you optionally add in ACO will not appear in the national CLIA database.

Facility Definition tab

For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app. Provider information that you optionally add on this tab will not appear in the national CLIA database.

Identification

Facility ID

Unique facility identifier assigned by the state for the lab, except it is system-generated for a 225 lab. Cannot be changed once the record is saved.

A provider must have this ID to be entered into ASPEN. It cannot match the ID of an existing provider in your state's ASPEN database.

CMS Certification Number

The Federal provider number, commonly referred to as CLIA #/number; also sometimes called provider #/number/ID or Medicare #/number/ID. All labs requiring certification must have a CMS Certification Number (CCN). Labs that are licensed by the state typically do not have a CCN unless they also require certification. Some licensed-only labs may have a CCN for tracking purposes at the national level.

You cannot change the CMS Certification Number if an ADD of an initial certification is pending or has been accepted. If a pending ADD of an initial fails, then the CCN can be updated until an ADD is accepted.

225 NOCN labs are *not* assigned provider (CLIA) numbers. If a 225 lab applies for and receives a CLIA number, you need to update its Type on the Facility Definition tab and enter the CLIA number from the CLIA 116 web app.

Medicaid ID

If your state uses a separate Medicaid (vendor) ID for internal controls or billing, enter that number here.

Employer ID

Federal tax identification number known as the Employer Identification Number (EIN) used to identify a business entity, the provider in this case. The EIN is downloaded from the CLIA 116 web app during the nightly update and is read-only here.

State Key

Optional alternate state identification number for the provider. 16 alphanumeric characters maximum, uppercase only. Read-only in ARO.

License Number

State-assigned license identifier. Maximum number of characters is 10. Shared with the License Number field on the Licensing tab.

Type

Select the provider type. Licensure-only provider categories defined by your state are included in the list. The only Federal provider type that can be assigned to new labs is 225 Lab-CLIA-No CLIA Number.

Note: Type can't be changed here after a kit is accepted.

Current

Current operating status of the provider.

Opened

Date the lab opened.

Closed On

Date the lab closed. When a Closed On date is specified, an **X** appears on the lab's icon in the Tree view and the label is gray. If accessibility options are enabled, the label will not change to gray.

Plan Approval

Date the building plan was approved.

NPI

Provider's National Provider Identifier (NPI). Not currently supported for labs.

Title 18 (Medicare)

Select this box if the provider is a Medicare provider.

Title 19 (Medicaid)

Select this box if the provider is a Medicaid provider.

Title 18/19

Select this box if the provider is a dual provider, both Medicare and Medicaid.

Licensure

Select this box to indicate the provider is inspected by the state.

Description

Name

Enter the working name of the lab, up to 50 characters (depending on character width). The working name appears in the Tree and List views, and in survey forms, reports, and letters that you create in ACO for this provider.

ACO displays the name in upper case (all capital letters) in this window, but displays it in mixed case (initial capital letters) in lists, reports, and letters.

Legal Name

By default, it is the same as Name, but you can change it. No matter what case you use here, ACO displays the legal name in mixed case (initial capital letters, up to 80 characters) in lists, reports, and letters.

When it is necessary to include the provider's legal name in a letter, you can insert the Facility Legal Name macro in the form letter template.

Address

Street address of provider.

Address 2

Second line of street address, if applicable.

Zip

9-digit Zip+4 code for the provider. Click Find to find and enter the Zip Code, which is required, in the first part of the field. You can manually enter the optional 4-digit extension in the second part of the field.

If the Zip Code covers more than one City or County, ACO provides a drop-down list that you can select from.

City

City in which the provider is located.

State

2-character postal code for the state in which the provider is located.

County

County name must match a value in the database table.

Phone

Phone number of the provider, including area code.

Fax

Fax number of the provider, including area code.

OSCAR State Region

OSCAR State Region code of the region in which the provider is located.

OSCAR State Region

OSCAR State Region code of the region in which the provider is located. Changed “OSCAR” to ‘national’ July 18 2016. JH

Contact Information

Emerg. Contact

Name of an emergency contact for the provider.

Phone

Phone number of the emergency contact.

Extension

Phone extension of the emergency contact.

E-Mail

Email address of the emergency contact.

Assessment Contact

Name of the assessment contact for the provider.

Remote Login ID

ACO generates a Remote Login ID for each new provider after you close the Define New Facility window. It consists of the state postal abbreviation plus the state Facility ID. You will see it when you open the Facility Properties window for the provider.

CLIA

Lab Class

Extracted from the CLIA 116 web app. Read-only. Lab classification code. Values are: 00 Regular, 05 Exempt, 10 VA.

Lab Type

Extracted from the CLIA 116 web app. Read-only. The type of provider or organization the lab is associated with.

Director

Extracted from the CLIA 116 web app. Read-only. The lab director's first name, middle initial, and last name.

Addresses tab

For CLIA lab subtypes 221-224, you cannot populate or modify fields that are updated by the nightly extract from the CLIA 116 web app. Address information that you optionally add on this tab will not appear in the national CLIA database.

Add

Click to open the Mailing Address window and add an additional mailing address.

Modify

Select an address in the grid, then press this button to open the Mailing Address window and modify the address.

Delete

Select an address in the grid, then press this button to delete it. If you delete the primary address, you are reminded to select another.

Make Primary

Select an address in the grid, then press this button to designate it as the primary address.

Mailing Address window

Care Of

Name of recipient to which mail should be addressed. This is the only field you can modify for the physical address here; other changes must be made on the Facility Definition tab.

Address

Street address or post office box number where the lab receives its mail.

Address 2

Second line of street address, if applicable.

City

Name of the city where the lab receives its mail.

State

Name of the state where the lab receives its mail.

Zip

9-digit Zip+4 code for the mailing address. Enter the Zip code, which is required, in the first part of the field, and the optional 4-digit Zip extension in the second part of the field.

Addr Type

ACO determines the Addr (Address) Type. The address listed on the Facility Definition tab is the physical address (01 Physical). ACO designates all additional addresses as 02 Mailing.

Associations tab

Information that you optionally add on this tab will not appear in the national CLIA database.

Management Unit

Select the management unit of the State Agency responsible for the provider.

Supervisory/ Work Unit

Select the supervisory/work unit responsible for the provider. Listed units are determined by which management unit was selected.

LSC/DSI Unit

LSC/DSI unit of the State Agency responsible for the provider.

Accreditation

Does not apply to labs. Accreditation details are entered through the CLIA 116 web app on the Accred Org Info tab of the lab record.

House District

Select the congressional House District representative for the provider.

Senate District

Select the congressional Senate District representative for the provider.

Administration tab

Information about lab administrators that you optionally add on this tab will not appear in the national CLIA database.

Administrator Directory Search

Name/Find Now

To search for an administrator, enter all or part of the name here and click Find Now.

List of returned names

List of all administrators that met the search criteria specified in the Name field.

Create Administrator button

Click to open the Enter Administrator Information window and add an administrator to the Administrator Directory.

Click Here to Assign >>

Click to assign the selected administrator to the lab. The Administrator Information window will appear for you to enter start date, end date, and type for the administrator.

<FacName> Administrators

Administrators Linked to this Facility

List of administrators who are linked (assigned) to the lab.

Make Primary button

Click this button to designate the selected administrator as the primary administrator for the lab. The primary administrator is indicated by an asterisk. The first administrator assigned is automatically designated the primary administrator. Admin macros use the primary administrator when form letters are generated.

Modify button

Select a linked administrator and click this button to open the Administrator Information window where you can modify assignment information.

Remove button

Click to delete the selected administrator from the list of linked administrators. If you delete the existing primary administrator, a message reminds you to pick another primary administrator.

Administrator Information

Started

The date the administrator started.

Ended

End date of the administration.

Administrator Type

Select from 01 Administrator, 02 Asst Administrator, 03 Medical Director, 04 Director of Nursing, 05 Coordinator, 06 Hospital Administrator.

Enter Administrator Information

Sal

The administrator’s salutation (title).

First

Administrator’s first name.

M.I.

Administrator’s middle initial.

Last

Required. Administrator’s last name.

Address

Administrator’s street address.

System ID

ID code assigned by the system.

City

Administrator’s location city.

State

Administrator’s location state.

Zip

State postal code.

Phone Number

Administrator phone number.

Fax Number

Administrator fax number

Title

Administrator's formal title.

Default Administration Type

The administration type.

Email Address

Administrator email address.

License

Number

Shared from the License Number field on the Facility Definition tab. Read-only here.

Expiration Date

Date the license expires.

Type

Provider type. Licensure-only provider categories defined by your state are included in the list.

Licenses

Select this button to add administrator licenses.

Ownership tab

Ownership information that you optionally add on this tab will not appear in the national CLIA database.

Owner Directory Search

Name/Find Now

To search for an owner company, enter all or part of the company name here and click Find Now.

List of returned names

List of all owner companies that met the search criteria specified in the Name field.

Create Owner button

Click to open the Enter Owner Company Information window and add an owner company to the Owner Directory.

Click Here to Assign >>

Click to assign the selected owner company to the lab. The Owner Properties window will appear for you to enter information about the owner.

<FacName> Owners

Officers button

Select an owner company and click this button to open the Select/Enter Owner Officers window. From there you can add, modify, or delete officers of the owner company, and designate the primary officer.

List of linked owners

List of owner companies that are linked (assigned) to the lab.

Make Primary button

Click this button to designate the selected owner company as the primary owner of the lab. The primary owner is indicated by an asterisk. The first owner company assigned is automatically designated the primary owner. The Facility Owner Name macro inserts the primary owner when form letters are generated.

Modify button

Select a linked owner and click this button to open the Owner Properties window where you can modify ownership information.

Remove button

Click to delete the selected owner company from the list of linked owners. If you delete the existing primary owner, a message reminds you to pick another primary owner.

Owner Properties

Financial Category

Select the Financial Category. Options are: 01 Profit, 02 Non-Profit, 03 Other.

Owner Of

Select what is owned; 01 Building, 02 Health Care OPS, 03 Land, 04 Building, Land, 05 Health Care OPS, Building, Land, 06 Management Company.

Ownership Type

Select the type of ownership.

- 01 RELIGIOUS AFFILIATION
- 02 PRIVATE
- 03 OTHER
- 04 PROPRIETARY
- 05 GOVERNMENT-CITY
- 06 GOVERNMENT-COUNTY
- 07 GOVERNMENT-STATE
- 08 GOVERNMENT-OTHER

Start

Start date of ownership.

End

End date of ownership.

Is this a Management Company?

Click to select if this is a management company.

Enter Owner Company Information

Company Name

Required. Name of the company that holds ownership.

Company System ID

The company's system ID.

DBA

Company Doing Business As name.

Tax ID

Company Tax ID number.

Contact Information

Phone

Company telephone number.

Fax

Company fax number.

Email

Company contact email address.

URL

Company Internet address.

Mailing Address

Street Address

Company street address.

City

City in which the company is located.

State

Two digit state code in which the company is located.

Zip

Company postal code.

Select Parent Company

Click to Lookup Parent

Select this button to look up a parent company already in the system.

Clear

Use this button to clear the inserted parent company.

Parent ID

Read-only. Parent ID number that is filled upon selection of a parent company.

Parent Name

Read-only. Parent name that is filled upon selection of a parent company.

Parent Type

Select the parent company type.

Licensing tab

License information that you optionally add on this tab will not appear in the national CLIA database.

License Number

Shared from the License Number field on the Facility Definition tab. Read-only here.

License Type

Select the applicable license type, i.e., renewal interval.

License Issue Date

Date the license was issued to the provider.

License Effective From

Starting effective date of the license.

License Effective To

Ending effective date of the license.

License Continuing?

Select if the license is continuing.

Other tab

Miscellaneous information about a lab that you optionally add on this tab will not appear in the national CLIA database.

Latitude

Latitude of lab location in decimal degrees–12 characters maximum, e.g., 39.55.

Longitude

Longitude of lab location in decimal degrees–12 characters maximum. e.g., -87.683333.

Insurance Expiration

Date the provider's insurance expires.

Surety Bond

Status of surety bond.

Fiscal Year End

Month in which provider's fiscal year ends. You must specify it as a number, e.g., 02 for February.

Special Operating Hours?

Select if the lab has special operating hours. If yes, click the Notes button at the bottom of the window to enter the hours.

Bankrupt

Select if provider has declared bankruptcy and enter Petition Date and End Date (below).

Petition Date

Enabled only if Bankrupt checkbox is selected. Enter the date that the provider filed the bankruptcy petition.

End Date

Enabled only if Bankrupt checkbox is selected. Enter the date of the final bankruptcy court order.

Special Focus

Indicates a Special Focus Facility (SFF).

Begin Date

Enabled only if the Special Focus checkbox is selected. Enter start date of closer monitoring of the SSF.

End Date

Enabled only if the Special Focus checkbox is selected. Enter end date of SSF monitoring. If substantial improvement has not been achieved, the lab is subject to termination.

Media Contact

Name of provider's media contact.

Chain

Name of chain that provider belongs to.

DOJ Contact

Name of DOJ contact for lab.

Intermediary/Carrier No.

Current active MAC. Carried forward from L31 on the CMS-1539. Read-only here. If you change the MAC on the CMS-1539, it is updated here.

CLIA Certification Kit Fields

This section provides detailed descriptions of the fields and buttons in CLIA certification kits. Their order corresponds to the order of the screen graphics in the previous chapter, "CLIA Screens" on page 297.

Certification & Surveys tab

Certification Properties and Responsible Parties

Kit Accepted / Kit Not Accepted

Indicates whether or not the kit has been successfully uploaded to the national reporting system. Not displayed for Prior kits, which by definition have been successfully uploaded.

If information for any form is changed after the kit has been accepted by the national reporting system so that all the information required for upload is no longer entered, the green checkmark on the form's tab changes to red but the Kit Accepted indicator remains.

Facility and CMS 670 Edits Passed/Not Passed

Indicates whether or not facility and CMS-670 edits have been passed. If passed, the button is disabled. If not passed, the checkmark is red and selecting the button displays a list of failed edits.

TrackID

A unique identifier supplied by ACO.

All surveys associated with the certification use this number in their Event ID.

Category

Category of the kit is determined by the national reporting system.

If there has been a prior successful upload of a certification kit for the current provider, the new kit is a Recertification. If there are no prior uploads, the new kit is an Initial Certification.

Release for CMS Review?

When the Release for CMS Review? checkbox is selected, either manually or automatically when the kit is submitted to the national reporting system, a flag icon appears that indicates whether or not the certification is flagged for RO review.

A blue flag icon means that the certification requires RO review.

An icon with circle/slash imposed on a blue flag means no need for RO review has been indicated.

Status

This field is not uploaded to the national reporting system. Users can change the status to Closed so when they see the certification listed in the Tree or in the Tracking window, they will know that no further action is necessary.

Facility Details button

Opens a read-only view of information about the provider.

CLIA 116 button

Starts the CLIA 116 web app and opens the 116 form (lab record) for the current lab.

Responsible Parties/Edit

Lists responsible parties assigned to the certification kit. There must always be at least one responsible party. When a certification kit is first created, the kit's creator is made a responsible party automatically.

Click the Edit button to open the Responsible Parties window, where you can update the assigned parties. The fields are the same as on the Responsible Parties subtab on the Tracking tab. When you enter a responsible party in one location, it is automatically entered in the other locations.

Citation List

Conditions exist - is there an IJ?

Does not apply to CLIA labs.

Tag

Number of the tag that was cited. The citation list is sorted by tag number.

Type

Tag Type as entered in the Regulatory Tag Properties window. Possible values are:

C - Condition
E - Element
L - Licensure
M - Memo
R - Requirement
S - Standard

Description

Tag Title from the Regulatory Tag Properties window.

SS

Not applicable for CLIA labs.

Cert, Complnt

These checkboxes indicate whether the citation applies to the Recertification and Complaint survey categories. ACO marks Cert when Initial Certification or Recertification is selected in the Citation Properties window, and Complnt when Complaint Investig. is selected.

Completion (X5)

This is the Facility POC Complete date from Citation Properties. It is the date the provider states the deficiency will be corrected. You can edit the date on the grid and the change will be stored in Citation Properties or vice versa.

Not required for CLIA validation surveys with standard-level deficiencies only.

Corrected

The Correction Date from Citation Properties. It is the date the deficiency was found to be corrected during a revisit.

Refused

If selected, indicates the provider refused to correct the citation.

Status

ACO assigns status as follows:

- 5 - Not Corrected. A tag has been cited and no Corrected date has been entered.
- 6 - Accepted. A Completed date has been specified, but not a Corrected date. The Completed date is the date by which the provider says corrections will be implemented.
- 7 - Corrected. A date has been entered for Corrected, or the Completed date is the same as the Exit date of the survey, which indicates the correction was made during the survey, and there is no need for a Corrected date.
- 9 - Refused. Assigned when the Refused checkbox is selected (two columns to left).

Survey List

Surveys grid

EventID

Unique identifier assigned by ACO when the survey is created. In certification kits, the first four characters of survey EventIDs match the four-digit TrackID of the kit.

Event Type

Category of survey, always Health for CLIA labs, standard or revisit.

Start Date

Date the survey started as entered in Survey Properties.

Exit Date

Final date of survey as entered in Survey Properties.

Survey Category

From Type(s) of Survey selected in Survey Properties.

Status

Indicates whether the survey is Open or Closed.

Signoff (X6)

Date the administrator signed the Plan of Correction. Enabled only if correctable citation(s) are present.

Not required for CLIA validation surveys with standard-level deficiencies only.

2567 Issued

Date CMS-2567 (Statement of Deficiencies) was sent to the provider.

You will receive a message if you enter this date and the survey has no correctable citations. You can choose to retain the 2567 Issued date and allow revisit scheduling anyway, or not.

This field is also seen on the 2567/POC/IDR tab in the third section on the Tracking tab.

Track/POC

POC button is enabled when a 2567 Issued date is entered. Click to open the POC Tracking window, where you can enter dates and notices relevant to the POC tracking process.

Survey List: Buttons

New

Creates a new standard Health survey. After you create the standard survey, this button is disabled. For subsequent surveys, use Create Revisit.

Update

Opens the Survey Properties window for the selected survey. You first select a survey by clicking anywhere in the survey row, then click this button.

Remove

Removes the selected survey from the kit and sends it to the Recycle bin, where it is listed under the associated provider. If you intend to create a new survey to replace the one you “recycled”, locate and delete the recycled survey from the Recycle node. This will re-activate the New button in the certification kit.

Citations Manager

Opens the Citation Manager window for the selected survey.

Survey Forms

Opens the Select Form(s) to print window.

Update 670

Opens the CMS 670 Workload Detail window for the selected survey. You can enter both surveyor team hours and office supervisory and clerical hours.

Create Revisit

Creates a followup survey to the selected survey.

Special Fields

Flag Indicator (SF08)

Determined by ACO when the certification kit is sent to the national reporting system. When an upload is attempted, certifications are automatically flagged for RO review (SF08 is set to 1) if condition-level citations exist or L12 on the 1539 is B - Not in Compliance.

A count of condition-level tags is sent to national to indicate existing COPs whether or not an upload is successful. If the number of condition-level tags changes on a flagged kit, the count is updated on national. If a flagged kit with condition-level tags is deleted prior to upload, all data for the kit is removed from national.

Staff Override (SF12)

When pre-validating the kit for upload, ACO compares current staffing levels with those in the latest survey prior to the current certification. If there is a significant change in staffing numbers, office personnel must select this checkbox to complete the upload.

Beds Override (SF11)

When pre-validating the kit for upload, ACO compares the number of certified beds in the kit to those in the latest survey prior to the current certification. If there is an increase or decrease of 25% or more, office personnel must select this checkbox to complete the upload.

Prior Intermediary # (SF01)

Read-only. If the MAC for the provider is changed on the CMS-1539 (L31), ASPEN stores the number of the prior MAC here.

