



Clinical Laboratory Improvement Amendments (CLIA)

How to obtain a CLIA Certificate

NOTE: 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. While every effort has been made to ensure the accuracy of this restatement, this brochure is not a legal document. The official CLIA program requirements are contained in the relevant law, regulations and rulings. Please note that state, local, and accreditation requirements may be more stringent.

Do I need to have a CLIA certificate?

CLIA generally requires all facilities that perform even one applicable test, including waived tests, on “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” to meet certain Federal requirements. If a facility performs tests for these purposes, it is considered a laboratory under CLIA and generally must apply and obtain a certificate from the CLIA program that corresponds to the complexity of tests performed. However, you may not need a CLIA certificate if your laboratory is located in the states of New York or Washington, as those States operate their own laboratory regulatory programs. Contact the appropriate [State Agency](#) to determine if you need a CLIA certificate.



What are the different types of CLIA certificates and how long are they effective?

All types of certificates are generally effective for two years, and the different types of certificates are:

- **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 or dentist performs specific microscopy procedures during the course of a patient’s visit. A limited [list of provider-performed microscopy procedures](#) is included under this certificate type, which are categorized as moderate complexity testing.
- **Certificate of Registration*:** Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
- **Certificate of Compliance (COC):** Issued to a laboratory once the [State Agency](#) or CMS surveyors conduct a survey (inspection) and determine that the laboratory is compliant with the applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.
- **Certificate of Accreditation (COA):** Issued to a laboratory on the basis of the laboratory’s accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

*A registration certificate is valid until an inspection is conducted and compliance is determined.

As of the date of this publication’s release, there are seven CMS-approved accreditation organizations:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Association for Hospitals and Health Systems/ Healthcare Facilities Accreditation Program (AAHHS/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission

Contact information for the above CMS-approved accreditation organizations is available on the CMS CLIA website under [Accreditation Organizations/Exempt States](#). If you apply for accreditation by one of the CMS-approved accreditation organizations, you must concurrently apply to CMS for a COA.

What is a waived test?

As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result”. The Food and Drug Administration (FDA) determines which tests meet these criteria when it reviews a manufacturer’s application for test system waiver.

Where can I find a list of waived tests?

For a list of waived tests sorted by analyte name, visit the FDA website at: [CLIA – Currently Waived Analytes](#)

Where can I find a list of Provider-performed Microscopy Procedures?

A [list of provider-performed microscopy procedures](#) is available on the [CMS CLIA website](#).

Where can I find information about tests categorized as nonwaived (moderate and/or high complexity)?

To determine which tests are categorized as waived or nonwaived (i.e., moderate or high complexity), refer to the [FDA CLIA Database](#).

How do I apply for a CLIA certificate?

The CLIA application ([Form CMS-116](#)) is available online. Send your completed application to the address of the local [State Agency](#) for the State in which your laboratory is located. Additionally, check with your [State Agency](#) for any other state-specific requirements. If you do not have online access and do not have information about your [State Agency](#), you may contact the CLIA program at 410-786-3531 for the address and phone number of your [State Agency](#).

Is there any type of laboratory testing of human specimens that is not subject to a CLIA certificate?

Yes, there are some testing exceptions that do not require CLIA certification.

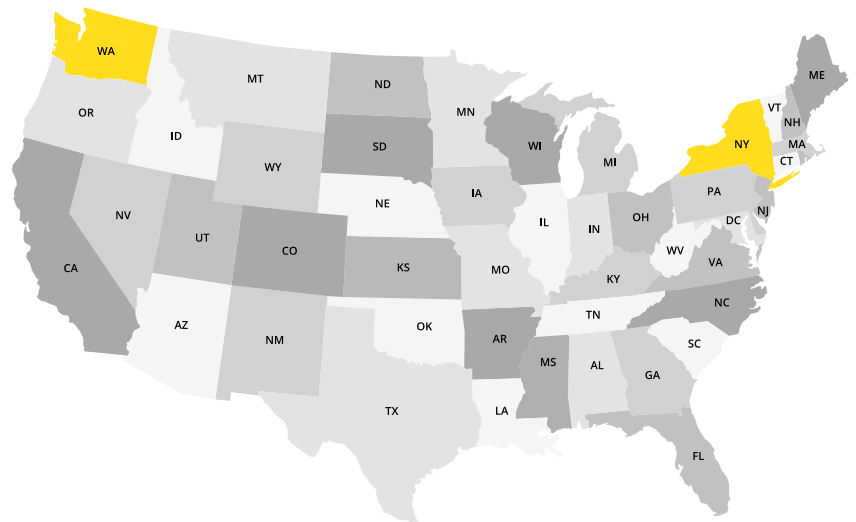
The following *exceptions to CLIA certification* apply regardless of a laboratory's location:

- Any laboratory that only performs testing for forensic purposes;
- Research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, individual patients; or
- Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. However, a CLIA certificate is needed for all other testing conducted by a SAMHSA-certified laboratory.

NOTE: The purpose for which the test is conducted, not the test itself, determines whether a facility conducting testing is subject to the CLIA requirements. Testing that is used to gather evidence for legal purposes, and is not performed for purposes of clinical treatment, medical diagnosis, health assessment or disease prevention is not subject to CLIA.

Are there any states in which I do not have to apply for a CLIA certificate?

Any laboratory located in a state that has a CMS approved laboratory program is exempt from CLIA certification. Currently, there are two states with approved programs: Washington and New York. New York has a partial exemption; therefore, if your laboratory is located in that state, contact the [New York State Agency](#) concerning your need for a CLIA certificate.



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 exceptions listed below:

- Laboratories that are not at a fixed location; that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing (not more than a combination of 15 moderately complex or waived tests per certificate) may file a single application.
- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.

