Clinical Laboratory Improvement Amendments (CLIA)

CLIA CERTIFICATION

GENERAL INFORMATION

What's CLIA?

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and its implementing regulations at 42 CFR Part 493 are federal laws and regulations that apply to all U.S. and CLIA-certified international laboratories or sites that test specimens from humans (e.g., blood, tissue, and body fluid) to assess health or to diagnose, prevent, or treat disease. The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Centers for Disease Control (CDC) and the Food & Drug Administration (FDA), support the CLIA program to ensure quality laboratory testing.

Why is CLIA important?

CLIA ensures that applicable laboratories meet standards to conduct accurate, reliable, and timely testing. This is important for patient care because accurate laboratory test results are essential for making correct diagnoses and treatment decisions.

What's a CLIA certificate?

Under the CLIA program, clinical laboratories are generally required to have the appropriate certificate before they can accept human samples for testing. There are different types of CLIA certificates based on test complexity and the types of testing a laboratory conducts.

If a facility performs even one test on human samples to assess health or to diagnose, prevent, or treat any disease, it's considered a laboratory under CLIA and must apply for and get a CLIA certificate.

However, there are some exceptions for certain testing or laboratories in certain states that don't require a CLIA certificate.

What are the exceptions for certain testing that don't require a CLIA certificate?

The following exceptions to CLIA certification apply no matter where your laboratory is located:

- Any laboratory that only performs testing for forensic purposes (like criminal investigations).
- Research laboratories that test human specimens but do not report patient-specific results for clinical diagnosis or treatment decisions.
- Substance Abuse and Mental Health Services Administration (SAMHSA)-certified laboratories when performing drug testing (like employment-related drug testing). However, **all other testing** conducted by a SAMHSA-certified laboratory does require a CLIA certificate.

Are there any states where a laboratory does not have to apply for a CLIA certificate?

You may not need a CLIA certificate if your laboratory is in New York or Washington state since these states operate their own HHS-approved laboratory regulatory programs. Contact the appropriate State Agency (the state where your laboratory is located) to determine if you need a CLIA certificate.

Note: *New York has a partial exemption. If your laboratory is located in that state, contact the New York State Agency to determine whether you need a CLIA certificate.*

How does CLIA define test complexity?

Laboratory tests are categorized by their complexity – from the least to the most complex. Laboratories need to know whether each test their laboratory performs is a waived or nonwaived test (i.e., moderate or high complexity) because this determines which CLIA requirements are applicable to the laboratory. In general, the more complicated the test, the more stringent the requirements under CLIA. To determine which tests are categorized as waived or nonwaived, refer to the FDA CLIA Database.

- **Waived tests:** These are simple tests with a low risk of an incorrect result. The FDA determines which tests meet these criteria when it reviews a manufacturer's test system waiver application. If you only perform waived testing, you must have a CLIA certificate and follow the manufacturer's instructions for the waived tests; other CLIA requirements may not apply to these laboratories.

A list of waived tests sorted by analyte name is available on the FDA website at: CLIA – Currently Waived Analytes

Tip: It's good laboratory practice to read the entire package insert of the manufacturer's instructions before you begin testing. Make sure you perform the test according to the step-by-step procedure outlined in the package insert. Some waived tests also include quick reference instructions, like cards or small signs with diagrams or flow charts to outline essential steps for conducting the test. Remember, the quick reference guide is only a synopsis of the package insert and cannot be used without the manufacturer's instructions. Make sure any instructions are current for the test system in use and are available to the individuals performing the test.

- **Nonwaived tests:** These tests are more complex and may be referred to as moderate or high complexity tests. Laboratories that perform these tests must have a CLIA certificate, be surveyed (inspected), and meet the quality standards outlined in the CLIA regulations.

Note: *"Survey" and "inspect" are interchangeable terms. CMS uses "survey" throughout this brochure.*

What are the different CLIA certificate types?

Information about the different CLIA certificate types is listed below:

- **Certificate of Waiver (CoW):** Issued to a laboratory that performs only waived tests.
- **Certificate for Provider-performed Microscopy (PPM) procedures:** Issued to a laboratory in which a physician, midlevel practitioner (nurse midwife, nurse practitioner, nurse anesthetist, clinical nurse specialist, or physician assistant), or dentist performs specific microscopy procedures during a patient's visit. A limited list of provider-performed microscopy procedures is included under this certificate type and are categorized as moderate complexity testing.
- **Certificate of Registration (CoR):** Issued to allow the laboratory to conduct nonwaived moderate and high complexity testing until the laboratory is surveyed. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a CoR, which is valid until the initial survey is conducted and compliance with CLIA regulations is determined.
- **Certificate of Compliance (CoC):** Issued to a laboratory that performs nonwaived moderate and high complexity testing after the State Agency (SA) or CMS surveyors conduct a survey and determine that the laboratory is in compliance with the applicable CLIA requirements.
- **Certificate of Accreditation (CoA):** Issued to a laboratory that performs nonwaived moderate and high complexity testing and is based on the laboratory's accreditation by a CMS-approved accreditation organization (AO).

All certificate types are effective for two years. All certificate types allow waived testing to be performed**; however, the certificate a laboratory obtains must be for the most complex category of testing the laboratory performs.**

Note: *AOs are private nonprofits deemed to meet all applicable federal participation requirements but may have more stringent health and safety requirements.*

Currently, there are seven CMS-approved AOs:

- Association for the Advancement of Blood & Biotherapies (AABB)
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Commission for Health Care, Inc (ACHC)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- Commission On Laboratory Accreditation (COLA)
- College of American Pathologists (CAP)
- The Joint Commission

Contact information for these CMS-approved AOs is available on the CMS CLIA website. If you apply for accreditation by one of the CMS-approved AOs, you also need to apply for a CoA through CMS.

APPLYING FOR A CLIA CERTIFICATE

How do I get a CLIA certificate?

To get a CLIA certificate for your laboratory, follow these steps:

Step 1: Complete the CLIA application (Form CMS-116)

This fillable form is available online. Type your responses in each section and save the form to your computer. Make sure you check with your State Agency for any other state-specific requirements.

> **Tip**: When you're filling out the application, make sure you include your laboratory's most up-to-date email address – typically a business email address that many staff access and use. Make sure you check the box on Form CMS-116 or notify your SA to get email notifications from CMS as well as electronic CLIA certificates and fee coupons.

Step 2: Send your completed CLIA application to your State Agency

You can email (preferred), mail, or fax your completed application to your local State Agency (the state where your laboratory is located).

Step 3: Receive your fee coupon, which includes your CLIA identification number, to pay the applicable CLIA certification fee(s)

> **Important:** The unique CLIA identification number is a ten-character alpha-numeric code, which you can use to identify and track your laboratory throughout its entire history. You should use this number when you pay your certification fee or to contact your SA and CMS with questions.

Step 4: Pay your CLIA certification fee

You can pay your fee by:

1. Paying online using the U.S. Treasury platform (preferred). Your secure payment gets processed overnight – it's much faster than mailing hard-copy checks. We accept bank account (ACH), debit, or credit cards.
2. Mailing a check with the paper fee coupon. Allow 10 business days for your check to process.

Note: *You'll need your CLIA identification number to pay online or by check. Make sure you correctly enter your number to expedite payment. You'll need to pay your CLIA certification fee every two years to maintain your CLIA certificate.*

Step 5: Receive your CLIA certificate and begin testing

You'll receive your CLIA certificate after we receive your payment. Generally, you can begin testing once you receive your CLIA certificate. You should first check with your SA since some states have additional state-based requirements.

> **Tip:** You can print (or reprint) your official certificate online.

For additional information and other tips, review the "Laboratory Quick Start Guide to CMS CLIA Certification".

If I have more than one laboratory location, do I need a CLIA certificate for each location?

You will need a CLIA certificate for ***each*** location where you perform testing ***unless*** you qualify for one of the multiple site exceptions listed below:

- **Laboratories that aren't at a fixed location**. Laboratories that move from testing site to testing site, such as mobile units, health screening fairs, or other temporary testing locations, may be covered under the certificate of the designated primary site, using its address.
- **Laboratories that perform limited public health testing**. Limited public health testing is defined as not-for-profit or Federal, State, or local government laboratories that engage in limited testing (not more than a combination of 15 moderately complex or waived tests per certificate). You may file a single application to cover multiple locations.
- **Laboratories within a hospital.** Laboratories on the same campus that have the same laboratory director may file a single application for the laboratory sites under the designated primary site.

Contact your State Agency if you have questions about filing a single application for more than one testing site.

MAINTAINING YOUR CERTIFICATE

What are the fees to get and maintain a CLIA certificate?

You need to pay certain fees **every two years** to maintain your CLIA certificate. The table below outlines what you need to pay for each certificate type.