Cross Ref Provider # (SF03)

For state purposes only.

RO Date

Date text was entered in the RO Text field.

RO Text

Text field provided for entry of notes and instructions by RO personnel. 30-character limit.

SA Date

Date text was entered in the SA Text field.

SA Text

Text field provided for entry of notes and instructions by SA personnel. 30-character limit.

CLIA

Compliance Certificate Effective Date

This is the date the laboratory was determined to be in compliance with program requirements. It is:

- Enabled for initial certifications.
- Required if Certificate Type Change (below) is set to No (the default) in an initial certification. If set to Yes, this field should be blank, although you can override the edit that appears and enter a date; however, you won't be able to upload the kit.
- Automatically set for recertifications to the Compliance Certificate Effective Date of the pending Compliance certificate. It is read-only.
- Disabled for validations.

Certificate Type Change Due to Survey

Enabled and required for initial certification kits only. It is disabled when a kit has been successfully uploaded.

Set to No by default. Choose Yes if a lab has chosen to downgrade its certificate type to Waiver or PPM due to initial survey findings.

When this field is set to Yes, the Compliance Certificate Effective Date (above) is not entered, the CMS-2567 is optional, and the 1557 Specialties tab is disabled. After uploading the kit, you must wait a day, then change application status in the CLIA 116 web app as appropriate.

Note: If no survey will be done, you can delete the certification kit and immediately perform a status change.

Certification Kit Created On

Date the kit was created. Read-only.

Tracking tab

Certification Summary

Certification Date (L34)

The latest exit date of the standard surveys linked to a certification kit. For deemed kits that do not have surveys, ASPEN enters the Survey Date (L34) from the 1539.

Health Exit (X3)

Exit date of Health survey.

LSC Exit (X3)

Not applicable.

Tracking Status

AST assigns a Tracking Status of 01-Active Certification Process when a certification is created.

When all information is entered and the certification has been successfully uploaded (as indicated by Tracking milestone: Uploaded-Ready for Closure), change the Tracking Status to 10-Processing Complete. This signals AST to remove the certification from AST Tracking. For CLIA labs, AST calculates a target date for the beginning of the next certification cycle, and places the facility record in Certifications to be Scheduled for that date.

CLIA Authorization for State Validation Survey (CMS 2802)

Request for RO Approval

Select checkbox to send an RO APPROVAL REQUEST - VALIDATION action item to the RO Responsible Party. If no RO Responsible Party is specified, the message goes to all CLIA RO users in the region.

Today’s date is automatically entered as the date of the request. You can change it if necessary.

RO Response

RO’s response to the request for approval of a validation survey. Options are: 01 Approved, 02 Disapproved.

Date

Date of RO’s response. Today’s date is automatically entered. You can change it if necessary.

Regional Representative

Name of regional representative who approved or disapproved the survey.

Region

Region code of the responding RO; automatically entered by system. You can change it if necessary.

Comments

Regional representative can enter any comments that apply. They will appear on the CMS-2802A form.

Responsible Parties

Assignments made here are carried over to Responsible Parties on the Certification & Surveys tab and vice versa.

Name

Name of SA/RO staff member.

Email Address

Email address from the staff member's personnel record.

SA/RO

Indicates whether the responsible party is a State Agency or Regional Office staff member.

Primary

Selecting the checkbox designates the primary responsible party.

Add S.A.

Add (assign) an SA responsible party to the activity and as a recipient of the related action item message.

Add R.O.

Add (assign) an RO responsible party to the activity and as a recipient of the related action item message.

Delete

Deletes the selected SA or RO.

Activities/Action Items

Sent

Date activity/action item was sent to responsible party.

Due

Due date of activity/action item entered in Define Activity window.

Completed

Completed date of activity/action item entered in Define Activity window.

Type

Type of activity/action item entered in Define Activity window.

Responsible Party

Responsible Party designated in Define Activity window.

Add

Click to open the Define Activity window and add a new activity.

Modify

Select the activity, then click the Modify button to open the Define Activity window and edit the activity.

Delete

Select the activity, then click the Delete button.

Define Activity

Activity

Read-only. Unique identifier for the activity.

Type

Required. Select the Type of activity from the drop-down list.

Sent

Required. The date the activity is originated.

Start

Required. Date on which the activity should be started.

Due

Optional. Date by which the activity should be completed.

Completed

Enter a date here after the activity is finished. When a Completed date is entered for an activity, the status of related action items is automatically changed from Open to Closed.

Staff

Required. To add a staff member, click the appropriate button under the Staff grid (see below), and select an individual or team from the drop-down list in the Add Activity Recipient window.

When you add an individual, the activity is added to that person’s action items. If you add a team, all team members are added to the Staff grid and will receive an action item for the activity.

Only one individual listed in the Staff grid can be designated the Responsible Party. The Activities/Action Items grid in the Termination Tracking Event window lists only the Responsible Party for each activity.

Add SA

Add (assign) an SA staff member to the activity and as a recipient of the related action item message.

Add RO

Add (assign) an RO staff member to the activity and as a recipient of the related action item message.

Add Team

Add (assign) a team to the activity. All team members will be added to the Staff grid and will receive the related action item message.

Remove

Removes (de-assigns) the selected Staff member from the activity. All members of an assigned team must be removed individually.

Comments

Enter relevant notes about the activity in this text box.

Processing Steps

The Processing Steps subtab provides detailed information about individual tasks in the certification process. In many cases, steps are created and dates are entered automatically as information is entered in ASPEN. You can add and modify items manually as needed.

Add Step

Select this button to add a processing step or sub-step.

Remove Step

Select this button to remove the selected processing step or sub-step.

Processing Steps: Grid

Process Step/SubStep

Number and title of the process.

Process Due

Date when the process is due.

Process Complete

Date the process was completed.

Not Req'd

Select this checkbox if the process is not required.

Responsible Party

The party responsible for completing the process. Options are: State, RO, or Both State & RO.

Other Info

Additional information regarding the process.

Letter

Letters sent as part of the process.

Message

Click this cell in the row to send a message to the responsible parties.

Other Info Description

Further information describing other process information.

2567/POC/IDR

Event ID

Unique identifier assigned by ASPEN when the survey is created. In certification kits, the first four characters of survey EventIDs match the four-digit TrackID of the kit.

Event Type

Category of survey. Health, standard or revisit.

Start Date

Date the survey started as entered in Survey Properties.

Exit Date

Final date of survey as entered in Survey Properties.

Survey Category

From Type(s) of Survey selected in Survey Properties.

Status

Indicates whether the survey is Open or Closed.

Adm Signoff (X6)

Date the administrator signed the Plan of Correction. Enabled only if correctable citation(s) are present.

2567 Issued

Date the CMS-2567 (Statement of Deficiencies) was sent to the provider.

You will receive a message if you enter this date and the survey has no correctable citations. You can choose to retain the 2567 Issued date and allow revisit scheduling anyway, or not.

Track/POC

POC button is enabled when a 2567 Issued date is entered. Click to open the POC Tracking window, where you can enter dates and notices relevant to the POC tracking process.

Revisit Status

Used by AST. Determines which providers go on the Revisits to be Scheduled list. Set by the system to 1-Required for standard surveys and to 2-Not Required for revisits. You can manually override the auto-entered value. For licensure-only surveys, Revisit Status is set manually.

When a 2567 Issued date is entered for any survey, Revisit Status is updated to 1-Required, and the survey is flagged for revisit scheduling. You will receive a message if the survey has no correctable citations. You can choose to retain the 2567 Issued date and allow revisit scheduling anyway, or not.

If an intake is finalized and Revisit Status is 1-Required for the most recent investigation revisit survey (based on exit date) associated with the intake, Revisit Status is automatically set to 2-Not Required for that revisit. If an investigation does not have any revisits, Revisit Status is not changed for the investigation.

CHOW

This section is not applicable in CLIA certification kits.

Transmittal (CMS-1539)

CMS-1539 Part I

Effective Date: Change of Ownership (L9)

Enabled only in ARO for Medicare providers. Not enabled for initial certifications that have not been accepted by the national reporting system.

If there has been a Change of Ownership since the last survey prior to the current certification, enter the date the change was made. This date must be later than current participation date (L24) and current CHOW date, if any. It cannot be later than one year from today’s date.

The CHOW date is kept in sync if there is more than one current kit. It is carried forward from prior recertifications.

Date of Survey (L34)

Appears on the printed 1539, but not in the window. Is displayed on the certification kit’s title bar as the Cert Exit date, and on the Tracking tab as Certification Date. It is the latest exit date of the Health standard survey.

Type of Action (L8)

Can be Initial, Recertification, or Termination. Enabled only for recertification kits that have not been accepted by the national reporting system. If there are no prior kits for the provider, Type of Action is designated as Initial and cannot be changed.

Must be 5 Validation for Accredited labs; Validation is not an option for other lab types; Initial, Recertification, or Termination are the options.

Fiscal Year Ending Date (L35)

Optional. MM/DD format. ACO supplies the /. Kept in sync if there is more than one current kit. Carried forward from prior kits.

LTC Certification Period From/To

These fields are not used, so they are always disabled.

Certified As (L12)

Select either A. In Compliance or B. Not in Compliance. When you generate the CMS-1539 form for a lab that is In Compliance, an X is placed by 10.A in the L12 field and the Code is A. If the lab is Not in Compliance, an X is placed by 10.B and the Code is B.

For a lab that is In Compliance, you can also select 1 -ACCEPTABLE POC for Based On, the only option for CLIA labs. The generated CMS-1539 form reflects this. An X is placed by 10.A and 10.A.1; the Code is A1.

This field is set to B - Not in Compliance and disabled when Type of Action (L8) is Termination. It is also set to Not in Compliance if condition-level citations exist and cannot be changed as long as there are uncorrected condition-level citations for the certification.

If L12 is set to B because of uncorrected condition-level deficiencies and an upload of the certification kit is attempted, it is automatically flagged for RO review, i.e., SF08 is set to 1. A count of condition-level tags is sent to national to indicate existing COPs whether or not an upload is successful. If the number of condition-level tags changes on a flagged kit, the count is updated on national. If a flagged kit with condition-level tags is deleted prior to upload, all data for the kit is removed from national.

See Below for 16. State Remarks

Brief remarks entered in 30 Remarks (at the bottom of the tab) will print under 16. State Remarks when you print the form. Longer remarks will print on additional pages to be attached to the form.

Surveyor Sign Date (L19)

Required. Date the surveyor signed the CMS-1539. Must be equal to or later than the survey date, but not later than today’s date. SAs cannot change this date once the kit is uploaded successfully.

State Agency Approval (L20)

Required. Date the State Agency approved the certification. This date must be equal to or later than the Surveyor Sign Date (L19), but not later than today's date. SAs cannot change this date once the kit is uploaded successfully.

CMS-1539 Part II

Determination of Eligibility (L21)

Not applicable.

Compliance with Civil Rights

Not applicable.

Statement of Financial Solvency (CMS-2572)

Not applicable.

Ownership/Ctrl Disclosure Stmt (CMS-1513)

Not applicable.

Original Date of Participation (L24)

Read-only for CLIA labs. The CLIA Application (116) Received date populates this field. It is downloaded from the CLIA 116 web app during the nightly update.

For recertifications, the only qualifier is that L24 should be earlier than the termination date, if there is one. L24 is kept in sync if there is more than one current kit, and is carried forward from prior kit(s).

Termination Code (L30)

For CLIA labs, the termination code is entered through the CLIA 116 web app in the Termination window. If you select anything but 00 Active Provider there, you must also enter an Exp (Expiration) Date.

If multiple current certification kits exist for a single laboratory, L30 is enabled in the newer current kit. It is disabled in the older current kit, but updated as necessary to match the value in the newer current kit.

Expiration Date (L28)

For CLIA labs, the expiration date is entered through the CLIA 116 web app in the Termination window. Must be entered when Term (Termination) Code there is anything but 00 Active Provider.

If multiple current certification kits exist for a single laboratory, L28 is enabled in the newer current kit. It is disabled in the older current kit, but updated as necessary to match the value in the newer current kit.

Note: If you reactivate a terminated CLIA lab, this field is cleared and disabled.

Intermediary/Carrier No. (L31)

Must be a valid and active Medicare Administrative Contractor (MAC). Kept in sync if there is more than one current kit, and carried forward from prior certifications.

If you change the MAC here, the prior MAC number is stored in SF01 on the Certifications & Surveys tab.

RO Receipt Date (L32)

Enabled in ARO only. Required for flagged initial certifications, recertifications, and validations.

If nothing is entered, ACO will insert the date and time of the first upload attempt except for validation certifications or unflagged recertifications.

If the RO chooses to review, this date must be equal to or earlier than the Determination Approval date (L33), except in the case of unflagged recertifications, when it is equal to or later than L33.

RO Analyst

ARO only. 3 characters. Enter the initials of the RO reviewer.

Determination Approval (L33)

Enabled and required in ARO. Must be equal to or later than RO Receipt date (L32).

When an unflagged recertification is uploaded, ACO attempts to insert the date of the upload if this field is blank. It can also be entered manually. This date *must* be entered manually for flagged initial certification, flagged recertification, and validation kits.

Remarks

Used to enter notes and instructions (up to 32 K characters) relevant to the certification. Brief remarks entered will print under 16. State Remarks when you print the form. Longer remarks will print on additional pages to be attached to the form.

Survey (CMS-1557)

State License Number

Read-only. Carried over from the Facility Definition tab of the Facility Properties window.

Simultaneous Survey

Enabled and required only for validation kits. Yes or No. Select Yes if the SA or RO does a survey at the same time an AO is surveying the lab.

Survey Status

Read-only. Entered by the system based on Type of Action (L8) and Type of Survey.

Medicare Provider Number(s)

Enter up to six CLIA numbers (aka CLIA #'s, CLIA provider numbers, CCNs, provider numbers/#'s)) of associated labs as applicable.

Personnel

Grouped into three regulatory areas: Moderate Complexity, High Complexity, and Cytology. Enter the number of qualified lab personnel for each applicable area.

1557 Specialties

Specialties and Sub-specialties

For each applicable specialty:

- Select (Compliance initial or recertification) or confirm (Validation) sub-specialties.
- For each sub-specialty, enter (Compliance initial or recertification, required) or confirm (Validation) Effective Date. Enter Expiration Date (Compliance initial or recertification) only to close out a specialty or sub-specialty.
- Enter (Compliance initial or recertification, required) or confirm (Validation) Test Volume.

Are Immunohematology Tests Performed

Required. Select Yes or No.

Are Blood Products Collected

Required. Select Yes or No.

Total Annual Test Volume

Read-only. Calculated and updated based on current specialty data.

Certificate Schedule

Read-only. Calculated and updated based on current specialty data.

Compliance Schedule

Read-only. Calculated and updated based on current specialty data.

Discrepancy Found

For Accredited kits, indicate if you found any discrepancies in the data reported by the AO. Options are:

- None
- Specialty
- Test Volume
- Specialty/Test Volume

Upload tab

Prior Certification Kit Uploads

Action

Type of action, i.e., transaction type, can be:

- 00 Chgdate - changed certification exit date; i.e., survey Exit date (X3)
- 01 Delete - deleted an uploaded kit, RO only
- 03 Add - uploaded a new certification kit
- 04 Update - uploaded change(s) to an existing kit
- 05 Prior - uploaded change(s) to a Prior kit

The traffic light icon is red if the transaction failed, yellow if the transaction is pending, and green if the transaction was successful.

Date

Date of the transaction.

Status

Status codes are:

- -1 - Failed: Invalid or missing data detected, transaction terminated.
- 00 - Pending Upload: Transaction successful, but certification kit not yet uploaded to the national reporting system.
- 05 - Upload in Process: Certification kit is in the process of being uploaded to the national reporting system.
- 10 - Successful: Certification kit accepted by the national reporting system.
- 15 - Failed: Transaction failed at the national level.

By

If the transaction was initiated in ACO, this is the name and Federal ID of the person who initiated the upload. If the transaction was initiated in ARO, “Regional Office” is displayed here.

Error

Type of error.

Transaction ID

Identifier assigned by ACO to each transaction uploaded to the national reporting system.

Sender Type

R (Region) or S (State).

Prevalidate and Upload button

Prevalidates (checks the kit to make sure required information is present and in the appropriate formats), and initiates an upload transaction. This button is disabled when the kit is read-only (locked for use by another user).

Refresh List button

Returns the list to the original sort order.

Print Entire List button

Prints a Transaction Report listing all upload transactions in ascending or descending order.

Delete Pending

Deletes a pending transaction. Only the person who uploaded the transaction can delete it. Disabled for a provider terminated as the result of a change of status.

Upload Transaction Errors

When you select a transaction that had errors, this section appears and lists the errors.

Ex:

670 Workload for staff [survey] … is not complete.

Regional Office has not approved Validation survey.

You can cut and paste the error information to send to support personnel.

Other Certification Fields

POC Tracking

POC data

Track POC progress by providing the following information:

- POC Due
- Received POC
- POC Status
- POC Status Date
- POC Revised Due Date

Letter

Opens the Notices History window, where you can see the letters that have already been sent concerning the investigation, and select a new letter to send.

POC Notes

A text editor in which you can enter notes about the POC process.

Certification Kits (Tracking)

Provider Type

Select the provider type(s) to include.

Status

You can filter this list to show All certifications, Open certifications, or Closed certifications.

Dates

You can also specify a date range for the list. ACO will show only those kits with a certification exit date between the dates you select.

Set

After choosing Status and Dates, click Set to activate the filter.

Show Kits Modified ...

Select if you want to see only kits that have been modified, but not uploaded again since the last upload. If not selected, all kits meeting current filtering criteria are shown, whether modified or not.

Total Certifications

The number of certification kits listed in the window.

RO Quick List

When selected, lists certification kits of interest to ROs, i.e., initial and unaccepted flagged kits. Filters settings are ignored.

Cert ID

4-character unique tracking ID for the kit.

Facility

Lab name.

Provider ID

Federally-assigned provider number (aka CLIA #/number, CLIA provider number, CCN, Medicare provider number, provider #).

Type

Provider type.

Certification Type

Options are:01 Initial Certification, 02 Recertification.

ODIE

Shows indicators of transaction status, if any. An envelope means at least one attempt has been made to upload the kit. A green checkmark means the kit has been accepted.

Kit Status

Options are:01 Open, 02 Closed. Status is set on the Certifications & Surveys tab of the certification kit.

Flag

Indicates whether the kit has been flagged for RO review.

Survey Date

This is the Health survey exit date, shown as Cert Exit in the title bar of the certification kit.

CLIA Payment Rcvd

Date the compliance fee payment was received. NA for a lab with a Certificate of Accreditation. Blank if fee not received.

Print Tracking Report

Prints information about the listed certification kits, using any filters that have been applied in the Filters section. You can specify Sort Order in the window that appears.

View Highlighted Certification

Opens the highlighted certification for viewing and editing.

Print List

Prints the list of certification kits and details in report form.

Please Specify Transactions To List

Start Date

Enter desired start date of transaction date range.

End Date

Enter desired end date of transaction date range.

Facility Types

Click to open the Filter Select Dialog, which lists the facility types in your active My Selections setting. Select the ones you want; only transactions for the selected types will be displayed.

If you don't select any, you'll receive a message, the checkbox will be cleared, and all facility types–not just those in your selection set–will be included.

Transaction Selection Options

Choose which group of transactions to display. Options are:

- All Transactions for Specified Period (Certifications)
- RO Quick List - Initials and Flagged Kits
- All Failed Transactions With No Following Success
- ODIE Overnight Failures (15s) with No Following Success
- All Failed Transactions For Current Work Unit
- All Transactions for Specified Period (Enforcements)
- All Failed Transactions For Non-payment of Compliance Fee

Transactions

Start Date

Enter desired start date of transaction date range.

End Date

Enter desired end date of transaction date range.

