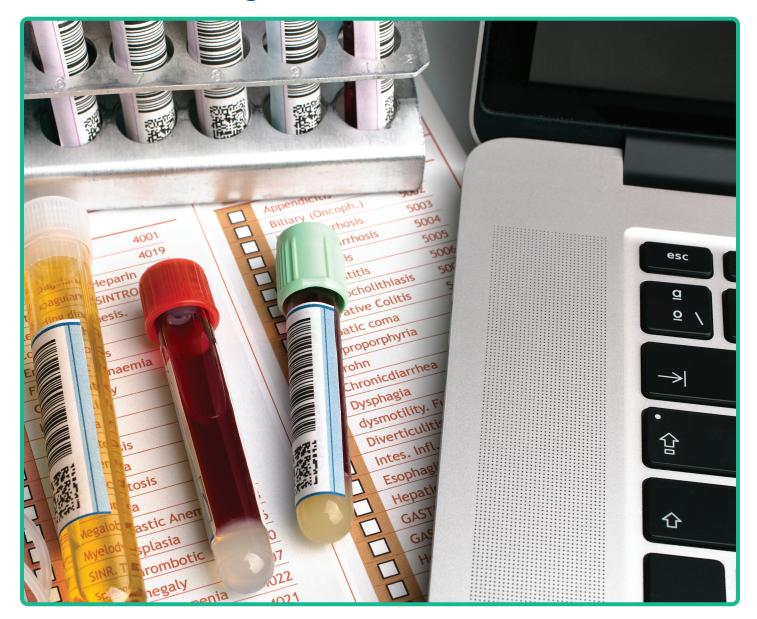


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# **CLIA Program & Medicare Lab Services**



# What's Changed?

Note: No substantive content updates.





The COVID-19 public health emergency (PHE) ended on May 11, 2023. View <u>Infectious diseases</u> for a list of waivers and flexibilities that were in place during the PHE.

The Clinical Laboratory Improvement Amendments (CLIA) Program regulates labs testing human specimens and ensures they provide accurate, reliable, and timely patient test results no matter where the test is done. CMS oversees all lab testing (except some research) done on humans in the U.S. through CLIA.

#### **CLIA Research**

CLIA regulates research testing for returned patient-specific results. CLIA doesn't apply when a statistical research center keeps patient-specific test results for possible use by investigators, and the entity doesn't report patient-specific results.

According to <u>42 CFR 493.2</u>, CLIA applies to all labs examining "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."

CLIA applies to all entities providing clinical lab services and requires these labs to meet applicable federal requirements. CLIA requires these labs to have a current CLIA certificate, including those labs that don't file Medicare test claims. CLIA requirements also apply to labs in physician offices.

#### **CLIA Agency Administration Responsibilities**

Federal Agency	Responsibilities
CMS	Approves and reapproves private accreditation organizations doing inspections
	Approves state exemptions
	Collects user fees
	Inspects and enforces regulatory compliance
	Issues lab certificates
	Monitors lab proficiency testing (PT) performance and approves PT programs
	Develops, implements, and publishes CLIA rules and regulations
FDA	Categorizes tests based on complexity
	Reviews in vitro diagnostic (IVD) applications for marketing devices
	Develops CLIA complexity categorization rules and guidance



#### **CLIA Agency Administration Responsibilities (cont.)**

Federal Agency	Responsibilities
CDC	Performs lab quality improvement studies
	Develops and distributes professional information and educational resources
	<ul> <li>Develops technical standards and lab practice guidelines, including cytology guidelines</li> </ul>
	Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC)
	Monitors PT practices
	Provides analysis, research, and technical help

Fees from regulated facilities cover all CLIA Program administration costs, including certificates and surveys.

# **Getting CLIA Certification**

To get CLIA certification, labs must:

- Complete the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification
   Form (CMS-116) and mail it to their CLIA state agency. For help with the application, see the
   Quick Start Guide.
- Pay applicable <u>certification-type fees</u>. Annual testing volume and scope determine moderate and high complexity labs' additional fees.
- Be surveyed, if applicable.
- Meet CLIA certification requirements.

#### International Labs

If your lab is outside the U.S. (and its territories) and seeking CLIA certification, contact CLIA-IOIntake@cms.hhs.gov before completing Form CMS-116.

You can find the certification application at the <u>How to Apply for a CLIA Certificate</u>, <u>Including International Laboratories</u> webpage. Contact your state agency for help with enrolling.

Include your unique CLIA number on all lab services claims. This 10-character alpha-numeric code identifies and tracks your lab's history. Use this number when contacting your state agency or us.



### **Lab Certificates**

The CLIA Program grants 5 types of lab certificates.