If you apply for:	You pay a:	Important!
CoW or PPM Certificate	Waiver fee or PPM fee.	There are no registration or compliance fees associated with these certificate types.
CoC	• One-time registration fee that covers CLIA enrollment costs. At this time, CMS will send you a CoR. • Compliance survey fee that covers the survey by the SA. • Compliance certificate fee once we determine your laboratory is in compliance with CLIA regulations. At this time, CMS will send you a CoC.	**Every two years, you'll get surveyed and need to pay a compliance survey fee, compliance certificate fee, and any applicable onsite revisit fees.** As long as the survey determines your laboratory is in compliance, CMS will send you a renewed CoC after your compliance certificate fee payment is processed. If deficiencies are found during the survey, you won't get your certificate until you've fixed the deficiencies, you're in compliance, and paid your fee.
CoA	• One-time registration fee that covers the cost of CLIA enrollment. At this time, CMS will send you a CoR. • Accreditation certificate fee and a validation survey fee once CMS receives verification from your AO. At this time, CMS will send you a CoA. • Fees to the AO.	**Every two years, you'll pay a validation survey fee and an accreditation certificate fee.** As long as your laboratory remains in compliance, CMS will send you a renewed CoA after your fee payments are processed.

For more information about:

- **Certificate fees:** visit the CMS CLIA website under "downloads" to find the most up-to-date "CLIA Certificate Fee Schedule" or contact your SA.
- **Survey fees:** contact your State Agency or Accreditation Organization. These fees are based on the number and types of testing your laboratory performs and cover the cost of the CLIA program.

Will my laboratory get surveyed?

Your laboratory's certificate type dictates whether you get surveyed.

- **If your laboratory has a CoW or PPM**, you **aren't** subject to routine surveys. However, if CMS or the SA gets a complaint against your laboratory, you may receive an unannounced onsite survey, even though you only perform waived tests or PPM procedures.
- **If your laboratory has either a CoC or CoA and performs any nonwaived testing**, you need to meet all nonwaived testing requirements and get surveyed every two years by CMS, the SA, or by a CMS-approved AO (if your laboratory elects to be accredited).

A limited percentage of laboratories with a CoA will receive a validation survey by CMS or a SA surveyor. This survey evaluates the results of the most recent survey performed by an AO to ensure compliance with CLIA regulations.

> ***Important:*** *CoA laboratories must also meet their AOs health and safety requirements, which may be more stringent than CLIA requirements.*

Do I need to notify anyone if I make changes to my laboratory?

Yes. For ***all*** CLIA certificate types, you must notify the State Agency within 30 days of any changes to:

- Ownership that affects the Tax ID (EIN)
- Name
- Location or address
- Laboratory Director

For laboratories with a CoA, you should also notify your AO within 6 months of any changes in specialties or test methodology.

For laboratories with a CoC performing high complexity testing, you should also notify the SA within 30 days of any changes in the Technical Supervisor and within 6 months of any changes in specialties or test methodology.

When would I need to change my laboratory's certificate type?

When adding or removing tests from your test menu, for example, if you:

- Only perform waived testing and want to add microscopy procedures or other nonwaived (moderate or high complexity) testing to your menu. Change from CoW to PPM, CoC, or CoA.
- Have a PPM certificate and want to add other nonwaived (moderate or high complexity) testing. Change from PPM to CoC or CoA.
- Have a CoC, CoA, or PPM and only want to perform waived testing. Change from CoC, CoA, or PPM to CoW.
- Change from a CoA to a CoC or vice versa.

You'll need to reapply for the appropriate certificate using the same CLIA application Form CMS-116 you used for your initial CLIA certification and return it to your SA. You

cannot begin to use your new certificate type until you've paid any additional fees and received the updated certificate.

> ***Note:*** *Written notification is requested when you have a change in email address or if the laboratory stops testing or closes. If you have a CoC or CoA and want to add or remove tests categorized under a different laboratory specialty, subspecialty, or test menu, contact your SA or AO.*

For more information about laboratories and their CLIA certificate status or AO performance, visit Quality, Certification & Oversight Reports (QCOR).

WHERE CAN I FIND MORE INFORMATION?

For more information and resources about the CLIA program, visit:

Resource	Website
CMS CLIA Website	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
CDC CLIA Website	https://www.cdc.gov/clia/php/about/index.html
FDA CLIA Website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CLIA State Agency Contacts	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf
CLIA QuickStart Guide	https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf
Form CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
List of Provider-performed Microscopy Procedures	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf
CLIA – Currently Waived Analytes	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CLIA Certificate Fee Schedule	https://www.cms.gov/files/document/clia-certificate-fee-schedule-updated-06/7/2024.pdf
Accreditation Organizations	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/accreditation-exemptions
Quality, Certification & Oversight Reports (QCOR)	https://qcor.cms.gov/main.jsp
FDA CLIA Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
CLIA Requirements 42 CFR 493	https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

You can also email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

Note: *This brochure presents information about CLIA Certification. It's not intended to replace or substitute CLIA regulatory requirements. Note that state, local, and accreditation requirements may be more stringent.*

Revised May 2025

Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. The information provided in this brochure is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This brochure summarizes current policy and operations as of the date it was published. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.