

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

First Quarter 2023

In This Issue...

- **General CLIA information:**

Types of CLIA certificates, applying for a certificate, making changes to certificates, fees associated with CLIA, renewal process for certificates, and terminating CLIA certificates.

What are the different types of CLIA certificates?

Certificate of Waiver

This certificate type is issued to laboratories in which only waived testing is performed. These tests are simple laboratory examinations and procedures that are so simple and accurate that the likelihood of erroneous results is negligible. The only requirement for waived testing is that the laboratory must follow the manufacturer's instructions exactly. It is recommended that each laboratory follow Good Laboratory Practice, which includes performance and documentation of training for each individual performing testing.

Certificate for Provider-Performed Microscopy Procedures (PPMP)

This certificate type is issued to laboratories in which personnel qualified as a physician, midlevel practitioner or dentist perform one or more of the nine microscopy examinations designated as provider-performed microscopy procedures. PPM tests are considered moderately complex, therefore, the laboratory must comply with CLIA regulations for moderate complexity testing. This certificate also permits the laboratory to perform waived testing.



Certificate of Registration

This certificate type is initially issued to a new laboratory that has applied for a Certificate of Compliance or a Certificate of Accreditation. It permits the laboratory to perform moderate and/or high complexity testing until an initial survey is performed and the laboratory is found to be in compliance with the CLIA regulations or the accrediting organization's requirements, as applicable. This certificate also permits the laboratory to perform PPM and/or waived testing.

Certificate of Compliance

This certificate type is issued to laboratories in which a survey conducted by the CLIA State Agency (SA) determines that the laboratory is in compliance with all applicable CLIA requirements. Under this certificate type, the laboratory is permitted to perform moderate and/or high complexity testing, as well as PPM and waived testing. The laboratory must meet compliance with the CLIA Regulations and Interpretive Guidelines, and routine surveys are conducted on a biannual basis.

Certificate of Accreditation

This certificate is issued to laboratories in which a survey conducted by an Accreditation Organization (AO) of the laboratory's choosing, determines that the laboratory is in compliance with all applicable AO requirements. The AO must be CMS approved and conducts biannual surveys (for an additional fee) instead of the CLIA SA. Under this certificate, the laboratory is permitted to perform moderate and/or high complexity testing, PPM, and waived testing.

How does my facility obtain a CLIA certificate?

Any facility wishing to apply for a CLIA certificate must complete the [CMS-116](#) application. The Iowa State Agency requires the individual listed as the laboratory director to sign page 5 of the application. In addition, if applying for a Certificate of Provider Perform Microscopy (PPM), Compliance or Accreditation, the laboratory must also submit a copy of the laboratory director's qualifications. For a certificate of waiver, there are no laboratory director qualifications.

When applying for a CLIA Certificate, what documentation is required to qualify the laboratory director?

When applying for a Certificate of Provider Performed Microscopy Procedures (PPM), a Certificate of Compliance, or a Certificate of Accreditation, the laboratory director must be qualified to oversee non-waived testing. The documentation required for director qualification is dependent on the type of certificate for which the laboratory applies:

Certificate Type	Qualifications Requirements
Waiver	No additional documentation required
PPMP	A copy of the current Iowa license; and A copy of the medical diploma/transcript*: MD, DO, midlevel practitioner, or dentist.
Compliance or Accreditation	<ol style="list-style-type: none"> 1. A copy of the current Iowa license; and 2. A copy of the medical diploma/transcript*: MD, DO, DPM and 3. <u>One</u> of the following, based on the level of complexity testing: <ul style="list-style-type: none"> For a laboratory performing moderate complexity testing: <ul style="list-style-type: none"> ⇒ Documentation of at least one (1) year directing or supervising non-waived testing; or ⇒ Completion of 20 CME credit hours from one (1) of the CME courses for Laboratory Directors of Moderate Complexity Laboratories listed on the CMS web site; or ⇒ Documentation of lab training equivalent to 20 CME credit hours in lab practice during medical residency. For a more detailed list consult §493.1405 of the Code of Federal Regulations. For a laboratory performing high complexity testing: <ul style="list-style-type: none"> ⇒ Documentation of board certification in Anatomic and/or Clinical Pathology; or ⇒ Documentation of one (1) year of high complexity lab experience during residency; or ⇒ Documentation of two (2) years directing or supervising high complexity lab testing. For more detailed list consult §493.1443 of the Code of Federal Regulations. <p>If the individual listed as the laboratory director is not an MD, DO, or DPM; refer to Subpart M of the CLIA Regulations and Interpretive Guidelines for qualification requirements.</p> <p><i>*Diploma or transcript must be from an accredited institution. Individuals who have degrees from foreign schools must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States.</i></p>