Selection Criteria

Lets you select from seven groups of transactions. Same as Transaction Selection Options in the Please Specify Transactions window.

Sort Order

Offers three sort order options.

Refresh List

When you change criteria, the checkmark turns red. Click the button to refresh the display to reflect the changed criteria. The checkmark then turns green to indicate the display is current.

Facility Type Filter

Click to open the Filter Select Dialog, which lists the facility types in your active My Selections setting. Select the ones you want; only transactions for the selected types will be displayed.

Cert ID

4-character unique tracking ID for the certification kit.

Facility

Facility name.

Provider ID

Federally-assigned provider number (aka CLIA #/number, CLIA provider number, CCN, Medicare provider number, provider #) for the facility.

Action

Indicates what kind of transaction was performed. Possible actions are:

- 00 Chgdate - changed certification exit date, i.e., survey Exit date (X3)
- 01 Delete - deleted an uploaded kit, RO only.
- 02 Purge - deleted a provider, or changed provider type in an Initial kit that’s been uploaded
- 03 Add - uploaded a new certification kit
- 04 Update - uploaded change(s) to an existing kit
- 05 Prior - uploaded change(s) to a Prior kit
- 06 Implicit Update - implicitly (automatically) uploaded a change in value

Send Date

Date the transaction was sent.

Status

Status codes are:

- -1 - Failed: Invalid or missing data detected, transaction terminated.
- 00 - Pending Upload: Transaction successful, but certification kit not yet uploaded to the national reporting system.
- 05 - Upload in Process: Certification kit is in the process of being uploaded to the national reporting system.
- 10 - Successful: Certification kit accepted by the national reporting system.
- 15 - Failed: Transaction failed at the national level.

By

Staff member who entered the transaction. If the transaction was initiated by an RO, “Regional Office” is displayed.

Message

A brief descriptor for failed transactions. Click a failed transaction to open the Upload Transaction Errors window, which has a more complete list of error messages.

Transaction ID

Unique ID given to every upload transaction.

Type

Provider type.

Certification Type

Options are:01 Initial, 02 Recertification.

Kit Status

Options are: 01 Open, 02 Closed. Status is set on the Certifications & Surveys tab of the certification kit.

Cert Date

This is the Date of Survey (L34).

CLIA Payment Rcvd

Date the compliance fee payment was received. NA for a lab with a Certificate of Accreditation. Blank if fee not received.

View Related Certification Kit

Highlight a row and click this button to open the certification kit.

Print

Prints the transaction data as a report.

Failed and Overdue Certification Kit Uploads

Filter Options

Show items at least x days old

Enter the desired number of days; the default is 45.

Use My Selections filter

Selected by default. Filters the list of certification kits according to your active My Selections settings. If not selected, all applicable certification kits are shown. Checkbox disabled if there is no active My Selections filter.

Refresh List

The checkmark is green on the Refresh List button until you reset filter options. Then it turns red. At that point, click the button to update the display according to the new criteria. The checkmark turns green again after you refresh the list.

Failed and Overdue Certification Kit Uploads: Grid

Track ID

Unique identifier assigned to the certification kit by ASPEN.

Provider Number

Provider’s CCN.

Created Date

Date certification kit was created.

Age (in Days)

Age in days of the certification kit; today’s date minus the Created Date.

Facility Name

Name of the provider.

Last Upload Date

Date the certification kit was last uploaded.

Upload Status

Status options are:

Failed

The most recent upload attempt failed, or the certification kit was previously successfully uploaded but can no longer be uploaded because of missing or incorrect data.

Overdue

Certification kit is overdue for an upload,i.e., Age is more than 30 days.

Incomplete

Additional data required before an upload can occur.

Certification Kit

Button opens the Certification window for the selected certification kit.

Print

Button prints the displayed list of certification kits as a report.

Surveys (Merge Surveys)

ID

Survey EventID for the listed survey.

Start

Survey Start Date.

Exit

Survey Exit Date.

Status

Options are:01 Open, 02 Closed.

Define Activity

Activity

Read-only. The unique identifier for the activity.

Type

Required. Select the Type of activity from the drop-down list.

Sent

Required. The date the activity is originated.

Start

Required. Date on which the activity should be started.

Due

Optional. Date by which the activity should be completed.

Completed

Enter a date here after the activity is finished. When a Completed date is entered for an activity, the status of related action items is automatically changed from Open to Closed.

Staff

Required. To add a staff member, click the appropriate button under the Staff grid (see below), and select an individual or team from the drop-down list in the Add Activity Recipient window.

When you add an individual, the activity is added to that person's action items. If you add a team, all team members are added to the Staff grid and will receive an action item for the activity.

Only one individual listed in the Staff grid can be designated the Responsible Party. The Activities/Action Items grid in the Termination Tracking Event window lists only the Responsible Party for each activity.

Add SA

Add (assign) an SA staff member to the activity and as a recipient of the related action item message.

Add RO

Add (assign) an RO staff member to the activity and as a recipient of the related action item message.

Add Team

Add (assign) a team to the activity. All team members will be added to the Staff grid and will receive the related action item message.

Remove

Removes (de-assigns) the selected Staff member from the activity. All members of an assigned team must be removed individually.

Comments

Enter relevant notes about the activity in this text box.

Survey Fields

Create Survey, Survey Properties

Survey Info

Start date

Start date for the onsite survey. Click the down arrow to display the ACO calendar and select the date, or type the date in the format mmddyyyy. A provider should not have more than one survey with identical dates.

This field is disabled for standard surveys associated with Prior certification kits, but you can change revisit start dates.

Exit date (X3)

Exit date of the onsite survey. Click the down arrow to display the calendar in which you can select the date, or type the date in the format mmddyyyy. A provider should not have more than one survey with identical dates.

This field is disabled for standard surveys associated with Prior certification kits, but you can change revisit exit dates. It is also disabled after the certification kit is successfully uploaded.

The Survey Pending Date in the national reporting database is set to this date when an initial or recertification survey shell (type E or I) is created.

Status

By default, the status for a new survey is 1 Open. To change the status to Closed, click the down arrow and select 2 Closed.

IQCP

Enabled if:

- The regulation set selected in Regulation(s) has at least one tag eligible for IQCP (per regulation set definition).

  and

- At least one selected Type of Survey option supports IQCP (Recertification, Initial Certification, Complaint Investig., or Federal Monitoring).

Select only if the lab has implemented IQCP for one or more test systems and is following the IQCP process for the survey.

Shell Only

Selected by default for new surveys and revisits. When this indicator is selected, the survey will not be added automatically to an AEM case. When the checkbox is cleared, AEM determines if the survey belongs on an existing enforcement case. If so, AEM automatically adds it to the case.

Users can manually clear this checkbox. ACO will automatically clear it in the following cases:

- 2567/B Complete checkbox selected
- 670 hours entered
- Tags entered (other than 0000 and 9999)
- Correction Dates entered

Note: When a revisit is created, uncorrected tags from the previous visit are carried forward. If tags are added after the initial creation, the Shell Only checkbox is cleared.

If you select the Shell Only indicator when any of the above conditions exist, a warning message indicates that if the survey is on an enforcement case, it will not be removed.

Category

Read-only. Health automatically selected because you can create only a Health survey for labs.

Regulation(s)

Select one or more regulation sets that apply to the survey. The regulations that appear in this list box are determined by selections in the Regulation Set Properties and Define New/Modify Facility Type windows. If you want to add or change the regulation sets in the list, use these two windows.

For Health surveys, only current applicable Federal regulation sets and any applicable state regulation sets for the provider type are listed. You can use the Show All button (described below) to toggle the display to show additional regulations using.

If you specify both Federal and state survey types (see Type of Survey below), you must select at least one Federal regulation set. You cannot select more than one Federal set with the same prefix. You can select state regulation set(s) as well, but you cannot select only state regulation set(s).

Show All/Filter

This button toggles the list of regulation sets between the primary (filtered) list of regulation sets and a secondary (unfiltered) list.

For Health surveys–in the most basic case–the primary list displays current applicable Federal regulation sets, and the secondary list adds all state regulation sets.

The applicable regulation sets shown in the primary display are determined by selections in the Regulation Set Properties and Define New/Modify Facility Type windows. If a state regulation set is selected, for instance, it will be included in the primary list for the specified provider types. After a reg set is selected for the survey, whether from the primary or secondary list, it is included in the primary display.

Team Roster

IDs and names of surveyors on the survey team. Click the Update button to add or remove surveyors.

Update

Accesses the Staff Availability List window, where you can select the surveyors you want on the survey team. You can add out-of-state and other special surveyors (icon has a red "jacket") if your state allows it.

A message appears if you select a staff member whose General Staff Type is 02 Clerical/Support (in the Enter/Update Surveyor Information window). You can choose whether to go ahead and add that staff member or not.

A warning message appears when you attempt to remove a team member from a survey when that team member has citations on the survey. You can continue or cancel the removal.

Type of Survey

Click the checkbox next to a survey type to select it. For a complete list of survey types available for CLIA labs, see "Survey Categories/Types" on page 552.

If a Federal regulation set is linked to the survey, you must select at least one Federal survey type.

You can select a maximum of 5 survey types.

Only ROs can create surveys of type C-Federal Monitoring.

Special surveys are listed after M-Other. They are specific to provider type with the exception of U-COVID19, which is available to all Federal provider types. For details about special CLIA surveys, see "Special Surveys" on page 553.

Type M-Other can be selected by itself for standalone surveys, i.e., surveys not linked to certification kits or intakes, and not assigned special survey type(s).

Extents

Click the checkboxes next to the extents that apply to the survey. Extent options are specific to provider type. Extent options for CLIA labs are:

A-Routine/Std Survey

D-Other Survey

F-Offsite/Paper

I-COVID19

J-Federal Jurisdictional

K-Participating

SOD Tracking

SOD Sent

Date the Statement of Deficiencies was sent to the provider.

POC Rcvd

Date the Plan of Correction was received from the provider.

Revisit Status

Used by AST. Determines which laboratories go on the Revisits to be Scheduled list. Shared with the 2567/POC/IDR subtab on the Tracking tab in a related certification kit.

Set by the system to 1-Required for initial surveys and to 2-Not Required for revisits. You can manually override the auto-entered value. For licensure-only surveys, you set Revisit Status manually.

When a 2567 Issued date is entered for any survey, Revisit Status is updated to 1-Required, and the survey is flagged for revisit scheduling in AST. You will receive a message if the survey has no correctable citations. You can choose to retain the 2567 Issued date and allow revisit scheduling anyway, or not.

Adm Signoff (X6)

Date the administrator signed the Plan of Correction. Enabled only if correctable citation(s) are present.

Not required for CLIA validation surveys with only standard-level deficiencies.

2567/B Entry Complete

Select this checkbox when all CMS-2567 or CMS-2567B data entry in ASPEN is complete. Shared with 2567/B Entry Complete for the survey in the Surveys grid on the Certification & Surveys tab of a related certification kit.

When selected, an audit record is created. The system retains the date the checkbox was first selected and the date it was last changed (selected or cleared). This audit date cannot be changed. The date is used in national performance reports.

Special Survey Tracking

Checkmark

Red - Survey Not Accepted

Survey has been uploaded to national, but not accepted.

Yellow - Survey Not Uploaded

Survey has not been uploaded to national.

Green - Survey Accepted

Survey has been uploaded to national and accepted.

Black - Pending Delete

Survey is pending delete from national.

A checkmark of the appropriate not necessarily matching) color also appears on the icon for a special survey in Tree view.

Action

Upload transaction type: 00 ChgDate, 01 Delete, 03 Add or 04 Update.

Date

Date of the transaction.

Status

Status codes are:

-1 - Failed

Invalid data detected, transaction terminated.

00 - Pending Upload

Transaction successful, but survey not yet uploaded to national.

05 - Upload in Process

Survey is in the process of being uploaded to national.

10 - Successful

Survey accepted by national.

15 - Failed

Transaction failed at the national level.

By

Party that initiated the upload.

Error

Type of error.

Transaction ID

Identifier assigned to transaction by the system.

Sender Type

S = State, R = Region

Refresh List

Button returns the list to the original sort order.

Show Edits

Button opens a list of edits associated with the upload transaction.

Responsible Parties

Button opens the Manage Special Survey Responsible Parties dialog, which lets you assign non-surveyors to a special survey as responsible parties. The surnames of the assigned responsible parties are displayed on the Responsible Parties button as they fit. An ellipsis (…) is added if they do not all fit.

Citation Manager

Citations

Tags cited during the survey. Condition-level tags are displayed in green.

Right-click in this area to give yourself supervisor privileges, delete a citation, view citation properties or POC text, or to rearrange the order of the citations.

A red checkmark appears to the left of a citation in the Citations list if the deficiency has been corrected and a correction date has been entered. Only revisits can have corrected deficiencies.

To add a citation, select a tag in the Regulations section and drag it to this section. To edit or view your citation text for a single tag, double-click the tag. If you are in Supervisor mode, you can edit or view all surveyors' citation text when you double-click the tag. To edit or view one citation, double-click the surveyor's name beneath the tag.

'P' is appended to tags marked as IQCP. They are included on the CMS-2567 and *are* uploaded.

'Q' is appended to tags marked as QC exclusion prior to 01/01/16. They are not included on the CMS-2567 and are not uploaded.

Regulations

This section lists the regulation sets that were selected when the survey was originally defined. Tags are listed beneath each set. Condition-level tags are displayed in green.

Bold tags have content library text available. You can add content library text to any tag: right-click the tag, select Edit Content, then click New in the Content Library Tag Text window.

To enter a citation, you must be the active surveyor. You can click a tag and drag it to the Citations field, or you can right-click a tag and click Add Citation.

To view the text of the regulation, tag, or interpretive guideline, right-click the regulation or a tag, then click Regulation Text or Interpretive Guidelines.

Quick Find

If you know the tag number, enter all or part of it in the Find field above the Regulations list, and ACO will locate the tag in the list for you. This function is case-sensitive (upper/lower), so if the tag number is alphanumeric, use the correct case for the alpha characters. If you enter part of a number, start with the leftmost digit and include leading zeroes.

Double-click the tag in the Regulations list to move it to the Citations section.

Team Roster

The surveyors assigned to the investigation. From this list, you can change the active surveyor or change the roster of team members.

Citation Manager: Buttons

Roster

Opens the survey Team Roster window. You can add or remove surveyors from the team, and designate a team leader.

A message appears if you select a staff member whose General Staff Type is 02 Clerical/Support (in the Enter/Update Surveyor Information window in ACO). You can choose whether to go ahead and add that staff member or not.

Activate

Makes the selected surveyor the active surveyor. New citations entered are associated with the active surveyor's name. The active surveyor's name appears in the Survey Information area of the Citation Manager.

To make a surveyor active, click the name or ID in the Survey Team list and then click Activate. Click Yes in the confirmation message.

Remarks-Non-Confidential

Opens the Pre-decision remarks - Non-Confidential window, which displays the selected surveyor’s notes about the survey, if any. You can enter or edit remarks for the surveyor.

If you are in Supervisor mode, the Pre-decision Remarks for Entire Team - Non-Confidential window opens and displays all team members’ remarks. You can enter or edit notes for any listed surveyor.

Survey Information

General information about the survey, including:

Event ID

The ID assigned to the survey by ASPEN. ACO uses this number to identify the surveys and to merge information collected by different surveyors into the same survey record.

Medicare ID

6-digit Medicare Provider ID of the provider being investigated.

Fac ID

State facility ID generated by ASPEN when the provider record is created.

Active Surveyor

New citations entered are attributed to the Active Surveyor. If you are not listed as the active surveyor, click your name in the Survey Team field and then click Activate.

Mode

Displays either Normal or Supervisor. Normal mode means that the active surveyor is on the team and can add citations. Supervisor mode means that the active surveyor opened the Citation Manager as supervisor and can review but not add citations.

Survey Dates

Start and exit dates of the investigation.

Button Bar

Find

Opens the Find window, in which you can type text that you want to find in a citation, a regulation, or an interpretive guideline. Use this feature to find citations that already address a problem, or to find the tag and regulation that applies to a problem you've found.

Forms

Opens the Select Form(s) to print window, from which you can print survey-related forms.

Letters

Opens the Letter Selection window, where you can generate a new letter, or view letter and notification history.

Attach

Opens the Survey Attachment Documents window. You can attach supporting documents and digital pictures to the survey. You can also view existing attachments.

Repeat Deficiencies

Lists tags cited in the current survey that were cited in previous surveys conducted for the lab using the same regulation set. This can help you identify any repeated deficiencies that remain unfixed.

Citation Properties

Severity/Scope

Not applicable for CLIA labs.

Grid

Not applicable for CLIA labs.

Correction Date

This field is displayed only for revisits. It is the date on which the provider corrected the original problem. If multiple surveyors have cited a tag and one surveyor enters a correction date, that date is automatically entered in this field for the other surveyors' cites.

For current non-compliance tags, the Correction Date cannot be earlier than the exit date of the survey on which the tag was first cited, or later than the exit date of the latest revisit that included the tag.

QC Exclusion

This checkbox appears for D-tags that were flagged as QC exclusion prior to 01/01/16. QC exclusion tags are not included on the CMS-2567 and are not uploaded.

IQCP

This checkbox appears only for tags that are IQCP-eligible (per regulation set definition). Select if the tag is being cited under the lab’s IQCP and the citation references deficiencies related to IQCP, even if non-IQCP deficiencies are also included. Tags marked as IQCP are included on the CMS-2567 and are uploaded.

Citation Category

This list comes from the Type(s) of Survey that were selected in Survey Properties. Select the category (or categories) appropriate for the current tag.

POC Received from Facility

Date the Plan of Correction for the current tag was received from the lab. Disabled if the QC Exclusion checkbox was selected for a tag prior to 01/01/16.

Facility POC Complete (X5)

Date by which the provider states the deficiency will be corrected. This date appears as the Completion date (X5) for the tag in the Citation List section of the Certification & Surveys tab. If you change the date in one location, the change is stored in both locations.

Not required for CLIA validation surveys with standard-level deficiencies only. Disabled if the QC Exclusion checkbox was selected for a tag prior to 01/01/16.

Set All Tags to These POC Dates

Applies the POC dates entered for the current tag to all other tags cited in the survey. Disabled if the QC Exclusion checkbox was selected for a tag prior to 01/01/16.

SA POC Accepted

The date the State Agency accepted the POC for the current tag. Disabled if the QC Exclusion checkbox was selected for a tag prior to 01/01/16.

Specialties

Enabled only for tags that require specialty information. Click to open the Select CLIA Specialties/Sub-specialties window and associate applicable tests with the citation. Only specialties applicable to the current D-tag are listed. For each selected test, specify its Complexity.

Survey Attachment Documents

Document Information

- Event - The Event ID of the survey.
- Description - User-defined description of the attachment. A description is required before you can attach a file.
- File Name - File name and extension of the attachment.

Attach/View

Click this button to add a new attachment, or to view an existing attachment. Some attachment types open minimized, so check your Task bar if you do not see your attachment in full window display.

Delete

Deletes the selected attachment. You will be asked to confirm the deletion.

Select Form(s) to print

CMS 2567

Generates the Statement of Deficiencies and Plan of Correction for the survey. When you select this form, the Customize Survey Report Form window opens so you can customize the report as needed.

Citations moved to another tag or removed due to IDR/Independent IDR and tags marked as QC Exclusion prior to 01/01/16 are excluded from CMS-2567. If state tags are cited, they print separately on the CMS-2567 State Form.

CMS 2567B

Generates the Post Certification Revisit Report. Citations moved to another tag or removed due to IDR/Independent IDR are excluded from CMS-2567B. If state tags were cited and the deficiencies corrected, they print separately on the State CMS-2567B Revisit Report.

CMS 670

When you select CMS 670 and click OK, the Form 670 Print Preferences window appears. You can indicate whether you want a combined report or separate CMS-670 reports. For a combined survey–a recertification and a complaint/incident investigation, for instance–you can choose to print a separate CMS-670 for each survey type (category), or combine the data for the survey types you select into one CMS-670 report. State licensure hours cannot be combined with Federal survey hours.

