

CLIA Cert Kit with Special Survey

CLIA Compliance labs are surveyed every 2 years and must pay a fee to be surveyed. State defined process is used to determine if a CLIA lab needs to be surveyed (possible processes include using AST or running Casper reports 80D or 850D).

1 Locate facility

- Open **ACO**.
- Change My Selection to **CLIA COMPLIANCE**.
- Expand the node for your training letter.

2 Check CLIA certificates

- Expand the node for **<A> CLIA Special**, where A is your training letter.
- Click on the **Certificates** node

See the CLIA certificates listed in the right hand pane. Your lab should have a Pending Compliance certificate listed at the top. Note the effective date of that certificate.

3 Create certification kit

- Right-click on facility **<A> CLIA Special**, where A is your training letter.
- Select **Create Certification**.

If the current certification kit is still Active, you will receive a message indicating that if you continue with creating a new kit the system will automatically close the current kit. If you receive this message then left-click Yes to continue.

The compliance fee must be paid in full before the kit can be uploaded. This lab has already paid the compliance fee, indicated by the green checkmark on the Upload tab. If the fee is not paid, you will receive a warning message when you create a survey and upload will be prevented.

4 Schedule initial Health survey

- On the Certification & Surveys tab, scroll to the bottom of the screen.
- For recertification surveys, the Compliance Certificate Effective Date will be filled in and match the effective date of the lab's pending compliance certificate noted above.

For initial certification kits, the Compliance Certificate Effective Date will be blank and must be entered as the date the lab was determined to be in compliance.

The Certificate Type Change Due to Survey field will also be enabled for initial certification kits and is set to Yes if the lab cannot come into compliance and wished to downgrade the certificate type to Waiver or PPM.
- Go to the Surveys sub-tab, click **New**.

- **Health Survey** will be pre-selected (CLIA does not have LSC surveys), click **OK**.
- In the **Survey Properties** window, enter the following:
 - Start: **07/15/2015**
 - Exit (X3): **07/15/2015**
 - Regulations: **Select the Federal regulation set**
 - Type of Survey: **I - Recertification**

The system automatically selects Recertification.

- Extent: **A – Routine/Std Survey**

A Routine/Std Survey is automatically selected.

5 Add survey team members

- In the Team Roster section, click **Update** to display the Staff Availability List.
- Assign yourself to the survey.
- Click **OK** to close the Staff Availability List.
- Click **OK** to close the survey window.
- Click **No** to the question about proceeding to Citation Manager.

Once the survey shell has been created, the CLIA system will not allow the laboratory to change their certificate type or be terminated. Certification kit must be completed and uploaded OR deleted.

6 Complete CMS-670 hours

- On the Certification & Survey Tab go to the surveys sub-tab and highlight the survey created above. Click the **Update 670** button.
- Enter 1 hour under the following categories: **Pre-Survey, On-Site** (E, F or G), **Travel** and **Off Site**.
- Click the **Office Hours** button.
- Enter 1 hour in the **Total SA Supervisory** and **Total SA Clerical** hour columns.
- Click **OK** to close the 670 form and **Close** the workload detail.

7 Complete CMS-1539

- Go to the **Transmittal (CMS-1539)** tab.
- For CLIA, only **L12, L19** and **L20** are required for non-condition level tags. RO dates are required if condition level tags are cited. Enter the following:
 - L12: **A In Compliance**
 - L19: **current date**
 - L20: **current date**

SAs use CMS-1557 (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 the ACO Certification window respectively replicate the Personnel and Specialties/Subspecialties portions of the CMS-1557 form.

Specialty information is also used to determine the fees that a laboratory must pay to hold their CLIA certificate.

8 Complete CLIA 1557 form information

- Go to the Survey (CMS-1557) tab.
- Click **Yes to All** to override edit checks.
- **State License Number** and **Medicare Provider Number** fields are optional.
- For validation surveys performed on Accredited labs the **Simultaneous Survey** field can be answered Yes if surveying with Accrediting Organization.
- Set at least one of the complexity fields to a value greater than 0, indicating the number of staff qualified under the applicable regulatory section.
- Go to the 1557 Specialties tab.
- Click **Yes to All** to override edit checks.

Existing specialties and test volumes that the laboratory is testing will be pre-populated along with the date the lab began the testing of that specialty.

For initial certification kits the information provided by the laboratory as to what specialties they will be testing is populated, but there will be no effective date. The state must confirm the reported specialties and enter the effective date.