### **Certificate of Waiver**

The Certificate of Waiver (CoW) allows labs to do tests the FDA categorizes as waived tests, including:

- Certain glucose and cholesterol testing methods
- Fecal occult blood tests
- Pregnancy tests
- Some urine tests

Labs that do **only** waived testing must:

- Enroll in the CLIA Program
- Pay applicable certificate fees every 2 years
- Follow manufacturer's test instructions

Labs with a CoW don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect waived tests information.

The Categorization of Tests webpage has more CLIA-waived tests information.

#### What are Waived Tests?

The FDA <u>waives</u> tests it categorizes as simple, low-risk tests for an incorrect result or with no reasonable risk of harm. Labs with a different certificate type can do waived tests without getting a separate CoW.



# **Provider-Performed Microscopy Procedures Certificate**

The Provider-Performed Microscopy Procedures (PPMP) certificate is a subset of moderate complexity tests and a unique lab classification and certification where a physician, mid-level practitioner, or dentist provides **only** certain microscopy procedures and waived tests during a patient's visit.

A PPMP is a moderate complexity test using a bright-field or phase-contrast microscope (for example, urine sediment exams or potassium hydroxide (KOH) preparations).

A physician, mid-level practitioner (under supervision if state law requires), or dentist must personally perform the specimen procedures during the visit.

Labs with a PPMP certificate don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect PPMP information

# **Certificate of Registration**

Labs applying for a Certificate of Compliance (CoC), or Certificate of Accreditation (CoA), first get a Certificate of Registration (CoR). A CoR is temporary and allows a lab to perform moderate and high complexity tests until it gets surveyed to verify it meets CLIA regulations.

If a lab is applying for a CoA or CoC, a CoR shows registration with the CLIA Program and allows it to operate until initial compliance is assessed. A CoR is valid only for 2 years.

# **Certificate of Compliance**

A lab gets a CoC after an on-site survey finds it meets all applicable CLIA regulations. Surveys happen every 2 years at CoC labs doing moderate and high complexity testing. The surveys:

- Help labs improve patient care through education and emphasize requirements directly impacting
  its quality test performance
- Determine labs' regulatory compliance

The surveyor decides whether labs meet CLIA regulations by:

- Interviewing personnel
- Observing current practices
- Reviewing relevant records



#### **Certificate of Accreditation**

Labs that do moderate and high complexity tests get CoAs when they meet the standards of a private non-profit accreditation organization (AO) approved by CMS:

- To get approved, a non-profit AO's standards must meet or exceed CLIA regulatory requirements
- Every 6 years or sooner, each organization reapplies for continued authority to ensure its standards meet or exceed CLIA's requirements
- An AO inspects labs once every 2 years
- We do a <u>validation survey</u> on a representative sample of accredited labs or may do a complaint survey in response to substantial non-compliance allegations
- We complete annual validation surveys of each AO's performance

The Accreditation Organizations/Exempt States webpage lists approved AOs.

# **CLIA Proficiency Testing**

Labs doing moderate and high complexity testing must participate in PT for certain tests. PT offers each lab doing non-waived tests a way to measure performance and verify accuracy and reliability.

A CMS-approved PT program sends labs a set of PT samples 3 times each year. Labs test the PT samples the same way as patient specimens and report the results to the PT program. The PT program grades the results and returns the scores to labs, so they know how accurately they tested. CMS reapproves PT programs annually. The Proficiency Testing Programs webpage has more information.

#### Did You Know?

Even if it's common practice for patient specimens, don't refer PT samples to another lab for analysis.

# **Test Categorization**

The FDA categorizes each test based on complexity. Use the <u>CLIA database</u> to search by test system name, analyte name, complexity, specialty, and effective date.

The FDA categorizes tests into these complexity levels:

- Waived complexity
- Moderate complexity, including the PPMP subcategory
- High complexity



When categorizing a test, the FDA considers:

- Test knowledge needed
- · Test training and experience needed
- Reagents and materials preparation
- Operational steps characteristics
- Calibration, quality control, and PT materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment needed

CLIA quality standards requirements, personnel qualifications, and responsibilities are stricter for more complicated tests.

### **Medicare Lab Services**

We cover lab services and other diagnostic tests, including materials and technician services, when:

- A treating physician or qualified non-physician practitioner orders or refers the services or tests
- Services are medically reasonable and necessary and meet all CLIA regulations

The Clinical Labs Center webpage has more lab services payment and other diagnostic tests information.

### Resources

- CDC CLIA
- CLIA Brochures
- CLIA FAQs
- CLIA Regulations and Federal Register Documents
- Clinical Laboratory Fee Schedule
- Medicare Claims Processing Manual
- National Coverage Determinations (NCDs) for Lab Tests

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