670 Entry...

This button opens the CMS 670 Workload Detail window, which lists the IDs and names of surveyors on the survey team, and their hours. You can also enter State and RO clerical hours from this window. This information is required for a successful upload.

CMS 1539

For non-certification surveys, generates the Federal Medicare/Medicaid Certification and Transmittal Report for the survey. Click the 1539 Entry button to enter or review the information for this form. For certification surveys, you must enter 1539 information on the Transmittal (CMS-1539) tab of the certification kit.

1539 Entry...

For non-certification surveys, this button opens the C&T 1539 window, where you can enter information that will print on the 1539. For certification surveys, you must enter 1539 information on the Transmittal (CMS-1539) tab of the certification kit.

S/S Grid

Not applicable for CLIA labs.

Quick Report

Prints a draft of information that will be included on the CMS-2567. Useful for reviewing citation text before printing the final CMS-2567. Citations moved to another tag or removed due to IDR/Independent IDR are excluded from the Quick Report.

CMS 1557

Generates the CMS-1557 form, aka the Survey Report Form (CLIA) for the survey. This form combines data from the Survey (CMS-1557) and 1557 Specialties tabs.

1557 Entry…

This button displays a message directing you to enter 1557 information on the Survey (CMS-1557) tab of the certification kit.

CMS 2802 (Validation)

Generates the CMS-2802A. This checkbox is enabled only for validation surveys when: G-Validation is one of the selections for Type of Survey, the survey is part of a certification kit, and RO approval has been received.

Staff Availability List

The list of staff members is filtered by the Work Unit setting in the current My Selections set.

The list of staff members is also filtered by the Facility Type setting in the current My Selections set in ACO and by Allowed Facility Types in the Enter/Update Surveyor window, so that only active surveyors who are eligible to work on currently displayed provider types are included:

- *if* you have AST installed
- *and if* "Use facility types of active selection" is selected on the Scheduling tab of My Preferences in AST. It is deselected by default, so you must select it and then click the Save Settings button.

If these conditions are not met, the list of staff members in the Staff Availability List window is not filtered at all by provider type.

Show Staff By Disciplines

Lets you filter the list of staff members by discipline. Click the button showing an ellipsis (…) to open the Additional Federal Titles window and select the discipline(s) you want. For example, to display only surveyors, select 09 Generalist Surveyor.

Show Staff by Assigned Provider Categories

Lets you further filter the list according to provider categories assigned to staff members. Click to open the Allowed Facility Categories window, and select the provider category(s) you want.

If you have AST installed, the list of facility categories will be filtered by the Facility Type setting in the current My Selections set in ACO if "Use facility types of active selection" is selected on the Scheduling tab of My Settings in AST. It is deselected by default.

Show Terminated Staff

Select to include terminated staff members in the list.

Ignore Work Unit Filter

Select if you want to list staff members regardless of the Work Unit filter setting in the active My Selections set.

Icons

Indicates the focus is on the current row, i.e., the user has clicked in this row.

Indicates the user has clicked in the checkbox to the right to select or deselect the staff member.

Current staff member.

Special surveyor. You can add out-of-state and other special surveyors to survey teams if your state allows it

Terminated staff member.

StaffID

ID assigned in Enter/Update Surveyor Information window.

Name

Name of staff member from Enter/Update Surveyor Information window.

Work Unit

Work unit assigned in Enter/Update Surveyor Information window.

Primary Discipline

Federal Title assigned in Enter/Update Surveyor Information window.

Other Disciplines

If “Yes” appears on the button with an ellipsis (…), click it to show Additional Federal Titles assigned to the staff member in the Enter/Update Surveyor Information window.

Facility Type Qualifications

Click to show Allowed Facility Categories assigned to the staff member in the Enter/Update Surveyor Information window.

TIP: To assign a staff member to particular facility type(s): in the Enter/Update Surveyor window, click the Employee Details tab and select the Allowed Facility Types.

Show Schedule

Click the button with an ellipsis (…) to show Scheduled Activities for the staff member from AST. “Yes” appears on the button if the surveyor has a scheduling conflict with the dates of the current survey.

Conflict of Interest

Click the button with an ellipsis (…) to show Conflict(s) of Interest specified for the staff member in the Enter/Update Surveyor Information window. Yes” appears on the button if the surveyor has a current conflict of interest with the provider to be surveyed.

Special Surveyors

Click to search for and select a special surveyor to add to the list of available surveyors.

CMS 670 Workload Detail

For a combined survey, you can enter hours spent for each portion of the survey, and print either separate or combined 670 forms. If State Licensure is combined with an initial certification, recertification, or complaint/incident investigation/survey, the State Licensure row in the CMS-670 grid is disabled due to existing CMS-670 guidelines.

Staff Name

Each surveyor’s name and unique 5-digit ID is on a shaded row. Surveyors listed are those that are on the Team Roster in Survey Properties.

Category Description

Survey category. Those listed are the Type(s) of Survey specified for the survey in Survey Properties. For a complete list of survey types, see “Survey Categories/Types” on page 552.

Lead

Indicates the survey team leader. You can select only one.

On Team (A)

Select this checkbox for each category of survey in which the surveyor participated. You cannot enter hours for a survey category, and the surveyor is not included on the printed 670 for a survey category until you select this checkbox.

Arrival (B)

The date the surveyor arrived at the lab. Start date is brought forward from Survey Properties. If you change the Arrival date, it must be on or before the survey Exit date (X3), and you should also manually update Start date in Survey Properties.

Depart (C)

The final date the surveyor departed from the lab. Exit date (X3) is brought forward from Survey Properties. If you change the Depart date, it must be on or before X3, and you should also manually update X3 in Survey Properties.

Pre-Survey Hours (D)

Number of hours the surveyor spent preparing for the survey. Includes phone calls, conferences and paperwork. Enter hours to the nearest quarter hour.

Pre-survey hours are optional except for one surveyor on the team.

On-Site Hours (E), (F) and (G)

The number of working hours the surveyor spent onsite, in the specified time frames. There must be at least one entry in either (E), (F) or (G) for each surveyor on the team. Enter hours to the nearest quarter-hour.

Travel (H)

Hours (entered to the nearest quarter-hour) the surveyor spent traveling from home to site or office to site (the lesser of the two). ACO expects travel hours when onsite hours have been entered.

Off Site (I)

Hours (entered to the nearest quarter-hour) the surveyor spent offsite working on the survey and preparing reports.

Off Site hours are optional except for one surveyor on the team.

Print

Opens the Form 670 Print Preferences window, where you can choose to print either separate or combined CMS-670 forms.

Office Hours...

Opens the Form 670 Input Office Hours window, for entry of supervisory and clerical hours for both SA and RO. Also use this window to indicate whether or not a Statement of Deficiencies was given to the provider at the completion of the survey.

Office hours are required for upload.

As in the CMS 670 Workload Detail window, office hours can be split among different portions of a combined survey.

Set All Hours

Highlight a team member and click Set All Hours to copy that person's hours to all the other members of the team.

When there is more than one survey type/category (e.g., recertification and complaint), hours are copied from the selected surveyor to those surveyors who have the On Team box selected for those types.

Create Followup

Start Date

Beginning date of the revisit.

Exit Date

Date the revisit is completed. You cannot create multiple followups with the same exit date for the same survey.

Team Roster

IDs and names of members of the survey team. Click the Update button to add or remove surveyors.

Update

Opens the Select Surveyors window, in which you select the surveyors you want to add to the team roster. You can also add out-of-state and other special surveyors from this window.

A message appears if you select a staff member whose General Staff Type is 02 Clerical/Support (in the Enter/Update Surveyor Information window). You can choose whether to go ahead and add that staff member or not.

Carry Text Forward

Select this box if you want to copy all the surveyor tag text into the followup survey.

Failed and Overdue Special Survey Uploads

Filter Options

Show items at least x days old

Enter the desired number of days; the default is 14.

Use My Selections filter

Selected by default. Filters the list of special surveys according to your active My Selections settings. If not selected, all applicable special surveys are shown. Checkbox disabled if there is no active My Selections filter.

Refresh List

The checkmark is green on the Refresh List button until you reset filter options. Then it turns red. At that point, click the button to update the display according to the new criteria. The checkmark turns green again after you refresh the list.

Failed and Overdue Special Survey Uploads: Grid

Event ID

ID assigned to the survey by ASPEN.

Provider Number

Provider's CCN.

Exit Date

Final date of survey as entered in Survey Properties.

Age (in Days)

Age in days of the survey; today's date minus the Exit Date.

Facility Name

Name of the provider.

Last Upload Date

Date the survey was last uploaded.

Upload Status

Status options are:

Failed

The most recent upload attempt failed, or the survey was previously successfully uploaded but can no longer be uploaded because of missing or incorrect data.

Overdue

Survey is overdue for an upload,i.e., Age is more than 14 days.

Incomplete

Additional data required before an upload can occur.

Survey Properties

Button opens the **Survey Properties** window for the selected survey.

Print

Button prints the displayed list of surveys as a report.

FMS Tracking

Provider Type

Select the provider type(s) for which you want to display FMS events. The type(s) selected by default are those specified in your active selection set.

Deselect All/Select All

This button toggles the selected provider types between none and all.

FMS Exit Date … to

Enter the starting FMS Exit Date and the to (ending date) to filter listed FMS events by a range of FMS survey exit dates.

Revisits Only?

Select checkbox to include only FMS revisit events.

FMS Type

To filter listed FMS events by type, select the desired type.

State

Select a state (or multi-state entity) to view FMS events for that state/entity. The first option is All States in Region followed by states in the current region in alphabetical order, then the other states in alphabetical order with All (for all states) as the first option in that section.

CCN

Enter the CMS Certification Number (aka CLIA #/number, CLIA provider number, Medicare provider number, provider #/number) of a provider (lab) to view FMS events for that provider (lab) only.

Apply Filter Settings

Button refreshes the list of FMS events according to the filters you specified.

FMS Events grid

Shows FMS records filtered according to your specifications.

This grid includes the following columns:

- Upload Pending (Y or N)
- In Casper (Y or N)
- CCN (Provider #)
- Facility Name
- City
- State
- Provider Category
- FMS Type
- FMS Extent
- FMS Health Exit
- FMS LSC Exit (not applicable for CLIA labs)
- State Survey ID
- Assoc. State Exit
- Significant Citation Difference (Y or N)

- Health Event ID
- LSC Event ID (not applicable for CLIA labs)
- State Event ID

Add

Button opens the FMS Add/Update window where you can create a new FMS record.

Modify

Button opens the FMS Add/Update window where you can modify the FMS record selected in the FMS Tracking grid.

Delete

Button deletes the selected FMS record.

View Upload Transactions

Button opens the FMS Transactions window for the FMS event selected in the FMS Tracking grid. It lists prior uploads and transaction errors for the FMS record.

FMS Add/Update

CCN (Provider Number), Name, Address, City, State, Zip

Provider information is entered from Facility Properties. Read-only.

Type of Federal Survey

Type of Federal survey you plan to conduct.

Options are:

A Comparative

B Observational

C Complaint
D Reconsideration

E Special Cytology Survey

F Federal Jurisdictional

G Validation

H Look Behind

I Other Federal Survey

K CLIA Participatory

Extent of Federal Survey

Select the extent of the Federal survey.

Options are: 2 Full without LSC, 4 Partial without LSC.

In Casper

Automatically selected if the FMS record was successfully uploaded to the national reporting system (CASPER).

Upload Pending

Automatically selected if a manual or automatic upload transaction for the FMS record from ARO was sent, but the record hasn't yet been uploaded to national.

Federal Survey

Health/LSC

Always enabled; LSC is not applicable for CLIA labs. Click Health to enable View Survey and View Citations buttons if you want to view survey properties and citations of a linked Health or LSC survey. If you click LSC, the indicator is selected but nothing happens.

Event ID

Read-only. Event ID of the Federal Health survey linked to the FMS record. Entered from Survey Properties. For CLIA labs, never populated for LSC.

Start Date

Read-only. Start date of the Federal Health survey linked to the FMS record. Entered from Survey Properties. For CLIA labs, never populated for LSC.

Exit Date

Read-only. Exit (X3) date of the Federal Health survey linked to the FMS record. Entered from Survey Properties. For CLIA labs, never populated for LSC.

Select

Click to locate (or create) and link a Health survey to the FMS record. For CLIA labs, never enabled for LSC.

View Surveys

Click the Health indicator first; LSC is not applicable for CLIA labs. Then click this button for a read-only view of the Survey Properties window for the selected survey. Not enabled if a survey is not linked to the FMS record.

View Citations

Click the Health indicator first; LSC is not applicable for CLIA labs. Then click this button (enabled only if a survey is linked to the FMS record) for a read-only view of citations in the Citation Manager. Read-only except that the Forms button is enabled so that you can update 670 data if necessary.

State Agency Survey

Event ID

Read-only. Event ID of the state survey linked to the FMS record. Entered from Survey Properties.

Start Date

Read-only. Start date of the state survey linked to the FMS record. Entered from Survey Properties.

Exit Date

Read-only. Exit (X3) date of the state survey linked to the FMS record. Entered from Survey Properties.

Select

Click to locate and link a related state survey to the FMS record.

Survey Date (L34)

Read-only. Exit date of related state survey linked to the FMS event on national.

Match Occurred

Automatically selected if the system found a matching state survey having an exit date within 30 days of the Federal survey created and linked to the FMS event.

Was an interregional survey conducted

Yes or No.

Inter. Region Code

Enabled if an interregional survey was conducted. Select applicable interregional visiting region code.

Survey finding requires preparation of CMS-2567

Required. Yes or No.

Report was sent to state agency

Yes or No.

Date Sent

Enabled if a report was sent to the state agency. Enter the date the report was sent.

Significant differences noted between region and state

Yes or No. Indicate if substantial differences, e.g., in the number of citations or tags cited, exist between the Federal and state surveys.

CMS-2567 Sent to Facility

Yes or No. This field is read-only if the Federal Survey type is B Observational.

Date Sent

Date the CMS-2567 was sent to the lab after the FMS survey. Required if CMS-2567 Sent to Facility = Yes.

Complaint was Substantiated

Yes or No. Enabled only if Type of Federal Survey is C Complaint.

OSPATS

Enabled but not applicable for CLIA labs.

Conditions/Standards

Enabled only if Extent of Federal Survey = 4 Partial without LSC and a Federal survey is linked to the FMS record. Lists the condition and standard level tags in the Federal regulation set assigned to the linked survey. Select the tags that you plan to check for compliance on the survey.

Associated Regulations

The regulation set assigned to the linked Federal survey. Extent of Federal Survey must be 4 Partial without LSC.

Upload

Click to initiate an upload of the FMS record.

Data Transfer Fields

Export

Aspen Transfer Location

A drop-down list of transfer locations to which you can export the survey. ASPEN Transfer Locations are usually the root of the A and C drives.

Other Location

If you want to use a different transfer location, type the complete path to where you want to export the survey, or click the binoculars icon to browse to that location.

Survey Export

Survey list

Lists all the surveys selected for export with Event ID, Provider Name, Fac (Facility) ID, and Last Updated by Source and Destination (user, date, time) for each. Updates may be by transfer or changes made in the application.

Select the surveys you want to send to the transfer destination. If you exported a survey, only that survey is listed and it is selected by default. If you chose to export a provider, all surveys associated with that provider are listed; no survey is selected by default.

Select All

Click to select all surveys in the list.

Select None

Click to deselect all surveys in the list.

Include attachments

Select or deselect to include or exclude attachments in the transfer; selected by default.

Continue with Export

Select this button or press Enter to continue the export process.

Always Use Source: No/Yes

Click the button to toggle between No and Yes. If No (the default), you will be prompted to resolve conflicts between the export source and destination. If Yes, source values will be used for all data fields.

Cancel Export

Select to stop the export process.

Import - ACO/ARO

Import Type options

Click an option to tell ASE-Q to import surveys or regulations.

ASPEN Transfer Location

A drop-down list of transfer locations to which you can import the survey. ASPEN Transfer Locations are usually the root of the A and C drives.

Zip or mdb file

If the transfer file is in a location not specified in this window, enter the complete path here, or click the binoculars to browse to that location.

Import - ASE-Q

Import Type options

Click an option to tell ASE-Q to import surveys or regulations.

ASPEN Transfer Location

A drop-down list of transfer locations to which you can import the survey. ASPEN Transfer Locations are usually the root of the A and C drives.

Other Zip File Location

If you want to use a different transfer location, type the complete path from where you want to import the survey, or click the binoculars icon to browse to that location.

Locate ASE Database

Displays a list of ASE-Q databases on the current network, if any. For network direct or wireless connections, choose the database containing the transfer file or enter the IP address or name of the database.

Notices Fields

Notices History

Letter History section

Lists summary information about letters generated for the current certification kit or survey including: date Created, Letter ID, letter Description, Intake Number, Status (Batched/Printed), and Locked status (Yes/No).

Intake Number is not populated in ACO. If a letter has been added to the print batch, Status = Batched. Otherwise, Status = Printed whether or not the letter has been sent to a printer.

View/Print

Opens the selected letter in the old or new letter word processor, depending on which one was used to create it, so you can view and re-print if necessary. Click a letter to select it before clicking this button.

New

Opens the Select Letters and Distribution Lists window, so you can select the letter you want to send and its recipients.

Modify Date

Opens the Modify Letter History Date window, so you can change the date the letter was sent if necessary.

Delete...

Deletes the selected letter from the intake's letter history.

Lock/Unlock

Toggles to let you lock a letter so it is read-only, or unlock a locked letter. You can use button-level security to limit the availability of the Unlock function to system administrators or other designated individuals.

Notification History

Lists notifications that have been made concerning the current certification kit or survey. You can include or exclude (more likely) letters listed in the Letter History section.

New...

Opens the Notification Type window, where you specify the type of notification, the party sending it, the method (telephone, written, or email) and the date. All fields are required.

Modify

Opens the Notification Type window for the selected notification so you can make changes.

Delete...

Deletes the selected notification from the intake's Notices History.

Select Letters and Distribution Lists

Show All

When you open Select Letters and Distribution Lists from a facility, ACO displays only Facility type letters by default. If you open the window from a survey or Citation Manager, the default display is of Survey letters. Select this checkbox to show all letters.

Form Letter section

Lists form letters available to send out. You can modify individual letters before sending them. To create new form letter templates that will be added to this list, select Letter Management from the System menu.

Distributions section

Lists possible recipients for the letter. The list includes recipients from the ACO Distribution List (System menu | Lookup Values | Distribution Lists) and the provider.

Set Action

Select a recipient, then click this button to toggle through the action options: Letter (sends the letter to the recipient), cc (sends a copy with a notation on the main letter that a copy has been sent to this recipient), bcc (sends a copy with no indication on the main letter that a copy has been sent), or blank (no action).

Preview

Opens the letter in the old or new letter word processor, depending on which one was used to create it, where you can make changes. Once you print the letter from the word processor, it is added to the intake's Letter History.

Notification Type

Type

Select a type for the notification from the pre-defined list.

To modify the list: from the System menu, select Lookup Values | Dictionary | NOTIFICATION | NOTIFYTYPE, then make your modifications.

Party

Indicate whether the notification originated from the 01 Central Office, 02 Field Office, or 03 CMS Regional Office.

Method

Options are: 01 Telephone, 02 Written, 03 E-mail.

Date

Enter the date of the notification.

Letter word processor

File menu

File menu options are:

Save

Save As

Page Setup

Print Preview

Print

Save & Exit

Exit

The only format supported for Save As is RTF.

Edit menu

Standard editing tools such as cut and paste, find and replace.

View menu

Lets you choose among several view layouts, display headers and footers, choose toolbar display preferences, and set zoom level.

Insert menu

Options are:

File

Image

Object

Page Break

Page Number

Format menu

Define and change character and paragraph formats, set tab stops, apply bullets, define and apply styles, and choose text and background color.

Table menu

Options for creating and customizing tables.

Tools menu

Access a spell checker and thesaurus.

Save & Exit

Button saves the document and exits.

Print icon

Opens the Print dialog window.

Find icon

Opens the Find dialog window.

Cut icon

Removes selected text from the letter and pastes it into the Windows clipboard.

Copy icon

Copies selected text to the Windows clipboard.

Paste icon

Pastes the contents of the Windows clipboard into your text at the insertion point.

Undo icon

Undoes the last action performed.

Spell Check icon

Opens the spell checker.

Thesaurus icon

Opens the Thesaurus dialog.

Bold/Italic/Underline icon

Applies bold/italic/underline attributes to the selected text.

Alignment icon

Applies left, right, centered, and justified alignment to the selected text.

Bullet icon

Inserts a bulleted paragraph.

Number icon

Inserts a numbered paragraph. Use to create numbered lists or steps.

Tab Stop icons

Sets left, right, decimal, and center tab stops.

Other Fields

Find

Text

Enter all or part of alphanumeric text (name, ID, street address, etc.) that you want ACO/ARO to locate.

Type options

Click an option to tell ACO/ARO which field to search for the text you entered. If you entered a county name, for instance, select County.

The initial Type default in ACO (when Find is accessed from all tabs except Directory) can be Name (of lab) or CCN (aka CLIA #/number, CLIA provider number, Medicare provider number, provider #/number); there isn't a default in ARO. To change from one to the other in ACO, go to the System menu and select System Configuration | State Customization and make the change; Provider Number = CCN. The default when Find is opened from the Directory tab is Search By Surveyor's Name.

For subsequent searches, Type will default to the last option selected until you close the application.

You can choose whether to include closed facilities in Search Results.

Find Now

Click to locate matching records. Results are shown in the Search Results section.

Filter

This section appears in the Find window when accessed from the Alpha or Type tab in Tree view. The selected Filter option persists from session to session

Select Filtered to include in Search Results only those items specified in your active selection set (e.g., facility type) and allowed by your facility type permissions (if you are searching for a provider).

Select Show-All to display all items meeting the search criteria. This is the initial default. However, if you select an "inappropriate" item in the Search Results list, e.g., a provider of a facility type not included in your active selection set, you will receive a message and be denied access.

Search Results

All records that match the search string and selected Filter option (see above) are listed in this section.

Go to Facility

Highlight an item in the Search Results section and click this button to go to that item in the Tree, as allowed by the current Filter option. Or, double-click an item and ACO/ARO will locate it in the Tree for you.

Action Item Filter Settings

Date

Date range options for filtering the display of action item messages.

You can show messages for all dates, for a specified number of days, or for a specified date range. The default is all dates.

Status

Select Open if you want to see only open action item messages. Select Closed to see only closed action item messages. By default, both open and closed action item messages are displayed.

Type

This section lists the various types of action item messages. Select the type(s) you want to display.

Staff

This section lists the recipients whose action item messages you will see when this filter is active. The action items will all be filtered according to the criteria specified for this filter.

Public

Select this checkbox to make the action item filter available to other users.

Filter Name

Required. Type a brief descriptive name for the action item filter.

ASPEN word processor

File menu

File menu options are:

Save

Export

Import

Insert Backup File

Print

Page Setup

Print Preview

and (when applicable) Complainant Prompts

Edit menu

Standard editing tools such as cut, paste, and search.

Format menu

Change fonts, apply bullets, adjust paragraph and tab settings.

Bold/Italic/Underline icon

Applies (respectively) bold, italic, and underline attributes to the selected text.

Font Color icon

Applies color to selected text.

Alignment icons

Apply left, center and right alignment to the selected text.

Spell Check icon

Opens the Check Spelling window, from which you can check your text.

Import icon

Opens the Import window, from which you can import a text or RTF file.

Save icon

Disabled. Click OK to save your notes.

Find icon

Opens the Find dialog window.

Cut icon

Removes selected text from the letter and pastes it into the Windows clipboard.

Copy icon

Copies selected text to the Windows clipboard.

Paste icon

Pastes the contents of the Windows clipboard into your text at the insertion point.

Undo icon

Undoes the last action performed.

Tab Stop icons

Sets left, right, decimal, and center tab stops.

CLIA Maintenance Fields

Accreditation Fee Table

All fields in the Accreditation Fee Table are read-only.

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Page number box

Jumps directly to the results page you select.

Table

Fee Version

Fee version number.

A, B, C, ...J

Accreditation cert fee by schedule code.

First Column

Region code.

Second Column

State code.

LVA

Fee for low volume labs. Schedule code = V.

COMP

Validation survey fee.

Last Column

Per 500,000 test amount.

Accreditation Fee Table: Buttons

Print

Prints the screen contents.

Exit

Returns to ASPEN Web CLIA Maintenance - Select Application window.

Compliance/Certificate Fee Table

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Page number box

Jumps directly to the results page you select.

Table

Fee Version

Fee version number.

Cert. of Reg.

Certification of Registration fee.

Waiver

Waiver certificate fee.

Microscopy

Microscopy certificate fee.

A, B, C, ...J

Compliance cert fee by schedule code.

First Column

Region code.

Second Column

State code.

LVA

Fee for low volume labs. Schedule code = V.

COMP

Compliance survey fee.

Last Column

Per 500,000 test amount.

Compliance/Certificate Fee Table: Buttons

Print

Prints the screen contents.

Exit

Returns to ASPEN Web CLIA Maintenance - Select Application window.

State Agency List

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Find box

Jumps to the first page containing data for a specific State Agency. Enter full or partial **Name** and select **Go**.

Page number box

Jumps directly to the results page you select.

Search Results Grid

The State Agency List can be sorted by the first four columns by clicking on the column title. An arrow beside the column title indicates the current sort order.

SSA

SSA State code.

Region

Region code.

State

State name.

Name

State Agency name.

Name 2

State Agency name continued.

City

State Agency city.

State Agency List: Buttons

Print

Prints the screen contents.

Add

Opens the State Agency Address - Add window.

Update

Enabled when you select or tab into a row. Opens State Agency Address - Update window.

Inquiry

Enabled when you select or tab into a row. When selected, the State Agency Address - Inquiry window displays in read-only mode.

Exit

Returns to the ASPEN Web CLIA Maintenance - Select Application window.

PT Program List

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Find box

Jumps to the first page containing data for a specific Program. Enter full or partial program **Name** and select **Go**.

Page number box

Jumps directly to the results page you select.

Search Results grid

Click any column title to sort the PT Program List by that column. The up/down arrow displayed in the column header indicates the current sort order. The default sort is an ascending sort on the Program # column.

Program #

Program number.

Name

First program name field.

Name 2

Second program name field.

City/Locality

City for US programs; Locality for International programs.

State/Country

State for US programs; Country for International programs.

PT Program List: Buttons

Print

Prints selected programs in a report format.

Add

Opens the PT Program - Add window to add a new PT Program.

Update

Opens the PT Program - Update window for the selected PT Program.

Inquiry

Opens selected record in read-only mode in the PT Program - Inquiry window.

Delete

Deletes the selected PT Program. If Program Analyte records are associated with the selected PT Program, the button is disabled.

Exit

Exits back to ASPEN Web CLIA Maintenance - Select Application window.

PT Program - Add/Update/Inquiry

Program #

Read-only. On Adds, it is assigned by the system.

Type of Organization

Required field.

Options are:

01-State

02-State Designated Agency

03-Federal

04-Private Non-Profit

Last Batch Date

Read-only. Automatically calculated and displays the Batch Date of the last PT file successfully processed.

Effective Date

Enabled in Add mode. Read-only in Update and Inquiry modes.

Cannot be less than 1/1/1994.

Expiration Date

Program expiration date.

When an expiration date is entered, the system warns you if any score records exist with a PT Score Submission date after the entered expiration date. If you continue and save the record, the system automatically marks those score records with a status of removed.

If the expiration date is changed to a more recent date or removed, score records need to be re-activated.

Physical Address

Name

Required. Program name.

In Add/Modify mode, system displays warning if name already exists for another Program ID.

Street

Required. Street address.

US/International

Required. Defaults to US.

If US is selected, Zip, City, and State fields are enabled. Locality, Postal Code, and Country fields are enabled if International is selected.

Zip

Required if US is selected. Zip code.

zip extension

Enabled if US is selected. Zip code extension.

City

Required if US is selected. Drop-down list options are determined by zip code.

State

Required if US is selected. Determined by zip code.

Locality

Required if International is selected.

Postal Code

Enabled if International is selected. Not required.

Country

Required if International is selected.

Mailing Address

If a Street address is entered in this section, then the other fields in this section are required as in the Physical address section. Otherwise, the fields in this section are not required.

Contact

First Name

Required. Alphanumeric. Contact's first name.

Last Name

Required. Alphanumeric. Contact's last name.

US/International

Required. Defaults to US.

Phone

Required. Contact's phone number.

Email

Contact's email address.

PT Program - Add/Update/Inquiry: Buttons

Print

Prints screen contents.

Save

Shown in Add or Update mode. Saves changes to PT Program.

Exit/Cancel

Exits screen without saving changes. Labeled Cancel in Add or Update mode. Labeled Exit in Inquiry mode.

You receive a warning if changes are made in Add/Update mode and the Cancel button is selected.

PT Analyte List

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Find box

Jumps to the first page containing data for a specific analyte. Enter full or partial Analyte ID# or description in **Find** field and select **Go**.

Page number box

Jumps directly to the results page you select.

Search Results grid

Click any column title to sort the PT Analyte List by that column. The up/down arrow displayed in the column header indicates the current sort order. The default sort is an ascending sort on the Program # column.

Analyte #

Analyte ID number.

Short Description

Analyte short description.

Is Group

Is the listed analyte a group analyte: Y(es) or N(o).

Associated Group Analyte

If analyte is part of a group, list the analyte ID of the associated group.

Passing Score

Analyte’s passing score.

PT Analyte List: Buttons

Print

Prints all analytes selected in report format.

Add

Opens the PT Analyte - Add window to add a new PT Analyte.

Update

Opens the PT Analyte - Update window for the selected PT Analyte.

Inquiry

Opens the PT Analyte - Inquiry window in read-only mode for the selected PT Analyte.

Delete

Deletes the selected PT Analyte.

If program records are associated with the selected PT Analyte, the button is disabled.

Exit

Exits back to ASPEN Web CLIA Maintenance - Select Application window.

PT Analyte Add/Update/Inquiry

All fields are read-only in Inquiry mode.

Analyte #

Required in Add mode. Read-only in Update/Inquiry modes. Must be a unique, numeric, 4 digit Analyte ID number.

Is Group Analyte?

Is the listed analyte a group analyte: Y(es) or N(o).

Editable in Update mode only if there is no data for this analyte in the program.

Defaults to No in Add mode. If value is set to Yes, the Associated Group Analyte field is cleared and becomes read-only.

Associated Group Analyte

If Is Group Analyte is No, list the analyte ID of the associated group.

Editable in Update mode if there is no data for this analyte in the Program.

Defaults to No in Add mode. If Is Group Analyte field is set to Yes, the Associated Group Analyte field is cleared and becomes read-only.

Analyte Valid Starting In Test Year

Required in Add mode. Read-only in Update mode. The year the analyte becomes valid. Must be equal to or greater than the current year.

Cannot be associated with a PT program in years prior to it becoming valid.

Passing Score Threshold

Required in Add/Update mode. Analyte's passing score. Numeric value between 0 and 100 (inclusive).

Number of Tests per Year

Required in Add/Update mode for non-group analytes. Number of tests a lab is required to perform per year for the analyte.

Short Description

Required in Add/Update mode. Analyte short description.

Long Description

Analyte long description.

Deprecated

If checked, indicates analyte is no longer valid. If checked, **Analyte No Longer Valid After Test Year** is required.

Analyte No longer Valid After Test Year

Required if **Deprecated** is checked. Last year the analyte is valid.

Must be greater than **Analyte Valid Starting In Test Year**, and must be greater than or equal to the current year.

Cannot have any data in an associated PT Program in the year after the test year or you receive the following error message:

> This Analyte is associated with PT Programs for the year YYYY. Either uncheck the Deprecated field or enter another year.

PT Analyte Add/Update/Inquiry: Buttons

Print

Prints screen contents.

Save

Enabled in Add/Update mode. Saves changes made to the PT Analyte.

Exit/Cancel

Exits screen without saving changes. Labeled Exit in Inquiry mode; labeled Cancel in Add/Update mode. You receive a warning if changes are made and the Cancel button is selected.

Program Analyte Search

Search for Approved Program Analytes

Program #

Select Program #/Name from drop-down list.

Test Year

Select the calendar year in which the indicated proficiency testing takes place from drop-down list.

Search

Button opens the PT Program Analyte window for the selected **Program #** and **Test Year**. Requires that both **Program #** and **Test Year** are entered.

Copy Program Analytes Forward

Copy From Test Year

Select from drop-down list.

Copy To Test Year

Enter year. Must be greater than **Copy From Test Year.**

Search

Opens the PT Program Analyte Copy window for the selected test years. Requires that both **Copy From Test Year** and **Copy To Test Year** are entered.

Program Analyte Search: Buttons

New Search

Clears all fields on the Program Analyte Search window.

Exit

Exits to ASPEN Web CLIA Maintenance - Select Application window.

PT Program Analyte

Program

Read-only. Displays Program # selected on Program Analyte Search screen.

Test Year

Read-only. Displays Test Year selected on Program Analyte Search screen.

Analyte Id/Name

Analyte Id number and short descriptor for all analytes that are associated with the currently selected program.

Score Correct 1-3

Read-only. Value is set by the PT processing job. Defaults to 0 in when you add a new analyte.

Shows a count of corrected scores submitted by the PT program for each routine event.

PT Program Analyte: Buttons

Print

Prints the screen contents.

Add

Adds a new analyte for the existing PT Program and test year.

Select an analyte from the drop-down list and a new row is added. The drop-down list displays all analytes that have not already been selected for this PT Program, where the current test year is between the analyte effective year and the analyte expiration year.

The Score Correction counts are set by the processing job. Default to zero when analyte is added.

Delete

Deletes the highlighted row. Delete button is enabled if you have the correct security class to delete records AND there is no enrollment or score data for the selected PT Program, Analyte ID, and Test Year.

Strike thru is placed on deleted rows until changes are saved.

Save

Saves all new and removed rows and returns to the PT Program Analyte Search screen.

Cancel

Returns to the PT Program Analyte Search window without saving any changes. You will receive a warning if changes are made and Cancel is selected.

PT Program Analyte Copy

Copy From Test Year

The Program # and Name of all PT Programs approved for analytes for the specified year are listed in the Copy From Test Year column, in alphabetical order by name.

Copy

Checkbox indicates PT programs that will have their approved analytes moved from the Copy From Test Year to the Copy To Test Year. Enabled if there are no approved analytes for the PT program in the Copy To Test Year.

Set to N/A if approved analytes are entered for the PT program in the Copy To Year.

Copy To Test Year

Lists all matching PT Programs, if any, that already have data for the specified year.

PT Program Analyte Copy: Buttons

Print

Prints the screen contents.

Select All

Checks all available Copy checkboxes. Toggles between Select All and Unselect All.

Process

Performs the actual copy of the PT program analyte data. You receive a confirmation message before the processing begins. Any analyte that has been Deprecated for the Copy To Test Year is not copied.

Exit

Returns to the PT Program Analyte Search window without saving any changes. You receive a warning if changes are made and not saved.

PT Enrollment Search

Search By

Region

Select Region from drop-down list.

SSA State

Select SSA State from drop-down list.

State Code

Select State Abbreviation from drop-down list.

Program #

Select PT Program ID from drop-down list.

Test Year

Select Test Year from drop-down list.

Analyte #

Select Analyte ID from drop-down list.

Duplicate Event #1,2,3

Select one or more of the checkboxes to display labs that have enrolled in multiple programs for the same analyte and selected event(s).

Disabled if PT user is logged on.

Provider #

CLIA provider number.

Batch Seq #

Sequence number provided by PT Program when enrollment record was submitted.

Batch Date

Batch date of the submitted PT file. Use drop-down arrow to select from calendar.

Sort By

The sort order is used to determine how the data is displayed on the PT Enrollment List. Select one of the following sort orders on the search screen:

Provider #, Test Year, Analyte #, Program # (DEFAULT)

Test Year, Analyte #, Program #, Provider #

Analyte #, Test Year, Program #, Provider #

Program #, Analyte #, Provider #, Test Year

PT Enrollment Search: Buttons

Print

Prints contents of search screen.

New Search

Clears all entered search criteria.

Find

Opens PT Enrollment List based on selected search criteria.

Cancel

Returns to the ASPEN Web CLIA Maintenance - Select Application window.

PT Enrollment List

All fields on the PT Enrollment List are read-only.

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Find box

Jumps to the first page containing data for a specific provider number. Enter **Provider #** and select **Go**.

Page number box

Jumps directly to the results page you select.

Search Results grid

Provider #

CLIA provider number.

Test Year

Calendar year in which the indicated proficiency testing takes place.

Analyte #

Analyte number.

Program #

PT Program number.

Effective Date

Date the laboratory enrolled in the PT Program for the indicated analyte/event.

PT Score Submission Date 1-3

Date the PT Program must submit scores to CMS. It is sixty days after the date the laboratories must submit their values to the PT program for the indicated analyte/event.

Batch Date

Batch date of the submitted PT file. Use drop-down arrow to select from calendar.

Batch Seq #

Sequence number provided by PT program when enrollment record was submitted.

PT Enrollment List: Buttons

Print

Prints the contents of the screen in report format.

Inquiry

Opens the Provider Address Inquiry screen to show address information for the selected lab.

Main Menu

Returns to the ASPEN Web CLIA Maintenance - Select Application window.

Search

Returns to PT Enrollment Search window.

PT Score Search

Search By

Region

Select Region from drop-down list.

SSA State

Select SSA State from drop-down list.

State Code

Select State Abbreviation from drop-down list.

Program #

Select PT Program ID from drop-down list.

Test Year

Calendar year in which the indicated proficiency testing takes place.

Analyte #

Select Analyte ID from drop-down list.

Event #

Must be a numerical value between 0 and 3.

Duplicate Ind

Select the checkbox to display only scores where the selected event has multiple records for a given lab, analyte, test year, and event #.

Provider #

CLIA provider number.

Batch Seq #

Sequence number provided by PT program when enrollment record was submitted.

Batch Date

Batch date of the submitted PT file. Use the drop-down arrow to select from calendar.

Exclude Removed Scores

Select checkbox to exclude removed scores, or deselect to include all scores. Defaults to exclude removed scores (checked).

Failed Scores Only

Select checkbox to search for failed scores only; the reported score (for non-group analytes) or the calculated score (for group analytes) is below the minimum passing threshold.

Unsuccessful Scores Only

Select checkbox to search for unsuccessful scores only; there have been multiple failures (2 out of 3 scores have failed).

Sort By

The sort order is used to determine how the data is displayed on the PT Score List. Select one of the following sort orders on the PT Score Search screen:

- Provider #, Test Year, Analyte #, Event #, PT Score Submission Date, Program # (DEFAULT)
- Test Year, Analyte #, Event #, Program #, PT Score Submission Date, Provider #
- Analyte #, Test Year, Event #, PT Score Submission Date, Program #, Provider #
- Program #, Analyte #, Provider #, Test Year

PT Score Search: Buttons

Print

Prints contents of the search screen.

New Search

Clears entered search criteria.

Find

Opens the PT Score List based on the selected search criteria.

Cancel

Returns to the ASPEN Web CLIA Maintenance - Select Application window.

PT Score List

Navigation

Page 1 of <#>

Lists the number of pages of search results, and the page you are currently viewing.

First / Previous

First returns to the first page of search results.

Previous returns to the last page viewed.

Next / Last

Next advances to the next page of search results.

Last advances to the last page of search results.

Find box

Jumps to the first page containing data for a specific provider number. Enter Provider # and select Go.

Page number box

Jumps directly to the results page you select.

PT Score List grid

Provider #

CLIA provider number.

Test Year

Test year.

Analyte #

Analyte ID number.

Group

Indicates group analytes, Yes/No.

Event #

Event number.

Score Submission Date

Score submission date.

Program #

PT Program number.

Score

The percentage of correct responses the indicated PT Program gave the laboratory for the indicated analyte/event.

Batch Seq #

Sequence number provided by the PT Program when the enrollment record was submitted.

Reason Codes

Values assigned to reason statements submitted by the PT Programs. Score records explain scores of 0% or 100% assigned by the PT Program that have not resulted from actual values submitted by the laboratory.

Batch Date

Batch date of the submitted PT file. Use drop-down arrow to select from calendar.

Dup Score

Value of Y indicates that more than one PT Program submitted results for this score. Blank if not a duplicate.

Failed

Value of Y indicates that the individual score for the indicated analyte/event fell below the passing value.

Unsuccessful

Value of Y indicates that the score is the second failing score in the last two consecutive events or in the last three events.

Rmvd Ind

Value of A indicates that the indicated score is an active record. R indicates the score record has been removed from the PT data system due to issues with the enrollment record.

PT Score List buttons

Print

Print the screen contents in report format.

Main Menu

Returns to ASPEN Web CLIA Maintenance - Select Application window.

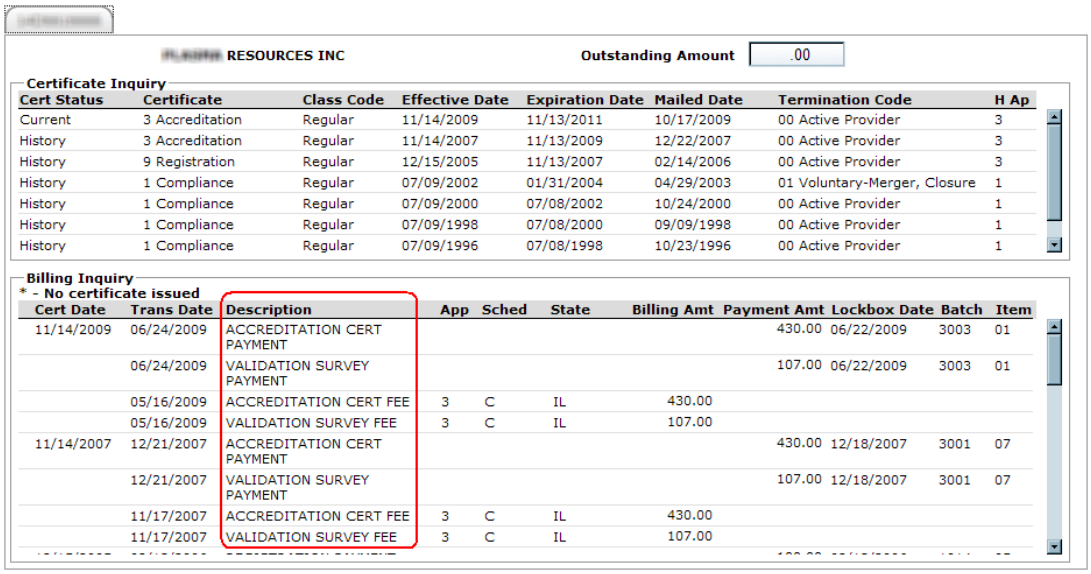
Search

Returns to PT Score Search window.

Supporting Materials

Billing Category Descriptions

The Billing Inquiry section of the Certificates and Billing Inquiry window includes applicable billing category descriptions.



RESOURCES INC

Outstanding Amount .00

Certificate Inquiry

Cert Status	Certificate	Class Code	Effective Date	Expiration Date	Mailed Date	Termination Code	H Ap
Current	3 Accreditation	Regular	11/14/2009	11/13/2011	10/17/2009	00 Active Provider	3
History	3 Accreditation	Regular	11/14/2007	11/13/2009	12/22/2007	00 Active Provider	3
History	9 Registration	Regular	12/15/2005	11/13/2007	02/14/2006	00 Active Provider	3
History	1 Compliance	Regular	07/09/2002	01/31/2004	04/29/2003	01 Voluntary-Merger, Closure	1
History	1 Compliance	Regular	07/09/2000	07/08/2002	10/24/2000	00 Active Provider	1
History	1 Compliance	Regular	07/09/1998	07/08/2000	09/09/1998	00 Active Provider	1
History	1 Compliance	Regular	07/09/1996	07/08/1998	10/23/1996	00 Active Provider	1

Billing Inquiry

* - No certificate issued

Cert Date	Trans Date	Description	App	Sched	State	Billing Amt	Payment Amt	Lockbox Date	Batch	Item
11/14/2009	06/24/2009	ACCREDITATION CERT PAYMENT					430.00	06/22/2009	3003	01
	06/24/2009	VALIDATION SURVEY PAYMENT					107.00	06/22/2009	3003	01
	05/16/2009	ACCREDITATION CERT FEE	3	C	IL	430.00				
	05/16/2009	VALIDATION SURVEY FEE	3	C	IL	107.00				
11/14/2007	12/21/2007	ACCREDITATION CERT PAYMENT					430.00	12/18/2007	3001	07
	12/21/2007	VALIDATION SURVEY PAYMENT					107.00	12/18/2007	3001	07
	11/17/2007	ACCREDITATION CERT FEE	3	C	IL	430.00				
	11/17/2007	VALIDATION SURVEY FEE	3	C	IL	107.00				

Figure 172: Billing category descriptions

All currently defined category descriptions are given below.

One-Part Descriptions

Some billing category descriptions are stored as one word or phrase in the database.

Overpayment

Returned to Treasury

Refund Sent

Refund Approval

Refund Approval Denied

Refund Recommended

Refund Recommended Denied

Used Overpayment

Prior Unresolved

Two-Part Descriptions

Other billing category descriptions are stored in two parts in the database, i.e., they are constructed from two lists of words and phrases.

Part 1

Waiver (if app type 2)

PPM (if app type 4)

Registration (if app type 9(1) or 9(3))

Compliance Survey

Survey Adjustment

Compliance Cert

Validation Survey

Accreditation Cert

Overpayment

Unresolved

Certificate Backout

Compliance Backout

Part 2

Rebill Fee

Final Fee

Fee

Partial Pmt

Payment

Fee Removed

Example

The category description **Compliance Survey Fee Removed** comprises Part 1, item 4 + Part 2, item 6.

Termination/Reactivation Scenarios

There are many rules governing the termination of labs and the reactivation of terminated labs. The specific details for various termination/reactivation scenarios are outlined below.

True Initial Pending

The lab has only a pending certificate.

When

Provider Term Code is Active

Current Certificate Term Code is None

Pending Certificate Term Code is Active

And

User Action is Terminate

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.

- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is None

Pending Certificate Term Code is Terminated

If

User Action is Activate: Reactivating no later than six months after the pending expiration date.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to 00.
- If the lab class is 00, the pending Exp Date is set to two years past the effective date (restore the original 2-year cycle).
- If the lab is exempt, the pending Exp Date is set to the expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.

If

User Action is Terminate: Updating with a different termination code.

Rules are:

- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Term Code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is None

Current Certificate Term Code is None

Pending Certificate Term Code is None or Terminated

And

User Action is Activate: Reactivating lab after six months from the pending expiration date.

Note: Cleanup program will have already cleared certificate information.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending/Gap App Type enabled.
- Pending certificate Term Code is set to 00.
- Pending Eff Date is set to today.
- If the lab class is 00, the pending Exp Date is set to two years past effective date.
- If the lab is exempt, the pending Exp Date is set to the expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- The provider Term Code is set to 00.

When

Provider Term Code is None

Current Certificate Term Code is None

Pending Certificate Term Code is None or Terminated

And

User Action is Terminate

Rules are:

- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.

- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

Initial Pending, Gap

The lab has an active pending certificate and a terminated current certificate. There is a gap between the current certificate expiration date and the pending certificate effective date.

When

Provider Term Code is Active

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Active

And

User Action is Terminate

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Terminated

If

User Action is Activate: Reactivating within six months of pending expiration date.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to 00.
- If the lab class is 00, the pending Exp Date is set to two years past the pending effective date.
- If lab is exempt, the pending Exp Date is set to the expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.

If

User Action is Terminate: Updating with a different termination code.

Rules are:

- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is None

Current Certificate Term Code is None

Pending Certificate Term Code is None

And

User Action is Activate: Reactivating lab after six months.

Note: Cleanup program will have already cleared certificate information.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to 00.
- Pending Eff Date is set to today.
- If the lab class is 00, the pending Exp Date is set to two years past pending effective date.

- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- The provider Term Code is set to 00.

Current and Pending, Fake Gap

The lab has an active pending certificate and a terminated current certificate. There is no gap between the current certificate expiration date and the pending certificate effective date.

When

Provider Term Code is Active

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Active

Note: There is no gap between the current certificate expiration date and the pending certificate effective date.

And

User Action is Terminate: Terminating lab within six months of pending effective date.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Terminated

If

User Action is Activate: Reactivate within six months of the pending expiration date.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to active.
- If lab class is 00, the pending Exp Date is set to two years past effective date (restore the original 2-year cycle).
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to active.

If

User Action is Terminate: Updating with a different termination code.

Rules are:

- Pending certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is None

Current Certificate Term Code is None

Pending Certificate Term Code is None

And

User Action is Activate: Reactivating after six months.

Note: Cleanup program will have already cleared certificate information.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to 00.

- Pending Eff Date is set to today.
- If the lab class is 00, the pending Exp Date is set to two years past the pending effective date.
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.

Current Only

The lab has no pending certificate.

When

Provider Term Code is Active

Current Certificate Term Code is Active

Pending Certificate Term Code is None

And

User Action is Terminate:

Rules are:

- Gap? disabled.
- Termination Date enabled, required and set to current expiration date. (User can update but cannot enter a termination date greater than six months (180 days) from today.)
- Current certificate Term Code and Exp Date are set to the values entered.
- Provider Term Code and Exp Date are set to the values entered.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is None

If

User Action is Activate: Reactivate within six months of current expiration date.

Rules are:

- Gap? enabled.
- Termination Date disabled.
- If Gap? set to Yes:
  - Gap Eff Date/App Type enabled.
  - Gap Eff Date may not be more than six months past today.
  - Pending certificate Term Code is set to 00.
  - Pending Eff Date is set to entered date.
  - If the lab class is 00, the pending Exp Date is set to two years past the new effective date.
  - If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
  - If lab is VA, the pending Exp Date is set to the VA expiration date.
  - The provider Term Code is set to 00.
  - Billing audit triggered.
- If Gap? set to No:
  - Current certificate Term Code is set to 00.
  - If lab class is 00, the current Exp Date is set to two years past current effective date.
  - If lab is exempt, the current Exp Date is set to expiration date of exempt state.
  - If lab is VA, the current Exp Date is set to the VA expiration date.
  - Provider Term Code is set to 00.
  - Exp Date is set to new current certificate expiration date.

If

User Action is Terminate: Updating with a different termination code.

Rules are:

- Current certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.

- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is None

And

User Action is Activate: Reactivating after six months.

Note: Cleanup program will have already cleared certificate information.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending App Type enabled.
- The pending certificate Term Code is set to 00.
- The pending Eff Date is set to today.
- If lab class is 00, the pending Exp Date is set to two years past today.
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.
- Exp Date is set to new pending expiration date.

Current and Pending, No Gap

The lab has an active pending certificate and an active current certificate. There is no gap between the current certificate expiration date and the pending certificate effective date.

When

Provider Term Code is Active

Current Certificate Term Code is Active

Pending Certificate Term Code is Active

Note: There is no gap between the current certificate expiration date and the pending certificate effective date.

And

User Action is Terminate

Rules are:

- Gap? disabled.
- Termination Date enabled, required and set to current expiration date. (User can update but cannot enter a termination date greater than six months (180 days) from today.)
- Current certificate Term Code and Exp Date are set to the values entered.
- Provider Term Code and Exp Date are set to the values entered.
- No change to the pending certificate values.
- Only qualified CO users and Billing Contractors can select termination code 08 and only qualified RO and CO users can select termination codes 80, 33, and 99.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Active

And

User Action is Activate: Reactivate within six months of current expiration date.

Rules are:

- Gap? enabled.
- Termination Date enabled.
- If Gap? set to Yes:
  - Gap Eff Date/App Type enabled.
  - Gap Eff Date may not be more than six months past today.
  - Pending certificate Term Code is set to 00.
  - Pending Eff Date is set to entered date.
  - If lab class is 00, the pending Exp Date is set to two years past new effective date.
  - If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
  - If lab is VA, the pending Exp Date is set to the VA expiration date.
  - Provider Term Code is set to 00.
  - Exp Date is set equal to new pending expiration date.
  - Billing audit triggered.
- If Gap? is set to No:
  - Termination Date is disabled.
  - Current certificate Term Code is set to 00.
  - If lab class is 00, the current Exp Date is set to two years past current effective date.
  - If lab is exempt, the current Exp Date is set to expiration date of exempt state.
  - If lab is VA, the current Exp Date is set to the VA expiration date.
  - Provider Term Code is set to 00.
  - Exp Date is set to two years past current certificate effective date.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Active

If

User Action is Activate: Reactivate after six months beyond the current expiration date (after cleanup has run).

Rules are:

- Gap? and Gap Eff Date disabled.
- Pending App Type enabled and set to pending certificate App Type.
- Termination Date disabled.
- Pending certificate Term Code set to 00.
- Pending App Type set to entered value.
- Pending Eff Date set to today.
- If lab class is 00, the pending Exp Date is set to two years past effective date.
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.
- Exp Date is set to new pending expiration date.

If

User Action is Terminate: Updating with a different termination code.

Rules are:

- Current certificate Term Code is set to entered Term Code.
- Provider Term Code is set to entered Term Code.
- Termination code can be changed to another value with the following restrictions on SA, Exempt, and VA users:
  - Changing any existing termination code on a terminated lab to termination code 80, 33, or 99 is not allowed.
  - Changing existing termination code 80, 33, or 99 to another termination code is not allowed.

Current and Pending, Both Terminated

The lab has a terminated pending certificate and a terminated current certificate.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Terminated

And

User Action is Activate: Reactivate within six months of pending effective date.

Rules are:

- Gap? disabled.
- Termination Date disabled.
- Pending certificate Term Code is set to 00.
- If lab class is 00, the pending Exp Date is set to two years past pending effective date.
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.
- Exp Date is set to new pending expiration date.

When

Provider Term Code is Terminated

Current Certificate Term Code is Terminated

Pending Certificate Term Code is Terminated

And

User Action is Activate: Reactivate within six months (cleanup has run).

Rules are:

- Gap? and Gap Eff date disabled.
- Pending App Type enabled and set to pending certificates App Type.
- Termination Date disabled.
- Pending certificate Term Code set to 00.

- Pending App Type set to entered value.
- Pending Eff Date set to today.
- If lab class is 00, the pending Exp Date is set to two years past effective date.
- If lab is exempt, the pending Exp Date is set to expiration date of exempt state.
- If lab is VA, the pending Exp Date is set to the VA expiration date.
- Provider Term Code is set to 00.
- Exp Date is set to new pending expiration date.

CLIA 221-224: Extracted Facility Properties

Provider records in ACO for CLIA labs of types 221 LAB-CMPL, 222 LAB-WAIV, 223 LAB-ACCR, and 224 LAB-PPMP are updated from the CLIA 116 web app via a nightly extract process. Extracted facility property fields, listed below, cannot be updated in the Facility Properties window. All other fields are available according to established rules.

Facility Definition tab

Facility ID

CMS Certification Number

Employer ID

Type

Current Operating Status

Opened

Closed On

Name

Address

Address 2

Zip

City

State

County

Phone

Fax

OSCAR State Region

Lab Class

Lab Type

Director

Addresses tab

all fields

Upload Monitoring Emails

This section contains descriptions and boilerplate text of the automatically generated email notices that alert applicable users to late certification kits. A kit is considered late if it has not been successfully uploaded within a specified number of days from the certification exit date, i.e., Date of Survey (L34).

Late Certification Kit Upload Review

This email lists certification kits that have never been uploaded and are past due for uploading.

Recipients

Management units, team/work units in the given state configured as recipients (File | Email Recipients).

Frequency

Every night.

Email Text

Subject: Late Certkit Upload Review - <State> - <MGMTUNIT> - <Team/Work Unit> - Facility Category - <Date>

The following certification kits have not yet been uploaded within x days of their certification exit date.

<Cert Track ID><Cert Exit Date><Days Since Exit><CCN><FacName>…

Please do not reply to this message.
Thank you.

Late Certification Kit Uploads

This email lists late certification kits. i.e., kits that:

- Have been uploaded but not accepted after a given number of days.
- Were previously accepted but can no longer be uploaded due to failed validation checks.

Recipients

SA/RO staff members who are a responsible party for at least one late certification kit.

Frequency

Every Sunday night.

Email Text

Subject: Late Certkit Uploads for <State> - <Staff ID> - <Staff Name>

The following certification kits have not yet been completed within x days of their certification exit date.

<Cert Track ID><Cert Exit Date><Days Since Exit><CCN><FacName>…

The following certification kits were previously uploaded but can no longer be uploaded.

<Cert Track ID><Cert Exit Date><Days Since Exit><CCN><FacName>…

Please do not reply to this message.
Thank you.

Survey Categories/Types

Abbreviations for survey types used in the:

- Survey Category column in certification kits (Certification & Surveys tab/Survey List)
- Category Description field in the CMS 670 Workload window

are listed below along with the corresponding Type of Survey from Survey Properties where available types depend on circumstances.

Note: Only "Other" types are abbreviated in the Category Description field.

Abbreviation	Type of Survey
RECERT	I-Recertification
INCERT	E-Initial Certification
CMPIVT	A-Complaint Investig.
REVST	D-Follow-up/Revisit
VALID	G-Validation
LICEN	K-State Licensure
INLIC	1-Initial Licensure
RELIC	2-Re-Licensure
CMPLI	3-Licensure Complaint
FEDMON	C-Federal Monitoring
SANCT	J-Sanctions/Hearing
OTHER	M-Other
ADDSPC	S-Add of Specialties
COVID	U-COVID19
PTRVW	V-PT Desk Review
CWPROJ	W-CW Project - obsolete, may appear on older surveys
CYT	X-Cytology
CRTW	Y-Certificate of Waiver
PPM	Z-PPM

Special Surveys

Special surveys can be specified for CLIA labs under Type of Survey in Survey Properties. They are listed after M-Other. The available special survey types for laboratories are:

U-COVID19 - available for all Federal provider types

V-PT Desk Review – Compliance labs only (221)

W-CW Project - obsolete, may appear on older surveys

X-Cytology - Compliance or Accredited labs (221, 223)

Y-Certificate of Waiver - Waiver labs (222) only; replaced W-CW Project

Z-PPM (Physician Performed Microscopy) - PPM labs only (224)

You cannot deselect M-Other when a special survey type is selected; when all special survey types are deselected, M-Other is automatically deselected.

The following rules apply to special surveys:

- Only one special survey per day is permitted for a provider.
- Z-PPM surveys cannot be combined with any other survey, standard or special.
- With the exception of Z-PPM, special surveys can be combined on a single survey event record.
- Special surveys can be combined with certification and/or complaint survey events. In this case, each transaction type is uploaded independently from the others.
- Special surveys cannot be combined with FMS surveys.
- Special surveys can be created for any CLIA lab type except 225.
- An initial survey must be a special survey for a revisit to be a special survey. That is, if special survey types are not selected on the initial, special types cannot be selected on follow-up surveys. Correspondingly, special types cannot be removed from an initial survey if they are still selected on related follow-up surveys.

You can assign non-surveyors to special surveys as responsible parties. They will be notified along with survey team members if an upload of a survey fails.

To assign a non-surveyor to a special survey:

1. Open **Survey Properties** for the survey.
2. In the **Special Survey Tracking** section, click the **Responsible Parties** button to open the **Manage Special Survey Responsible Parties** window.

3 Use the buttons to add SA and/or RO responsible parties, or delete assigned responsible parties as needed.

4 When you are done, click **Close**.

The last names of the assigned staff members are displayed on the Responsible Parties button. An ellipsis (…) is added if all the names do not all fit on the button.

COVID-19 Surveys

ASPEN provides support for surveys that focus on infection control practices relating to the COVID-19 outbreak. ASPEN includes two methods, which are available to all Federal provider types, for tracking inspections that involve a special focus on infection control/COVID-19. States wishing to adopt COVID-19 survey tracking can use the second method for licensure-only surveys.

Method 1: COVID-19 Special Survey

For standalone surveys focusing on infection control–surveys not related to any other survey type such as standard complaint or certification–you can create a COVID-19 special survey. You can also combine a COVID-19 special survey with a standard complaint or certification visit. This function is available for all Federal providers. Other special survey types are available only for a subset of providers.

When creating a survey for any Federal provider type, you will see the special survey value U-COVID19 in the Type of Survey list of the Survey Properties window.

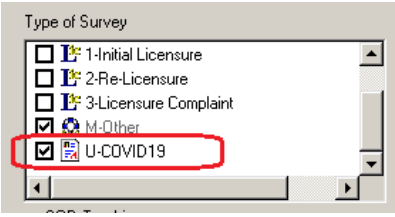


Figure 173: COVID19 special survey type

To create an infection control/COVID-19 special survey:

➥ In ASPEN 11.9.1 or later, follow the usual steps for scheduling a survey. For **Type of Survey**, choose **U-COVID19**.

Choose the COVID19 option alone for a standalone COVID-19 special survey or along with the applicable standard survey type for a combined survey.

Note: Special survey types are uploaded to national as independent transactions.

For existing surveys created before the ASPEN 11.9.1 release, you can include an infection control/COVID-19 focus as part of a revisit. You need to add U-COVID19 as a survey type to the initial survey *before* creating the revisit because special survey types not specified for the initial cannot be added to followups.

To add an infection control/COVID-19 focus to a new revisit:

1. In ASPEN 11.9.1 or later, open an existing standard visit created prior to ASPEN 11.9.1.
2. In **Survey Properties**, select **U-COVID19** under **Type of Survey**.

   You *must* add the COVID19 special survey type to the initial survey *before* creating the revisit as the COVID19 indicator cannot be assigned to the revisit after it is created.
3. Create the revisit survey.

For a revisit created prior to the ASPEN 11.9.1 release, you can use Method 2 to add an infection control/COVID-19 focus.

More ...

Procedure: “Create Survey Shells” on page 119
Procedure: “Create Revisit Survey Shells” on page 160

Method 2: Extension to a Standard Survey

An infection control/COVID-19 focused inspection can be set up as an extension of a standard survey process (certification or complaint) in ASPEN by selecting the COVID19 extent in the Survey Properties window.

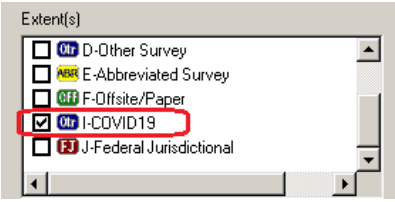


Figure 174: COVID19 survey extent

You can also use this method to add an infection control/COVID-19 focus for a revisit created prior to ASPEN 11.9.1.

When you use the extension method to combine a COVID-19 inspection with a standard process rather than the special survey approach, you avoid creating separate special survey upload transactions in addition to the standard survey uploads.

Special surveys are not supported for state licensure-only surveys, so states wishing to adopt the COVID19 indicator for state licensure surveys can use the extension method to track infection control/COVID-19 surveys.

To add a COVID-19 extension to a standard survey:

1. In ASPEN 11.9.1 or later, follow the usual steps for scheduling a survey.
2. Select the applicable **Type of Survey**.
3. For **Extent(s)**, choose **U-COVID19** along with any other applicable extent(s).

   In the following example, an infection control/COVID-19 focus was included as an extension of a standard complaint inspection.

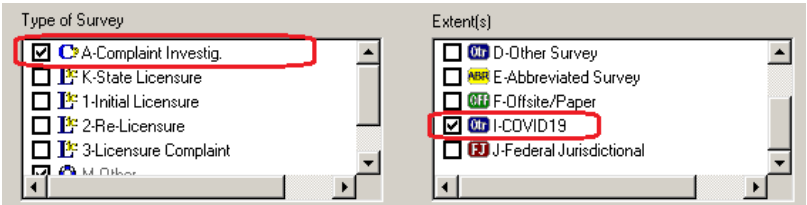


Figure 175: Complaint survey with COVID19 extension

Survey Pending Date

When field information in certification kits is updated in ACO, it is transmitted to the national reporting system via explicit or implicit transactions. Explicit updates to the corresponding fields in the national reporting database occur when the certification kit in which the changes were made is uploaded from ACO to the national reporting system. Implicit updates are automatically sent to the national reporting system; the kit does not need to be uploaded.

The Survey Pending Date is not visible to the user. It is set in the database to the survey Exit date when an initial or recertification survey shell (type E or I) is created, and it is sent to the national reporting system overnight as an implicit transaction. It is also set for validation surveys.

Any changes to the Exit date in the standard survey are sent to the national reporting system as implicit updates of the Survey Pending Date. It is not updated by revisits.

If the survey or certification kit is deleted, the Survey Pending Date value is removed from the national reporting database. It is also removed when the certification kit is accepted.

Since a laboratory may not move with a survey pending, changes to the Zip code, or City and State tied to the Zip code, in the Physical Address section on the Demographics tab are not permitted if there is a Survey Pending Date for the lab. If a certification kit with a pending survey is deleted or successfully uploaded from ACO and the Survey Pending Date therefore cleared, the Zip code/City/State for the lab can then be changed.

Status Values for Upload Transactions

Code	Type	Description
-1	Failure	Transaction failed ACO edits and was not uploaded. Data needs to be corrected and re-uploaded. The transactions must be manually re-uploaded once the data is corrected.
00	Pending	Transaction passed ACO edits and will be processed during the next overnight cycle. The Certification Kit will be read-only while there is a pending transaction.
05	In Process	Overnight cycle has begun. Transaction was pending (00) and has been sent to the national reporting system; waiting for response. Users will not see the 05 status value as it exists only during the nightly job cycle.
10	Successful	Transaction was successfully loaded in the national reporting system.
15	Failure	The transactions must be manually re-uploaded once the data is corrected.

CLIA Reports

You can generate and print several CLIA reports from ACO and from the CLIA 116 web app.

ACO - CLIA Reports

The CLIA Reports option on the Reports menu in ACO offers seven different CLIA reports.

- CLIA Nightly Facility Update
- CLIA 116 Application list
- No. of Sites Mismatch
- CLIA Laboratory Profile Report
- Discrepancy
- Workload Monitoring
- QC Exclusion

They combine and present information from multiple labs. A sample of each of the above reports follows.

Note: The ePOC Tardy SOD Issuance report is available for CLIA labs (Reports menu | ePOC Management Reports).

CLIA Nightly Facility Update

This report shows changes made to the lab record in the CLIA 116 web app that were applied to CLIA provider records in ACO by the nightly extract process.

Printed: 01/28/2016 1:37PM

CLIA Nightly Facility Update

Georgia Dept Health

07/01/2015 through 01/28/2016

CLIA #	License #	Processed Date	Field	Prior Value	New Value
		09/29/2015	DRCTR_MDL_INITL_N		
		09/26/2015	NAME		
		09/29/2015	DRCTR_1ST_NAME		
		09/29/2015	DRCTR_LAST_NAME		
		09/04/2015	DRCTR_LAST_NAME		
		09/04/2015	NAME		
		10/14/2015	NAME		
		07/30/2015	DRCTR_1ST_NAME		
		07/30/2015	NAME		
		07/30/2015	FACTYPE		
		07/30/2015	DRCTR_LAST_NAME		
		07/30/2015	DRCTR_MDL_INITL_N		
		10/14/2015	NAME		
		08/25/2015	DRCTR_LAST_NAME		
		08/25/2015	DRCTR_1ST_NAME		
		07/18/2015	DRCTR_LAST_NAME		
		07/18/2015	DRCTR_1ST_NAME		
		07/18/2015	MAIL_ADR		
		07/03/2015	ADDRESS		
		07/03/2015	MAIL_ADR		
		09/23/2015	DRCTR_LAST_NAME		
		09/23/2015	DRCTR_1ST_NAME		
		09/23/2015	DRCTR_MDL_INITL_N		
		08/11/2015	DRCTR_LAST_NAME		
		08/11/2015	DRCTR_1ST_NAME		
		08/04/2015	TELEPHONE		
		08/14/2015	ADDRESS		
		07/21/2015	DRCTR_1ST_NAME		
		07/21/2015	DRCTR_LAST_NAME		

CLIANightlyFacilityUpdate.rpt

Page 1 of 51

Figure 176: CLIA Nightly Facility Update report sample

CLIA 116 Application List

This report includes 116 applications based on the given range of 116 Complete dates. You can specify Sort Order and filter by several criteria, e.g., Lab Class. The report provides basic information about each laboratory. Application Type lists the current application type, with pending and new application types in parentheses.

Printed: 04/28/2011 9:34 am

CLIA 116 Application List

CLIA #	Laboratory Name/ Physical Address	SA Received Date/ 116 Complete/ Added By	Paid in Full Flag/ Upload Status	Lab Class/ Type of Lab	Application Type
		06/07/1993 08/15/2010	No	Regular Physician Office	4-PPMP 1-Compliance (Pending)
		12/23/1992 07/28/2010	No Success	Regular Physician Office	2-Waiver
		12/15/1992 07/28/2010	No Success	Regular Physician Office	1-Compliance
		12/22/1994 08/15/2010	No Pending	Regular School/Student Health Service	3-Accreditation 1-Compliance (New)
		03/15/1994 07/28/2010	No Success	Regular Ancillary Test Site	3-Accreditation
		12/24/1992 07/28/2010	No Failed	Regular Hospital	3-Accreditation
		03/09/1993 07/28/2010	No	Regular Other Practitioner	2-Waiver
		05/10/1993 07/28/2010	No	Regular Physician Office	2-Waiver

Figure 177: CLIA 116 Application List report sample

No. of Sites Mismatch

This report shows a list of all CLIA laboratories for a given date range where the number of sites that have detail entered in the 116 does not match the value entered in the Number of Sites field. For each lab, the answers to the three Multiple Site exception questions are indicated.

Printed: 01/15/2012 1:32 am

Number Of Sites Mismatch Report

From: 12/03/2010 **To:** 01/15/2012

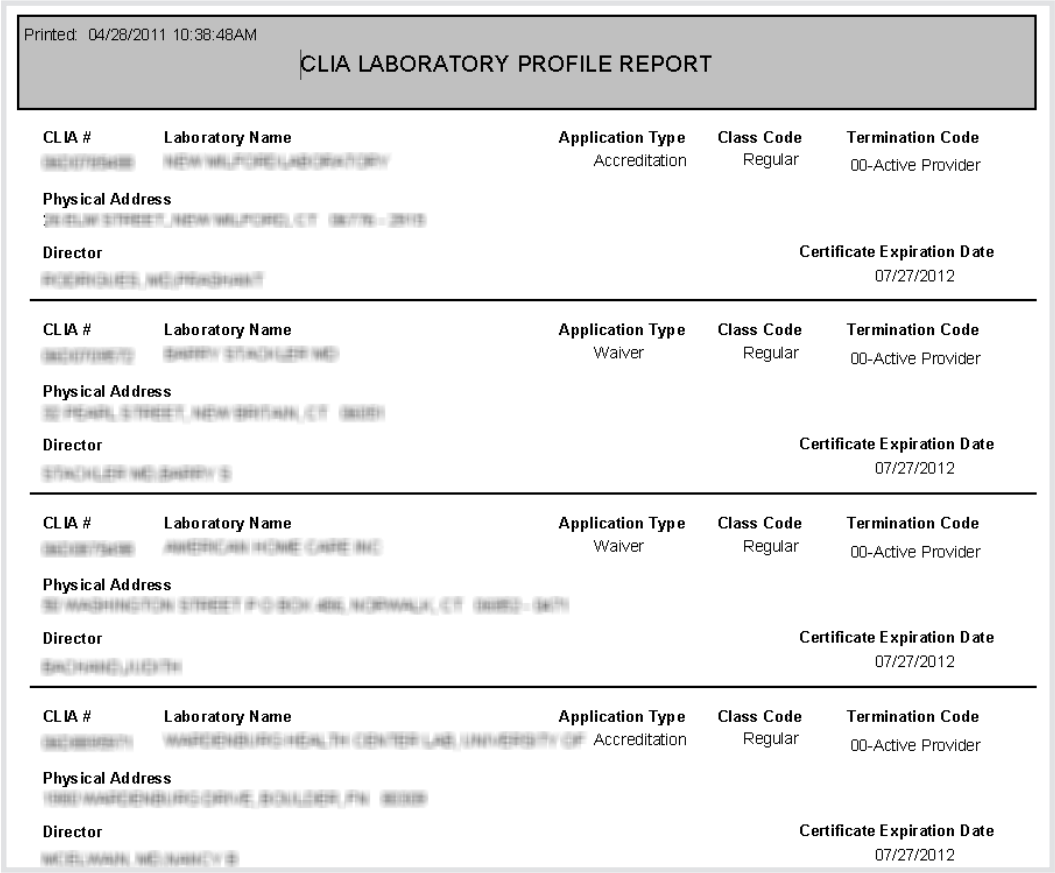
State: Connecticut

CLIA #	Laboratory Name	Application Received Date	No of Sites	Count of Entered Sites Including Primary	Tmp Test	Non-Prft	Hosp
07D107		02/05/2010	20		N	Y	N
07D108		03/06/2010	2		Y	Y	N
07D108		03/07/2010	2		Y	N	N
07D108		07/11/2010	2		N	Y	N
07D108		07/25/2010	3		N	Y	N
07D109		10/10/2010	7		N	Y	N
07D109		10/24/2010	4		N	Y	N
07D109		05/07/2011	3		N	Y	N
07D109		03/12/2011	3		N	Y	N

Figure 178: Number of Sites Mismatch Report sample

CLIA Laboratory Profile Report

When you select the CLIA Laboratory Profile Report menu option, you enter report search criteria in the Find window that opens. The report lists all the laboratories that match the search criteria and provides basic information about each.



Printed: 04/28/2011 10:38:48AM

CLIA LABORATORY PROFILE REPORT

CLIA #	Laboratory Name	Application Type	Class Code	Termination Code
[illegible]	[illegible]	Accreditation	Regular	00-Active Provider

Physical Address: [illegible]

Director: [illegible]

Certificate Expiration Date: 07/27/2012

CLIA #	Laboratory Name	Application Type	Class Code	Termination Code
[illegible]	[illegible]	Waiver	Regular	00-Active Provider

Physical Address: [illegible]

Director: [illegible]

Certificate Expiration Date: 07/27/2012

CLIA #	Laboratory Name	Application Type	Class Code	Termination Code
[illegible]	[illegible]	Waiver	Regular	00-Active Provider

Physical Address: [illegible]

Director: [illegible]

Certificate Expiration Date: 07/27/2012

CLIA #	Laboratory Name	Application Type	Class Code	Termination Code
[illegible]	[illegible]	Accreditation	Regular	00-Active Provider

Physical Address: [illegible]

Director: [illegible]

Certificate Expiration Date: 07/27/2012

Figure 179: CLIA Profile Report sample

Discrepancy

The Validation Survey Discrepancy Report lists CLIA labs with discrepancies in specialty and/or test volume found during validation surveys for a specified date range.

Printed: 12/09/2010 1:27PM

Validation Survey Discrepancy Report

Georgia Dept Health

09/07/2010 through 12/09/2010

	CLIA #	Provider Name	City	Survey Date	Discrepancy
AO - CAP					
	[illegible]	[illegible]	ATHENS	09/26/2010	Speciality/Test Volume
AO - COLA					
	[illegible]	[illegible]	AUGUSTA	11/21/2010	Speciality
AO - TJC					
	[illegible]	[illegible]	COLUMBUS	11/12/2010	Test Volume
	[illegible]	[illegible]	NASHVILLE	12/03/2010	Speciality

CLIADiscrepancy.rpt Page 1 of 1

Figure 180: Validation Survey Discrepancy Report sample

Workload Monitoring

When you select the Workload Monitoring menu option, you enter report criteria in the CLIA Report Options window that opens. The CLIA Workload Monitoring report is then generated. It provides counts for the following survey categories and subcategories (within each category) for the specified survey exit date range.

Categories

- Complaint Surveys
- Recertification Surveys
- Initial Surveys
- Validation Surveys

Subcategories

- Without Revisits (D not selected for Type of Survey/Survey Categ).
- With Onsite Revisits (D selected for Type of Survey/Survey Categ, F not selected for Extent(s).
- With Offsite Revisits (D selected for Type of Survey/Survey Categ, F selected for Extent(s).

Note: Surveys other than validation surveys may be counted more than once. For example, if Type of Survey/Survey Categ = A-Complaint Investig and I-Recertification, the survey is counted in both the Complaint and Recertification categories. However, if Type of Survey/Survey Categ = I-Recertification and G-Validation, the survey is counted only in the Validation category.

In the CLIA Report Options window, you can choose to:

- Print Report Definitions - Lists report definitions (criteria) on the last page of the report.
- Print Report Details - Lists surveys counted for each subcategory within category; includes basic details about each.

Printed: 01/05/2012 3:05PM

CLIA Workload Monitoring

Connecticut Dept Health

10/01/2011 through 12/31/2011

Total Complaints By Federal Surveyors	Total Complaints By State Surveyors	Total Initial Surveys	Total Recertification Surveys	Total Onsite Revisits	Total Validation Surveys Done OnSit
4	4	0	6	1	3

Complaint Surveys Without Revisits: 2

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			AI	A	08/01/2011	Successful
			A	A	08/21/2011	Pending

Complaint Surveys With Onsite Revisits: 1

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			A1D	A	08/15/2011	Successful

Complaint Surveys With Offsite Revisits: 1

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			AD	A	08/31/2011	Pending

TOTAL COMPLAINT SURVEYS: 4

Recertification Surveys Without Revisits: 2

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			AI	A	08/01/2011	Successful
			I	A	08/10/2011	Pending

Recertification Surveys With Onsite Revisits: 1

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			AID	A	08/15/2011	Successful

Recertification Surveys with Offsite Revisits: 1

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			ID	A	08/23/2011	Pending

TOTAL RECERTIFICATION SURVEYS: 4

Initial Surveys Without Revisits: 1

CLIA #	Facility Name	Event ID	Survey Categ	Survey Ext	Survey Date	Cert Kit Upload Status
			E	A	08/29/2011	Failed

Initial Surveys with Onsite Revisits: 0

Figure 181: CLIA Workload Monitoring report sample; Print Report Details selected

Printed: 01/05/2012 8:05PM

CLIA Workload Monitoring

Connecticut Dept Health

10/01/2011 through 12/31/2011

Total Complaints By Federal Surveyors	Total Complaints By State Surveyors	Total Initial Surveys	Total Recertification Surveys	Total Onsite Revisits	Total Validation Surveys Done OnSite
1	3	1	4	2	1

Complaint Surveys Without Revisits: 2
Complaint Surveys with Onsite Revisits: 1
Complaint Surveys with Offsite Revisits: 1

TOTAL COMPLAINT SURVEYS: 4

Recertification Surveys Without Revisits: 2
Recertification Surveys with Onsite Revisits: 1
Recertification Surveys with Offsite Revisits: 1

TOTAL RECERTIFICATION SURVEYS: 4

Initial Surveys Without Revisits: 1
Initial Surveys with Onsite Revisits: 0
Initial Surveys with Offsite Revisits: 0

TOTAL INITIAL SURVEYS: 1

Validation Surveys Without Revisits: 1
Validation Surveys with Onsite Revisits: 0
Validation Surveys with Offsite Revisits: 0

TOTAL VALIDATION SURVEYS: 1

Figure 182: CLIA Workload Monitoring report sample; Print Report Details not selected

QC Exclusion Report

The ASPEN: QC Exclusion Report lists all QC exclusions assigned during a specified date range. It indicates which D-tags were excluded and the number of times for each.

The Report Summary on the last page includes the following information:

- Number of QC Exclusion only surveys; no CMS-2567
- Number of QC Exclusion surveys with a CMS-2567
- Total number of D-tags cited

Printed: 12/09/2011 3:11PM

ASPEN: QC Exclusion Report

Georgia Department of Public Health & Environment

from 03/13/2011 thru 12/09/2011

QC Exclusion Tag	Number of Times Excluded
FED - FD03-D - 5453 - CONTROL PROCEDURES	1
FED - FD03-D - 5457 - CONTROL PROCEDURES	1
FED - FD03-D - 5461 - CONTROL PROCEDURES	2
FED - FD03-D - 5469 - CONTROL PROCEDURES	1
FED - FD03-D - 5471 - CONTROL PROCEDURES	1
FED - FD03-D - 5477 - CONTROL PROCEDURES	1

CLIAQCExclusion.rpt Page 1 of 2

Figure 183: ASPEN: QC Exclusion Report sample

Printed: 01/05/2012 9:28PM

ASPEN: QC Exclusion Report

Connecticut Department of Public Health & Environment

from 04/07/2006 thru 02/01/2011

Report Summary	
Number of QC Exclusion only surveys with no 2567	2
Number of QC Exclusion surveys with 2567	1
Total D tags cited	179

CLIAQCExclusion.rpt Page 2 of 2

Figure 184: QC Exclusion Report Summary sample

CLIA 116 Reports

Two reports are currently available in the CLIA 116 web app: CMS-116 and CLIA Search Results List. They are both generated in PDF format. Samples of the reports follow.

CMS-116

This report creates a CMS-116 form populated with data from the selected lab record.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)
APPLICATION FOR CERTIFICATION

CLIA 116 Form

I. GENERAL INFORMATION

[ ] Initial Application [ ] Survey
[ ] Change in Certification Type
[ ] Other Changes (*Specify*)

CLIA Identification Number
(If an initial application leave blank, a number will be assigned)

Facility Name

Federal Tax Identification Number

Email Address

Telephone No. *(Include area code)* (303)

Fax No. *(Include area code)* (720)

Facility Address - *Physical Location of Laboratory (Building, Floor, Suite if applicable.) Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified*

Mailing/Billing Address *(If different from street address, include attention line and/or Building, Floor, Suite)*

Number, Street *(No P.O. Boxes)*

Number, Street

City	State	Zip Code	City	State	Zip Code
BOULDER	CO	80303	BOULDER	CO	803019019

Name of Director *(Last, First, Middle Initial)*

For Office Use Only
Date Received 06/03/2003

II. TYPE OF CERTIFICATE REQUESTED *(Check one)*

[ ] Certificate of Waiver *(Complete Sections I - VI and IX - X)*

[ ] Certificate for Provider Performed Microscopy Procedures *(PPM) (Complete Sections I - X)*

[ ] Certificate of Compliance *(Complete Sections I - X)*

[ ] Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

[] The Joint Commission [] AOA [] AABB
[] CAP [] COLA [] ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be submitted with the application.

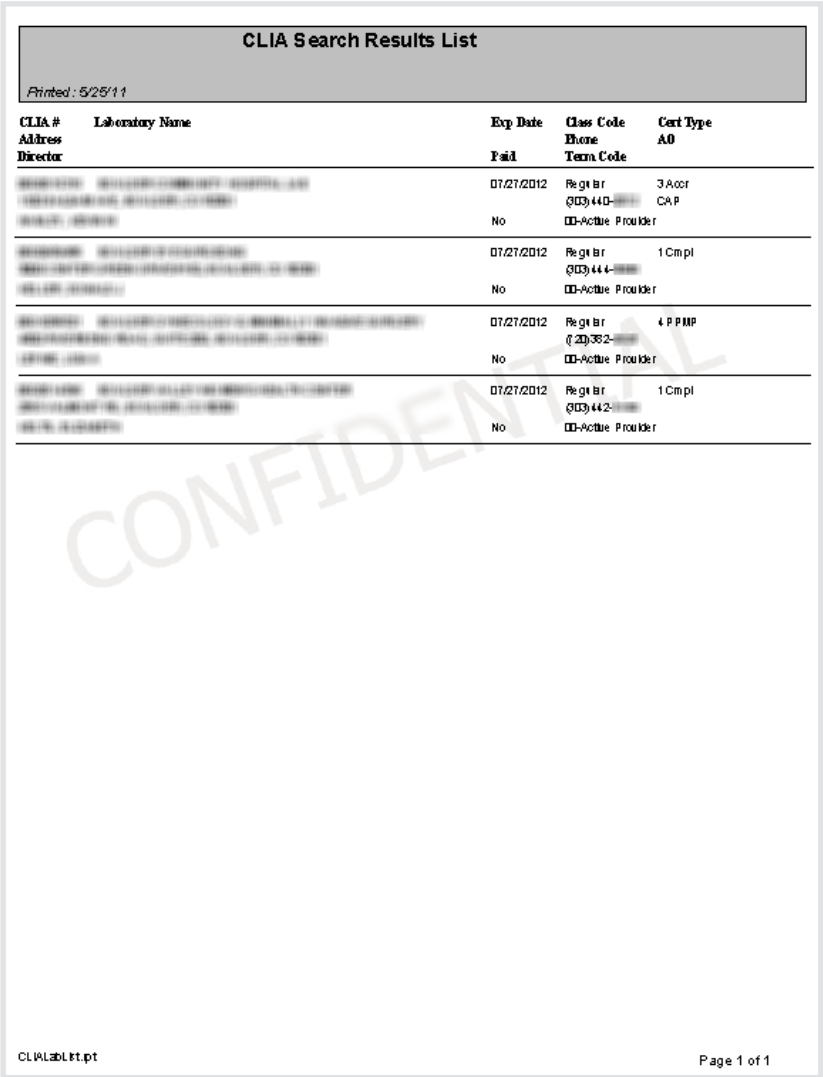
According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0581. The time required to complete this information collection is estimated to average 30 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Form CMS-116 (10/10) Page 1

Figure 185: CMS-116 form sample

CLIA Search Results List

This report lists all CLIA laboratories that matched the specified search selection criteria in the order they are displayed in the CLIA 116 Search Results window. It provides basic information about each laboratory.



CLIA Search Results List

Printed : 5/25/11

CLIA # Address Director	Laboratory Name	Exp Date Paid	Class Code Phone Term Code	Cert Type AO
[illegible]	[illegible]	07/27/2012 No	Regular (303) 440-[illegible] [illegible]-Active Provider	3 Accr CAP
[illegible]	[illegible]	07/27/2012 No	Regular (303) 444-[illegible] [illegible]-Active Provider	1 Cmpl
[illegible]	[illegible]	07/27/2012 No	Regular (720) 382-[illegible] [illegible]-Active Provider	4 PPMP
[illegible]	[illegible]	07/27/2012 No	Regular (303) 442-[illegible] [illegible]-Active Provider	1 Cmpl

CONFIDENTIAL

CLIALabList.rpt

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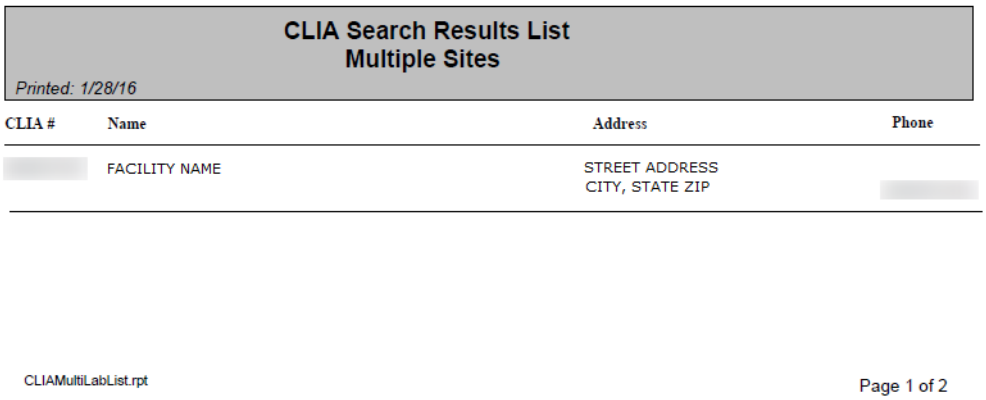
Figure 186: CLIA Search Results List sample

CLIA Search Results List–Multiple Sites

The report title indicates if the search was multi-site. Again, labs are listed in the order they are displayed in the CLIA 116 Search Results window. For example, if the search results are sorted by State, the report shows the labs sorted by State.



CLIA Search Results List
Multiple Sites

Printed: 1/28/16

CLIA #	Name	Address	Phone
	FACILITY NAME	STREET ADDRESS CITY, STATE ZIP	

CLIAMultiLabList.rpt

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Figure 187: CLIA Search Results List–Multiple Sites sorted by State

Batch Billing Jobs

The batch billing run includes the following jobs, which are listed in the order they are executed. The jobs are run weekly except for the Quarterly Refund job.

Reactivate Terminated Labs – Reactivates 08 labs, i.e., labs terminated for nonpayment, that have paid in full within six months of termination.

Application Change – Processes status changes. Updates lab data (e.g., specialties, provider information) to fit new application type. Ensures that all business rules are applied correctly.

Bubble – Pushes fully paid pending certificates within 30 days of the certificate effective date to current. Cleans up data (e.g., specialties) as needed.

Certificates – Determines labs that have paid (i.e., those with certificates that "bubbled" in the previous job) and are due to receive a new certificate. Creates two flat files for the Certificate and Issuance Billing Contractor (BC) to use: one for Type 2 (Waiver), 4 (PPM), and 9 (Registration) labs; the other for Type 1 (Compliance) and 3 (Accredited) labs.

Adjustment 1 – Enters changes in 1557 schedule codes for Type 1 (Compliance) labs that are unpaid or partially paid. Allows users with appropriate permissions to manually override schedule code changes in order to update fee amounts for Type 1 (Compliance) and 3 (Accredited) labs.

Adjustment 2 – Generates renewal fees for Type 1 (Compliance) labs, i.e., Bill Type 04 (Compliance Certificate Fee). Refunds money and updates records as appropriate.

Adjustment 3 – Generates initial and renewal fees as follows:

- Initial fees for all laboratory types, i.e., Bill Type 01 (Waiver/PPM/Registration Fee) and 02 (Compliance Survey Fee).
- Renewal fees for Type 2 (Waiver) and 4 (PPM) labs, i.e., Bill Type 01 (Waiver/PPM/Registration Fee).
- Renewal fees for Type 1 (Compliance) labs, i.e., Bill Type 02 (Compliance Survey Fee).

Adjustment 4 – Generates initial and renewal fees for Type 3 (Accredited) labs, i.e., Bill Type 05 (Validation Survey Fee) and 06 (Accreditation Certificate Fee).

Clean Up Terminated Labs – Cleans up data for labs that have been terminated for more than 190 days and up to two years. Audits off accounting records. Deletes pending cycle information (if a pending certificate existed), but keeps provider records.

First and Second Rebill – Sends Bill Code 2 (First Rebill) fees for labs that have unpaid Bill Code 1 (Initial Bill) fees with a fee date 60 days old or more. Audits off the Code 1 bills.

Also sends Bill Code 3 (Second Rebill) fees for labs that have unpaid Bill Code 2 (First Rebill) fees with an initial fee date 120 days old or more. Audits off the Code 2 bills.

Terminate Unpaid Labs – As applicable:

- Terminates labs for nonpayment, i.e., sets Term Code to 08 for labs having unpaid Bill Code 3 (Second Rebill) fees with an initial fee date 180 days old or more.
- Terminates Type 3 (Accredited) labs with no indication of affiliation with an accrediting organization (AO) when their current certification cycle ends; sets Term Code to 33.
- Terminates labs with terminated current certificates but with a new pending certificate that has not been fully paid within 6 months. Labs will be terminated 6 months after the pending effective date.

Bills – Locates Payment Status Code 10 bills (Ready to Send). Creates two files for the BC: one for Bill Type 01 (Waiver/PPM/Registration Fee), 02 (Compliance Survey Fee), 05 (Validation Survey Fee), and 06 (Accreditation Certificate Fee); the other for Bill Type 04 (Compliance Certificate Fee). These two files contain all required billing information.

Refunds – Creates a refund file for Treasury, updates and audits off refund records for:

- Approved manual refunds – money approved for refund by CLIA CO or CLIA contractor
- Automatic refunds – money marked as ‘overpayment’ for six months

Send Accreditation Letter – Identifies active Type 3 (Accredited) labs without AO affiliation and creates a file for the vendor that generates and sends an Accreditation Letter to the labs.

Cleanup Remarked AOs – Cleans up data for Type 3 (Accredited) labs with Accredited Remarks indicating a lack of affiliation with an AO.

Quarterly Refund – Runs the first Saturday of every quarter. Identifies refund records and audits them off.

Batch Complete – Runs if all other jobs complete successfully.

Keyboard Shortcuts

Keyboard shortcuts are combinations of two or more keys that, when pressed, can perform the same task as using a mouse or other pointing device.

CLIA 116 Keyboard Shortcuts

The CLIA 116 web application includes the following keyboard shortcuts.

Search Results window

Alt 1 - Add

Alt 2 - Update

Alt 3 - Inquiry

Alt 4 - Print

Alt 5 - Exit

Search Results list

These keyboard shortcuts work in the Search Results list and other read-only lists.

Tab/Shift Tab - Move into/out of the list.

Up/Down arrows - Move vertically. i.e., up and down in the list.

Enter - Open the CLIA 116 window in Inquiry mode for the selected lab (row) in the Search Results list.

CLIA 116 window

These keyboard shortcuts work for the buttons (if enabled) in the CLIA 116 window in Add, Update, and Inquiry modes.

Alt 2 - Notes

Alt 3 - Attachments

Alt 4 - Audit History

Alt 5 - Certificate/Billing Inquiry

Alt 6 - Status Change

Alt 7 - Termination

Alt 8 - Save

Alt 8 Tab - Cancel

Tabs

Ctrl Alt t - Move to the next tab.

Ctrl Alt Shift t - Move to the previous tab.

Drop-down Lists

Tab/Shift Tab - Move into/out of the field.

Up/Down arrows - Move vertically, i.e., up and down in the list.

Radio Buttons

The Multiple Sites and Specialties tabs include radio buttons.

Tab/Shift Tab - Move into/out of the radio button section.

Right/Left arrows - Move horizontally (left to right or right to left) to change selected radio button.

Affiliated Providers Find Results

Alt 1 - Select

Note: To add a provider in the Find Results list to Director Affiliations on the Additional Info tab, you can select it, press Alt 1 to activate the Select button, and press Enter; or you can simply press Enter to add the selected provider.

Alt 2 - Cancel

Help Fields

Tab - Go to name/label for a field/section with associated Help information.

Enter - Display the associated Help information for the field/section.

Tab - Move to the Close button in the Help window.

Enter - Close the Help window.

Windows keyboard shortcuts

Ease of Access keyboard shortcuts

Press this	To do this
Right Shift for eight seconds	Turn Filter Keys on and off
Left Alt + Left Shift+PrtScn (or PrtScn)	Turn High Contrast on or off
Left Alt + Left Shift + Num Lock	Turn Mouse Keys on or off
Shift five times	Turn Sticky Keys on or off
Num Lock for five seconds	Turn Toggle Keys on or off
Windows logo key + u	Open the Ease of Access Center

General keyboard shortcuts

Press this	To do this
F1	Display Help
Ctrl + c (or Ctrl+Insert)	Copy the selected item
Ctrl + x	Cut the selected item
Ctrl + v (or Shift+Insert)	Paste the selected item
Ctrl + z	Undo an action
Ctrl + y	Redo an action
Delete (or Ctrl + d)	Delete the selected item and move it to the Recycle Bin
Shift + Delete	Delete the selected item without moving it to the Recycle Bin first
F2	Edit/Rename the selected item
Ctrl + Right Arrow	Move the cursor to the beginning of the next word
Ctrl + Left Arrow	Move the cursor to the beginning of the previous word
Ctrl + Down Arrow	Move the cursor to the beginning of the next paragraph
Ctrl + Up Arrow	Move the cursor to the beginning of the previous paragraph
Ctrl + Shift with an arrow key	Select a block of text

Press this	To do this (Continued)
Shift with any arrow key	Select more than one item in a window or on the desktop, or select text within a document
Ctrl with any arrow key + Spacebar	Select multiple individual items in a window or on the desktop
Ctrl + A	Select all items in a document or window
F3	Search for a file or folder
Alt + F	Open the file menu for the active window
Alt + Enter	Display properties for the selected item
Alt + F4	Close the active item, or exit the active program
Alt + Spacebar	Open the shortcut menu for the active window
Ctrl + Spacebar	Activate the current grid row
Ctrl + F4	Close the active document (in programs that allow you to have multiple documents open simultaneously)
Alt + Tab	Switch between open items
Ctrl + Alt + Tab	Use the arrow keys to switch between open items
Ctrl + Mouse scroll wheel	Change the size of icons on the desktop
Windows logo key + Tab	Cycle through programs on the taskbar by using Aero Flip 3-D
Ctrl+Windows logo key + Tab	Use the arrow keys to cycle through programs on the taskbar by using Aero Flip 3-D
Alt + Esc	Cycle through items in the order in which they were opened
F6	Cycle through screen elements in a window
F4	Display the address bar list in Windows Explorer
Shift + F10	Display the shortcut menu for the selected item
Ctrl + Esc	Open the Start menu
Alt + underlined letter	Display the corresponding menu
Underlined letter	Perform the menu command (or other underlined command)

Press this	To do this (Continued)
F10	Activate the menu bar in the active program
Right Arrow	Open the next menu to the right, or open a submenu
Left Arrow	Open the next menu to the left, or close a submenu
F5 (or Ctrl + r)	Refresh the active window
Alt + Up Arrow	View the folder one level up in Windows Explorer
Esc	Cancel the current task
Ctrl + Shift + Esc	Open Task Manager
Shift	When CD is inserted, prevent it from automatically playing
Left Alt + Shift	Switch the input language when multiple input languages are enabled
Ctrl + Shift	Switch the keyboard layout when multiple keyboard layouts are enabled
Right or Left Ctrl + Shift	Change the reading direction of text in right-to-left reading languages

Dialog Box keyboard shortcuts

Press this	To do this
Ctrl+Tab	Move forward through tabs
Ctrl+Shift+Tab	Move back through tabs
Tab	Move forward through options
Shift+Tab	Move back through options
Alt+underlined letter	Perform the command (or select the option) that goes with that letter
Enter	Replaces clicking the mouse for many selected commands
Spacebar	Select or clear the checkbox if the active option is a checkbox
Arrow keys	Select a button if the active option is a group of option buttons
F1	Display Help
F4	Display the items in the active/drop-down list
Backspace	Open a folder one level up if a folder is selected in the Save As or Open dialog box