- Check a new specialty value, enter the effective date of 7/1/2015 and a test volume value (if not already populated).
- Scroll to the bottom of the page and answer the **Immunohematology** and **Blood Product** questions **No**.

9 Upload Tab

- Go to the **Upload** tab.
- Click **Prevalidate and Upload** button. Will receive warning that survey exit date cannot be changed once upload has completed successfully.

Green check mark indicates that the Compliance Fee has been paid.

Prevalidate and Upload button required for first upload. After first upload, system will automatically upload any changes.

Note the certification kit is now read-only.

- Click the **Delete Pending** button. Pending Upload is removed and certification kit can now be updated.
- Click **Done** to close the certification kit.

CLIA laboratories are required to enroll with a Proficiency Testing program. The PT organizations provide data on the test results to QIES and states can access thru the CLIA 116 application and Casper reports 153D and 155D. States need to create a PT Desk Review survey for all laboratories that fail 2 out of 3 tests for an analyte.

10 Create PT desk review survey

With 10.2 PT desk review, surveys do not have to be created as part of a certification kit. Create a stand- alone survey:

- Click the plus next to facility **A CLIA Special**, where A is your training letter.
- Right click the Survey node and select **New Survey**.
- In the Create Health Survey window, enter:
 - Start: **07/15/2015**
 - Exit (X3): **07/15/2015**
 - Regulations: **Select the Federal regulation set**
 - Type of Survey: **V-PT Desk Review**

The system automatically selects M-Other.

- Extent: **F-Offsite Paper**

A Routine/Std Survey is automatically selected, uncheck A.

- Click **OK** to create survey.

11 Cite Deficiency

- Click **Yes** on next message to continue to Citation Manager.
- On the Add Team Member screen, change response to **Add your user to Survey Team**, then click **OK**.
- In the Quick Find field, type **2016**.
- Drag 2016 to the Citations pane.
- In Citation Properties, **V-PT Desk Review** will be selected, click **OK**.
- Enter findings: **Failed PT Desk review for tag XX**
- Click **OK** to close the Citation window, and click **Done** to close the Citation Manager.

12 Track survey

- Right click on the survey event ID in the tree and select **Survey Properties**.
Note that special surveys will show a yellow or green arrow on the icon in the tree. This indicates whether the stand alone special survey has been uploaded (green) successfully or not (yellow).
- Click **Show Edits**.
Enter 670 information.
- Click **OK** to the edit message.

13 Enter Adm Signoff date

- In Survey Properties, for Adm Signoff, enter **current date**.
- Click **OK** to close Survey Properties.

14 Enter 670 hours

- Right-click on the survey event ID in the tree and select **CMS 670 Workload**.
- Enter **Pre-Survey** and **Off Site** hours for the Other (PTRVW) category.
- Enter **Office Hours** for the SA.
- Click **OK** and **Close**.
- Right-click the survey again and select **Survey Properties**.
- Select Show Edits.
Survey has no edit text.
- Click **OK** to close Survey Properties.

System will monitor for completed stand-alone special surveys and upload them to national when they are complete. The survey properties screen will show the upload status like the Upload tab in certification kits.

If it is determined that the PT desk review requires an onsite visit and you want to combine with an ongoing recertification survey, merge survey can be used.

15 Merge special survey into certification kit

- Right click on the Certification Kit in the tree and select **Merge Survey**.
- The stand-alone PT desk review survey created above will display on the surveys list. Highlight that survey and click **OK**.
- Click **Yes** to confirm you would like to merge the survey into the kit.
- Click **Yes** to merge the survey categories, the resulting survey will contain both the I-Recertification and M/V Other/PT Desk Review categories.
- On the next screen click **No** to leave the survey start and exit dates for the recertification.
- Click **OK** to refresh the tree.

16 Review results

- Find your facility in the tree, right-click on the Recertification kit and select **Certification Kit**.
- In the survey sub tab highlight the survey and click **Update**.
- View the survey categories to see they were combined and include all 3 types, **I-Recertification, M Other and V PT Desk Review**.
Note that the special survey is still managed as a separate upload on the Survey Properties screen while the upload of the certification kit will continue to be managed on the Upload tab.
- Click **OK** to exit survey properties.
- Click on the **Update 670** button.
- View the hours merged between **I – Recertification and M – Other**.
- Click Close, Yes to All, and Done to close the kit.