



CLIA Program & Medicare Laboratory Services



What's Changed?

- Updated the certification information to reflect the switch to electronic fee coupons and CLIA certificates (page 4)
- Updated the email address for international laboratories (page 4)

Substantive content changes are in dark red.

Through the Clinical Laboratory Improvement Amendments (CLIA) Program, CMS regulates all laboratory testing (with some [exceptions](#) and [state exemptions](#)) done on human patients in the U.S. to ensure accurate, reliable, and timely test results.

According to [42 CFR 493.2](#), CLIA applies to all laboratories 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 requires that all laboratories, including laboratories that don't file Medicare claims and laboratories in physicians' offices, meet applicable federal regulations and have a current CLIA certificate.

Laboratories that don't comply with CLIA conditions may face [principal sanctions or alternative sanctions](#). Principal sanctions are suspension, limitation, or revocation of any type of CLIA certificate. Alternative sanctions, which we can impose instead of or in addition to principal sanctions, include civil monetary penalties, state on-site monitoring, and a directed plan of correction or directed portion of a plan of correction.

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

CLIA Research

CLIA regulates research testing for patient-specific results that the laboratory reports to another entity. CLIA doesn't apply when a statistical research center that keeps patient-specific test results for possible trials, studies, or experiments doesn't report out those patient-specific results. Under the [Patient Access Rule](#), patients can request their test results directly from the laboratory.



CLIA Administration Responsibilities by Agency

| Federal Agency | Responsibilities |
|---------------------|--|
| CMS | <ul style="list-style-type: none"> • Approves and reapproves private accreditation organizations (AOs) doing inspections • Approves state exemptions and provides oversight for State Agencies • Collects user fees • Inspects and enforces regulatory compliance • Issues laboratory certificates • Monitors laboratory proficiency testing (PT) performance and approves PT programs • Develops, publishes, and implements CLIA rules and regulations |
| FDA | <ul style="list-style-type: none"> • Categorizes tests according to their complexity from the least to the most complex: waived tests, moderate complexity tests, and high complexity tests • Reviews requests for CLIA Waiver by Application • Develops CLIA complexity categorization rules and guidance |
| CDC | <ul style="list-style-type: none"> • Performs laboratory quality improvement studies • Develops and distributes professional information and educational resources • Develops technical standards and laboratory practice guidelines, including cytology guidelines • Monitors PT practices • Provides analysis, research, and technical help |

Getting CLIA Certification

To get CLIA certification, laboratories must:

- Complete the [CLIA Application for Certification Form \(CMS-116\)](#) and send it to their [CLIA State Agency contact](#). See the [Quick Start Guide](#) for more information.
- Pay [certification fees](#). Annual testing volume and scope determine moderate- and high-complexity laboratories' fees. Additional fees may apply.
- Be surveyed, if applicable.
- Meet CLIA certification requirements.

CMS transitioned to a paperless system and no longer mails CLIA certificates or paper fee coupons. All CLIA certification and survey fees must be paid online (payments by paper check are no longer accepted). Laboratories and providers that perform laboratory testing must have a valid email address on file to get electronic CLIA certificates, fee coupons, and other CMS communications. We recommend using a business email address or an email address that many staff can access and use. To update your email, contact your [State Agency](#) or AO (for accredited laboratories).

Note: This doesn't apply in CLIA-exempt states.

International Laboratories

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

Laboratory Certificates

The CLIA Program grants 4 types of laboratory certificates.

Certificate of Waiver

The certificate of waiver (CoW) allows laboratories to do tests FDA categorizes as waived, including:

- Certain glucose and cholesterol tests
- Fecal occult blood tests
- Some pregnancy tests
- Some urine tests

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

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

CMS or a [CMS agent](#) doesn't survey laboratories with a CoW every 2 years. Laboratory 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 information about waived tests

See the [Categorization of Tests](#) webpage for CLIA-waived tests information.

What Are Waived Tests?

FDA categorizes a test as [waived](#) if it determines the test to be simple with low risk of an incorrect result or with no reasonable risk of harm. Laboratories with a different certificate type can do waived tests without getting a separate CoW.