Contact your [State Agency](#) if you have questions or you are filing a single application for more than one testing site.

What kind of fees do I have to pay for a CLIA certificate?

- **If you apply for a COW or a PPM certificate**, you will pay a waiver fee or PPM fee every two years. There are no registration or compliance fees.
- **If you apply for a COC**, you will pay a one-time registration fee that covers the cost of the CLIA enrollment in addition to a compliance survey fee that covers the cost of the initial inspection by the State Agency. CMS will send you a Certificate of Registration. Once compliance has been determined by your inspection, you will pay a compliance certificate fee to CMS and CMS will send you a COC. A two-year certificate cycle is then established, and you will pay a compliance survey fee and have a survey every two years. As long as the survey finds your laboratory to be in compliance, you will pay a compliance certificate fee and CMS will send you a renewed COC.
- **If you apply for a COA**, you will pay a registration fee that covers the cost of the CLIA enrollment. Once CMS receives verification from the accreditation organization that you have selected, you will pay an accreditation certificate fee and validation survey fee to CMS and CMS will send you a COA. A two-year certificate cycle is then established and you will pay an accreditation certificate fee and a validation survey fee every two years. CMS will send you a renewed COA every two years, as long as your laboratory remains compliant. You will also pay fees to the accreditation organization.



You can obtain more information concerning the amount of certificate fees from the [CMS CLIA website](#) under “[CLIA Certificate Fee Schedule](#)” or from your State Agency. For information concerning compliance (survey) fees, you may contact your [State Agency](#) or [accreditation organization](#). These fees are based on the number and types of testing you perform and must cover the cost of the CLIA program because CLIA is entirely user fee funded.

Will I receive an identifying CLIA number?

You will receive a ten-character alpha-numeric code on the CLIA certificate. This number will be utilized to identify and track your laboratory throughout its entire history. You should use this number when making inquiries to the State Agency and CMS about your laboratory.

When can I begin testing?

After you apply for your certificate, you will receive a coupon notifying you of the corresponding fee. Follow the instructions on the fee coupon for payment. After your payment is received, your certificate will be mailed to you. You generally may begin testing once you have received your CLIA certificate, but you need to check with your [State Agency](#) since some states have additional state-based requirements.

Will my laboratory receive a CMS survey?

Laboratories that have a COW or PPM certificate are not subject to routine surveys.

If your laboratory performs any nonwaived testing, the laboratory may have either a COC or COA. All laboratories with either of these certificate types must meet all nonwaived testing requirements and are subject to biennial surveys, by CMS or a CMS agent (such as a surveyor from the State Agency) or by a CMS-approved accreditation organization, if the laboratory elects to be accredited. COA laboratories must also meet the requirements of their accreditation organization which may exceed or be more stringent than the CLIA requirements.

Additionally, a limited percentage of laboratories with a COA will receive a validation survey by CMS or a CMS agent. This is a survey performed by CMS or a CMS agent to evaluate the results of the most recent survey performed by an accreditation organization.

NOTE: If CMS or the State Agency receives a complaint against your laboratory, you may receive an unannounced on-site survey, even though you only perform waived tests or PPM procedures.

If I have a certificate for PPM procedures, a certificate of registration, a COA or a COC, can I also perform waived tests?

Yes, these certificates permit laboratories to also perform waived tests.

If I have a COA or a COC, can I also perform PPM procedures?

Yes, these certificates permit laboratories to perform PPM procedures as well as waived tests. The certificate you obtain should be for the highest (most complex) category of testing you perform.

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

For **all** types of CLIA certification, you must notify the [State Agency](#) within 30 days of any changes in:

- Ownership
- Name
- Location
- Laboratory Director

For laboratories with a Certificate of Accreditation (COA), you must also notify your accreditation organization, in addition to the State Agency, within 30 days of any changes mentioned above.

For Certificate of Compliance (COC) laboratories performing high complexity testing, you must also notify the State Agency within 30 days of any changes in Technical supervisor.

If you perform only waived tests and wish to add PPM procedures or other nonwaived (moderate or high complexity) testing to your menu, you must reapply for the appropriate certificate using the same CLIA application ([Form CMS-116](#)) you used for your initial CLIA certification.

However, you cannot begin nonwaived testing until you have paid the appropriate fee, and have received the appropriate certificate.

If you perform PPM procedures and wish to add other nonwaived (moderate or high complexity) testing, you must first apply for the appropriate certificate.

If you have a COC or COA and wish to add tests categorized under a different laboratory specialty or subspecialty than those on your current certificate or that employ a different test method from those you are already performing, you must notify the [State Agency](#) or the [accreditation organization](#) of the new testing.

If I have any questions about my certificate or changes in my test menu, whom should I contact?

You should contact the [State Agency](#) where your laboratory is located.

Where can I find additional information and guidance?

Refer to the “[State Operations Manual](#),” Appendix C – Interpretive Guidelines (CMS Publication 7) available on the CMS website. Links to other laboratory-related resources can be found at these websites:

[CLIA Law & Regulations](#)

[CDC CLIA website](#)

[FDA CLIA website](#)

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

Hyperlink Table

Embedded Hyperlink	Complete URL
State Agency	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf
List of Provider-performed Microscopy Procedures	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf
Accreditation Organizations Exempt States	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States.html
CLIA – Currently Waived Analytes	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm
CMS PPMP List website	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf
FDA CLIA Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
Form CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
CMS CLIA website	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/
CLIA Certificate Fee Schedule	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_certificate_fee_schedule.pdf
Accreditation Organization	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf
State Operations Manual	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf
CLIA Law & Regulations	https://wwwn.cdc.gov/clia/Regulatory/default.aspx
CDC CLIA website	https://wwwn.cdc.gov/clia/default.aspx
FDA CLIA website	https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm