



IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

Frequently Asked Questions for CLIA Certification to the Idaho Bureau of Laboratories (IBL)

What is CLIA, and why does it matter to me?

The objective of the federal Clinical Laboratory Improvement Amendments (CLIA) program is to ensure consistent, quality laboratory testing. CLIA established quality standards for laboratories to ensure the accuracy, reliability, and timeliness of patient test results, regardless of where the test is performed. CLIA regulations apply to laboratory testing in all settings, including commercial, hospital, and physician office laboratories on materials derived from the human body for the purpose of diagnosis, prevention, treatment, or the assessment of the health of human beings. More information can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>.

Is our practice considered a laboratory?

The CLIA definition of a laboratory is any facility that performs testing on materials derived from the human body for the purpose of diagnosis, prevention, treatment, or the assessment of the health of human beings. If you perform *any* testing as defined by CLIA – even one, and even if you do not charge for the test -- you are required to obtain a CLIA certificate.

What types of CLIA certificates are available?

Certificate of Waiver (COW): A COW certificate holder is only allowed to perform waived tests. CLIA waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”

Certificate for Provider Performed Microscopy (PPM): A PPM certificate allows the holder to perform tests in which a microscopic examination is performed by a physician, midlevel practitioner, or dentist performs during the course of a patient's visit – these tests are considered moderate complexity. These tests are categorized as moderate complexity. A PPM certificate also allows the lab to perform waived tests.

Certificate of Compliance (COC): A COC allows the certificate holder to perform non-waived laboratory tests of either moderate- (non-PPM) or high-complexity. The test complexity is determined by the Food and Drug Administration (FDA).

Certificate of Accreditation (COA): A COA allows a laboratory to perform CLIA waived, PPM, and non-waived (moderate and/or high complexity) testing. Inspections are conducted by the laboratory's accrediting body. CMS-approved accrediting agencies include: AABB, AOA, ASHI, COLA, CAP, and JCAHO. A list can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation Organizations and Exempt States.html>.

Where can I find a list of CLIA Waived, PPM, and Non-Waived tests?

Lists of Waived, PPM, and Non-Waived, and Non-PPM tests can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html.

How do I determine if a particular test is waived, PPM, moderate-, or high-complexity?

The FDA website offers a great search feature found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>, or you may contact the vendor from whom you purchased the test for further information.

How do I get a CLIA certificate?

You must complete the federal form [CMS-116](#), as well as the [Idaho Laboratory Registration Form](#). The forms can be found at the [IBL website](#), on the Lab Certification and X-Ray Licensure page. The State Registration is submitted online, and the CLIA form can be mailed, emailed, or faxed to our office.

Does the State of Idaho require laboratory registration, separate from CLIA?

Yes. The [Idaho Laboratory Registration Form](#) must be submitted to IBL in addition to the [CLIA 116](#) form.

What does CLIA certification cost?

At this time, there is no fee to IBL for Idaho Laboratory registration. Federal CLIA fees are as follows:

Certificate of Waiver: \$150

Certificate of Provider Performed Microscopy: \$200

Certificate of Compliance or Certificate of Accreditation: Fees vary based on the annual test volume and number of laboratory specialties/subspecialties.

You can download a full CLIA laboratory fee schedule from https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html.

Each certificate is valid for two years. CMS will bill your facility directly beginning six to twelve months in advance of your renewal date, depending on your certificate type.

It is not necessary to submit new applications with your biennial renewals.

We collect samples in our office and send them to a third-party, off-premises laboratory. We do no point-of-care testing. Do we need a CLIA certificate?

No. But be sure – CLIA covers every type of diagnostic test on materials derived from the human body. If you do even one simple test at your facility, such as blood glucose or pregnancy, your facility *must* be CLIA certified!

How long do I need to keep laboratory test results?

CLIA requires a retention time of 2 years for all lab tests. These results must be kept in the lab area and include the data, quality control, and proficiency testing results related to the test in question. The permanent repository for all lab tests is the patient's chart.

How do I make changes to my CLIA certificate?

You must notify the IBL Laboratory Improvement Section of changes in ownership, name, address, or director within 30 days of the change. Changes in certificate type must be submitted and processed before you begin the new testing, unless you are transitioning from a higher level of testing to waived (COW) only.

Address/Name changes:

You may complete the change form that is attached to your CLIA payment coupon (be sure to mail the form to IBL, not CMS), or you may submit a new [Idaho Laboratory Registration Form](#). Be sure to select "Change of Information," and include your CLIA or State Laboratory ID number.

A new *State of Idaho Notice of Laboratory Registration* will be issued by our office upon any changes of practice name, address, or director. A new CLIA certificate will be requested on your behalf as well, unless the date of the request is within six months of your current expiration date. In that case, your current certificate will remain valid until your new CLIA certificate is issued by CMS.

Change of Certificate Type or Director:

To change your certificate type (e.g., changing from a Certificate of Waiver to a Certificate of Compliance) or your Laboratory Director, it is necessary to complete a new [Idaho Laboratory Registration Form](#), as well as a new [CLIA 116](#) form, signed by the Laboratory Director.

You will typically receive a bill from CMS approximately two weeks from the date the change of certificate type was processed. Once the bill is paid, CMS will send issue a new CLIA certificate.

IBL will issue a new *State of Idaho Notice of Laboratory Registration* for every change in certificate type.

If you are changing your lab level from a COW or PPM to a moderate- or high-complexity COC, it is also necessary to submit the CV (*curriculum vitae*) of the prospective Laboratory Director.

We are an out-of-state lab that processes samples drawn from patients in Idaho. Do we need to register with the State of Idaho?

No. Idaho requires only that your laboratory is CLIA certified in your state.

I have specific questions about the CLIA regulations as they apply to the testing we are doing. Who do I call?

Call the IBL Laboratory Improvement Section at (208) 334-0528, or email labimprovement@dhw.idaho.gov.

Who can order lab tests in Idaho?

All tests must be ordered by an “authorized person” who, by definition in Idaho, is licensed to practice medicine in our state. Labs can honor written orders from out-of-state physicians and other categories of health providers, except for those not professionally licensed in the state of Idaho, such as Naturopaths and unlicensed Midwives.

My business provides drug testing for employment and/or forensic purposes. Do we need a CLIA certificate?

At this time, CLIA certification is NOT required to perform urine drug screens for employment or forensic purposes, since these screens do not go into a patient’s medical chart. Keep in mind, however, that if the result goes into a patient’s medical chart (i.e., for the purposes of behavioral health), CLIA certification *is* required.

We lost our CLIA certificate. Can we get a replacement?

We typically can request a duplicate CLIA certificate from CMS on your behalf, unless your certificate is less than six months from its expiration date. However, as long as your CLIA certification is current and in good standing, you may perform testing without the certificate on hand. To request a duplicate certificate, please call or email our office.

I’m new to this position, and I’m not sure of our CLIA status, or how all of this works. How can I find out more?

Call the IBL Laboratory Improvement Section at (208) 334-0528, or email labimprovement@dhw.idaho.gov. We will be happy to answer any questions you may have.

I just noticed our CLIA certificate has expired. What do we do?

Don’t panic! Give us a call. We can look into your situation and advise you of the steps necessary to confirm and/or reinstate your certification.

I paid our CLIA bill weeks/months ago, but we haven’t yet received our certificate.

CMS begins billing six to twelve months before your certificate expires (depending on your certificate type); however, new certificates are not mailed until approximately 30 days before your expiration date following payment of the certificate fee.

We are an out-of-state laboratory that performs clinical laboratory testing on specimens drawn from Idaho patients. Do we need to register our facility with the State of Idaho?

No. If the testing is performed outside the state of Idaho, no state registration is required. You must have a valid active CLIA certificate in the state in which you are located.

If a diagnosis is provided with the test results, it is required that the signing pathologist must be licensed to practice medicine in Idaho (per the [Idaho Board of Medicine](#).)

What are the education, experience, and training requirements for Laboratory Directors?

There are very specific requirements mandated by CLIA for Laboratory Directors, which depend on the type of CLIA certificate sought/obtained. For specific information, please contact our office, and we will be happy to assist you.

Is there laboratory personnel licensure in Idaho?

Idaho does not currently license laboratory personnel. CLIA however, has set minimum standards for personnel, based on the type of CLIA certificate.

Certificate of Provider Performed Microscopy: Individuals performing microscopic testing under a PPM Certificate must be a mid-level provider (e.g., PA, NP) or higher.

Certificate of Compliance (COC) – Moderate-Complexity: Individuals performing moderate-complexity testing under a COC must have earned a high school diploma, and have undergone documented orientation and competency training.

Certificate of Compliance – High-Complexity: Individuals performing high-complexity testing under a COC must have earned at least a 2-year degree, and have undergone documented orientation and competency training.

Certificate of Accreditation: Please contact the accrediting agency directly for personnel requirements.

There are no minimum requirements for personnel conducting waived tests.

For more detailed information, please download the CMS brochure, [What Do I Need to Do to Assess Personnel Competency?](#)

We are adding some tests to our lab testing menu. Do we need to notify someone?

No notification is necessary if you are adding tests within your certificate level. You are required to notify the IBL Laboratory Improvement Section only if you are increasing or decreasing the complexity of tests performed at your facility. If you have any questions concerning the complexity of a specific test, you may search for it on the FDA website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm> or contact the vendor from who you purchased/plan to purchase the test.

Will my laboratory be inspected? When and how often?

Certificate of Waiver (COW) and Provider Performed Microscopy (PPM) laboratories are not routinely inspected. However, all complaints are investigated regardless of certificate type and laboratories are required to permit inspections. A small number of Waived labs are inspected annually to collect information regarding COW testing.

All Certificate of Compliance (COC) laboratories are inspected once every two years; however, the initial inspection generally doesn't occur until the lab has been in operation for at least 6 months. Labs with a Certificate of Accreditation (COA) will be inspected every two years by their accrediting agency.

Is there a checklist available for the inspection?

There is no published checklist for CLIA inspections. If you have specific questions regarding the inspection process, you may contact the IBL Clinical Laboratory Inspector at (208) 334-0547.

For further information regarding Certificate of Accreditation inspections, please contact the accrediting agency directly.