Certificate for Provider-Performed Microscopy Procedures

Provider-performed microscopy (PPM) procedures are a unique laboratory [classification](#), referring to moderate-complexity tests using a bright-field or phase-contrast microscope (for example, urine sediment exams or potassium hydroxide preparations).

Under the certificate for PPM procedures, a physician, mid-level practitioner, or dentist performs **only** certain [PPM procedures](#) and waived tests and must perform them during a patient's visit.

CMS or a CMS agent doesn't survey laboratories with a PPM procedure certificate every 2 years. Laboratory 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 PPM procedure information

Certificate of Registration

Laboratories will get a certificate of registration (CoR) when applying for a certificate of compliance (CoC) or certificate of accreditation (CoA). A CoR is **temporary** and allows a laboratory to perform nonwaived moderate- and high-complexity tests until CMS or a CMS agent surveys the laboratory to verify that it meets CLIA regulations. A CoR is valid for only 2 years while the laboratory applies for the CoC or CoA.

Certificate of Compliance

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

- Help laboratories improve patient care through education
- Emphasize requirements directly affecting laboratories' test performance quality
- Determine laboratories' regulatory compliance

The surveyor decides whether laboratories meet CLIA regulations by:

- Interviewing personnel
- Observing current practices
- Inspecting all laboratory areas covered under the certificate
- Reviewing relevant records

Note: If it's necessary to investigate a complaint or review subsequent PT failure, the laboratory may need to pay additional fees.

Certificate of Accreditation

Laboratories that do nonwaived moderate- and high-complexity tests get CoAs when they meet the standards of an AO that we've approved. An AO inspects laboratories once every 2 years.

We may do a [validation survey](#) on a representative sample of accredited laboratories, or we may do a complaint survey following noncompliance allegations against accredited laboratories.

There are 7 [CMS-approved AOs](#), and we do validation surveys of each. To be approved, an AO's standards must meet or exceed CLIA regulatory requirements. Every 6 years, or more often if necessary, each organization must reapply for continued approval of deeming authority.

Laboratory Certificate Fees

Laboratories must pay a [certificate fee](#) that covers the costs of:

- Issuance
- Renewal
- Changes in certificate type
- Reinstating a terminated certificate with a gap in service
- Other direct administrative activities

There are additional fees for:

- [Revised and replacement certificates](#)
- [CoCs](#)
- [CoAs, CoWs, and certificates for PPM procedures](#)
- [Approved state laboratory programs](#)

CLIA Proficiency Testing

Laboratories doing moderate- and high-complexity testing must participate in PT for certain tests. PT enables each laboratory doing nonwaived tests to measure performance and verify accuracy and reliability.

Don't refer PT samples to another laboratory for analysis, even if it's common practice for patient specimens.

An HHS-approved PT program sends laboratories a set of PT samples 3 times a year. Laboratories 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 the laboratories so they know how accurately they tested. CMS reapproves PT programs annually. [Proficiency Testing Programs](#) has more information.

Test Categorization

FDA categorizes each test based on complexity. Use the [FDA Test System Database](#) to search by test system name, analyte name, complexity, specialty, and effective date.

FDA categorizes tests according to these levels:

- Waived complexity
- Moderate complexity
- High complexity

When categorizing a test, FDA considers:

- Test knowledge needed
- Test training and experience needed
- Preparation of reagents and materials
- Characteristics of operational steps
- Calibration, quality control, and PT materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment needed

More complex tests require stricter CLIA quality standards and personnel qualifications and responsibilities.

Medicare Laboratory Services

Include your unique CLIA number on all laboratory services claims. This 10-character alphanumeric code identifies and tracks your laboratory's history. Use this number when contacting your State Agency or us.

We cover laboratory 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

[Clinical Labs Center](#) has more information on payment for laboratory services and other diagnostic tests.

Resources

- [CDC CLIA](#) webpage
- [CLIA brochures](#)
- [CLIA Regulations and Federal Register Documents](#) webpage
- [Clinical Laboratory Fee Schedule](#) webpage
- [CMS CLIA](#) webpage
- [FDA CLIA](#) webpage
- [Medicare Claims Processing Manual, Chapter 16](#), section 70

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