Where do I send the completed CLIA application?

Each state has their own State Agency that the application must be submitted to. All facilities located in Iowa can send their completed application to:

Iowa CLIA Laboratory Program
State Hygienic Laboratory
UI Research Park
2490 Crosspark Road
Coralville, IA 52241-4721
Email: shl-clia@uiowa.edu



Click on the hyperlink for a list of all [State Agencies](#).

What are the next steps after submitting the CLIA application?

The state agency will process all CLIA applications upon receipt. Once the application is processed, a fee coupon will be generated and sent to the laboratory. After payment is posted to the laboratory's account, the new certificate will be printed and mailed. The entire process will take between 6 – 8 weeks.

CLIA certificates and fee coupons are generated and mailed from the U.S. Department of Health & Human Services in Baltimore, MD and usually take 10–14 business days to arrive.

What are the fees associated with obtaining a CLIA certificate?

- ➡ Certificate of Waiver = \$180 every two years
- ➡ Certificate of Provider Performed Microscopy = \$240 every two years
- ➡ Certificate of Registration = \$100 one-time fee
- ➡ Certificate of Compliance = There are always two fees, which are based upon the number of specialties and volume of testing performed by the laboratory. The first is a compliance (survey) fee and the second is the certificate fee. Each state has their own compliance fee schedule. [CLIA certificate fee schedule](#).
- ➡ Certificate of Accreditation = The laboratory will be responsible for paying the accrediting organization for the survey fees. Additionally, the laboratory will be assessed fees from CMS. The laboratory fees will include the certificate fee and 5% of the compliance fee, which covers the cost of performing validation surveys.

What are the instructions for submitting payment?

Do not send payment with the CLIA application. The CLIA program accepts check and credit card payments. Credit cards are the preferred and quickest payment option.

If submitting payment by credit card, go to the website: [pay.gov](https://www.pay.gov), or [pay.gov instructions](#).

If submitting payment by check, **please include the CLIA number of the facility on the check.** Submit payment to:



CLIA Laboratory Program
PO Box 3056
Portland, OR 97208-3056



What is the process for renewing the CLIA certificate?

CLIA certificates are renewed automatically. For Certificates of Waiver, Provider Performed Microscopy and Accreditation, the renewal fees are mailed six months prior to the expiration date of the certificate. Once payment is posted, the new certificate will arrive 2-3 weeks prior to the current certificate's expiration date.

For Certificates of Compliance, one year prior to the expiration date, the laboratory will receive a compliance (survey) fee. The laboratory submits payment for the compliance fee, and then will receive a Pre-survey packet to be completed and returned to the SA. The survey will be scheduled 6 – 9 months prior to the expiration date of the current CLIA certificate. After the survey is completed and the laboratory submits an acceptable plan of correction/allegation of compliance (if applicable), the laboratory will receive a certificate fee. Once payment for the certificate fee is posted, the new certificate will arrive 2-3 weeks prior to the current certificate's expiration date.



CLIA Fee coupons are generated and mailed from the U.S. Department of Health & Human Services in Baltimore, MD.

How does the laboratory make demographic changes to their CLIA certificate?



All demographic changes (name of facility, address, phone number, etc.) must be submitted in writing. Include the CLIA number of the facility and the information needing updated. In Iowa, all demographic changes can be emailed to: shl-clia@uiowa.edu. If you would like to make a demographic change for a laboratory outside of Iowa, please contact your [state agency](#).

What forms must be completed if the laboratory changes ownership?

In order to make a change in ownership for a facility located in Iowa, the laboratory must complete and return the CMS-116 application form and a Change in Ownership form. The Change in Ownership form varies from State to State. To request a Change in Ownership form for Iowa, please email our office at shl-clia@uiowa.edu.

Once the forms are completed, they can be emailed to shl-clia@uiowa.edu. If you would like to make a change in ownership for a laboratory outside of Iowa, please contact your [state agency](#).

How does the laboratory update the laboratory director on their CLIA certificate?

Certificate of Waiver: All laboratory director changes must be submitted in writing, include the CLIA number of the facility and the name of the new laboratory director.

Certificate of Provider Performed Microscopy: The laboratory must complete the [Form: CMS-116 Application](#) AND send a copy of the new laboratory director's medical diploma and current Iowa license.

Certificate of Accreditation: The laboratory must submit laboratory director changes to their accrediting organization.

Certificate of Compliance: The laboratory must complete the [Form: CMS-116 Application](#) AND send a copy of the new laboratory director's qualifications. For qualifications, see page 2 of the CLIA Corner.

Completed forms can be emailed to shl-clia@uiowa.edu. If you are a laboratory outside of Iowa, please contact your [state agency](#).

What is the best way to terminate a CLIA certificate?

Requests to terminate CLIA certificates must be submitted in writing to the state agency where the laboratory is located. The laboratory should include the CLIA number of the facility, the facility name, the reason for termination and the effective date of termination. Laboratories located in Iowa can email their termination request to shl-clia@uiowa.edu. If you are a laboratory outside of Iowa, please contact your [state agency](#).

Is a CLIA certificate needed to draw blood, collect specimens, or give immunizations?

A CLIA certificate is not required if the facility is only collecting specimens. A certificate is also not required for immunizations, PPD (skin tuberculin) or breath alcohol testing (BAT).



Educational Resources

1. CLIA Corner - The CLIA Corner is a publication written quarterly by the Iowa State Agency to help laboratories stay current with the CLIA Regulations and Interpretive Guidelines. It can be a beneficial tool used to assess the laboratory's compliance with the CLIA regulations and to ensure the laboratory is providing accurate and reliable test results. Be sure to check out the [CLIA Corner Archive](#) for past issues.

2. CLIA website - The CMS CLIA website has a wealth of information including [CLIA educational brochures](#) and the [State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services](#).



3. CDC Ready, Set, Test - This educational booklet was developed by the Centers for Disease Control (CDC) to provide information and example logs for waived testing; it is written for laboratories that hold a CLIA Certificate of Waiver. <https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf>

For additional educational materials regarding waived testing, visit the CDC's Waived Tests Homepage. <https://www.cdc.gov/labquality/waived-tests.html>

4. CDC Provider Performed Microscopy Procedures - This educational booklet was developed by the CDC to provide information and example logs for PPM testing; it is written for laboratories that hold a CLIA Certificate of Provider Performed Microscopy. https://www.cdc.gov/labquality/docs/PMP_Booklet_7252019.pdf

5. Basic Applications in Clinical Laboratory Quality Control— This is a free workbook which can be downloaded and reviewed at your own pace. The workbook will challenge or refresh your knowledge and understanding of quality control practices. [Basic Applications in Clinical Laboratory Quality Control \(technopathclinicaldiagnostics.com\)](http://technopathclinicaldiagnostics.com)

6. Advanced Applications in Clinical Laboratory Quality Control—The is a free workbook which can be downloaded and reviewed at your own pace. This workbook covers advanced quality control practice and concepts. [Advanced Applications in Clinical Laboratory Quality Control \(technopathclinicaldiagnostics.com\)](http://technopathclinicaldiagnostics.com)

If you would like your name added to our CLIA Corner google group, send an email to:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu