The Clinical Laboratory Improvement Amendments (CLIA) Program regulates laboratories that test patient specimens and ensures that laboratories produce accurate and reliable test results.

Learn about these laboratory services topics:

- Overview of the CLIA program
- Enrolling in the CLIA program
- Types of laboratory certificates
- CLIA Proficiency Testing (PT)
- Test method categorization
- Medicare laboratory services
- Resources

The information in this publication applies to all entities providing clinical laboratory services.

The Hyperlink Table, at the end of this document, provides the complete URL for each hyperlink.
OVERVIEW OF THE CLIA PROGRAM

Congress passed the CLIA in 1988 to establish quality standards for all non-research laboratory testing:

- Performed on specimens derived from humans
- For providing information for the diagnosis, prevention, and treatment of disease or impairment of or assessment of health

It establishes quality standards for laboratories to ensure the accuracy, reliability, and timeliness of patients' test results. Centers for Medicare & Medicaid Services (CMS) data indicates that the CLIA improved the quality of testing in the U.S. The number of quality deficiencies decreased about 40 percent from the first laboratory survey to the second under the CLIA. Reviews of PT over time resulted in similar findings.

The CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate to operate. The CLIA applies to all entities providing clinical laboratory services regardless of whether they or another provider file Medicare claims for the tests. Laboratories billing Medicare have additional responsibilities and requirements (see the Medicare Laboratory Services section for more information about these responsibilities and requirements).

It requires the U.S. Department of Health & Human Services (HHS) to certify laboratories performing non-research testing. CMS, the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) administer the CLIA program.

<table>
<thead>
<tr>
<th>Table 1. CLIA Agency Administration Responsibilities</th>
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<tr>
<td><strong>Federal Agency</strong></td>
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Table 1. CLIA Agency Administration Responsibilities (cont.)

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<thead>
<tr>
<th>Federal Agency</th>
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| CDC            | ● Conducts laboratory quality improvement studies  
                 ● Develops and distributes professional information and educational resources  
                 ● Develops technical standards and laboratory practice guidelines, including guidelines for cytology  
                 ● Manages the Clinical Laboratory Improvement Advisory Committee  
                 ● Monitors PT practices  
                 ● Provides analysis, research, and technical assistance |

Fees from regulated facilities cover all costs of administering the program, including certificate and survey costs.

ENROLLING IN THE CLIA PROGRAM

To enroll in the CLIA Program, laboratories must:

1. Complete Form CMS-116, Clinical Laboratory Improvements Amendments (CLIA) Application for Certification, and mail it to the appropriate State Agency.
2. Pay applicable fees, which are based on the type of certification. For moderate and high complexity laboratories, additional fees are based on annual volume and types of testing.
3. Be surveyed, if applicable.
4. Meet CLIA standards and become certified.

Include your unique CLIA number on all Medicare claims for laboratory services.

You can find the application for certification and enrollment instructions at How to Apply for a CLIA Certificate, Including International Laboratories. Contact the appropriate State Agency if you need help with enrolling in the CLIA Program.

TYPES OF LABORATORY CERTIFICATES

The CLIA program grants five types of laboratory certificates:

1. Certificate of Waiver (CoW)
2. Certificate for Provider-Performed Microscopy Procedures (PPMP)
3. Certificate of Registration (COR)
4. Certificate of Compliance (COC)
5. Certificate of Accreditation (COA)

DID YOU KNOW?

Laboratories that have a Certificate for PPMP, COR, COC, or COA, can perform waived tests without a CoW.
Each type of laboratory certificate is described below.

**CoW**

The CoW permits laboratories to perform only waived tests, which are so simple and accurate that little risk of error exists when done correctly. Examples of waived tests include:

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

Waived laboratories must:

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

Routine on-site surveys are not required for laboratories with a CoW unless there is a complaint, they are testing beyond the scope of the certificate, there is risk of harm due to inaccurate testing, or to collect information about waived tests.

For more information about CLIA-waived tests, visit [Certificate of Waiver Laboratory Project](#) and [Categorization of Tests](#), which includes a list of waived tests in the Downloads section.

**Certificate for PPMP**

A subset of the moderate complexity tests, the Certificate for PPMP is a unique classification and certification for laboratories where a physician, mid-level practitioner, or dentist performs only certain microscopy procedures and waived tests. A microscopy procedure is moderately complex using a microscope (for example, urine microscopic or potassium hydroxide KOH] smear).

Routine on-site surveys are not required for a Certificate for PPMP. Laboratories may be surveyed as part of a routine survey for non-waived tests or if there is a complaint. Moderate complexity requirements apply.

**COR**

Laboratories that apply for a COC or COA receive a COR, which provides temporary certification for it to conduct moderate and high complexity tests while it completes the certification process. The COR expires after 2 years or when the laboratory meets certification requirements (whichever is sooner). The certification process includes an on-site survey or verification of accreditation. Laboratories may choose to achieve their full CLIA certification through a CMS survey or a CMS-approved accrediting organization.
COC

Laboratories may receive a COC after an on-site survey finds that they comply with all applicable CLIA requirements. Laboratories with a COC that perform moderate and high complexity tests must be surveyed every 2 years. The surveys:

- Assist laboratories in improving patient care through education and emphasizing standards that directly impact their quality test performance
- Determine laboratories’ regulatory compliance

The surveyor determines whether laboratories meet CLIA requirements by:

- Interviewing personnel
- Observing past and current practices
- Reviewing relevant records

COA

Laboratories that perform moderate and high complexity tests and meet the standards of a private non-profit accreditation organization approved by CMS may receive a COA. To receive CMS approval, a non-profit accreditation organization’s requirements must equal or exceed CLIA Program requirements. Periodically, each organization must receive re-approval to ensure it maintains equivalent, or more than equivalent, requirements. Each year, CMS evaluates each organization’s performance in enforcing CLIA requirements.

An accreditation organization inspects laboratories once every 2 years, and CMS may perform a validation survey to evaluate the results of the most recent accreditation organization inspection.

For a list of approved accreditation organizations, visit Accreditation Organizations/Exempt States.

CLIA PT

Laboratories conducting moderate and high complexity testing must participate in PT for certain tests. PT offers each laboratory performing non-waived tests a way to measure performance and verify its accuracy and reliability.

A CMS-approved PT program sends laboratories a set of unknown samples about three times a year. Laboratories test the samples just like patient specimens and report the results to the PT program. The PT program grades the results and returns them to laboratories so they can see how accurately they performed testing. PT programs undergo annual and ongoing regulatory reviews by CMS. For more information about PT programs, visit Proficiency Testing Programs.

DID YOU KNOW?

Even if it is the protocol for patient specimens, you should not refer PT samples to another laboratory for analysis.
TEST METHOD CATEGORIZATION

The FDA categorizes and grades each test based on the complexity of the test method. To search the CLIA database by test system name, analyte name, complexity, specialty, and date of categorization, visit Public Databases.

It categorizes test methods into three levels of complexity:

1. Waived Complexity
2. Moderate Complexity, including the subcategory of PPMP
3. High Complexity

When categorizing a test, it considers:

- Amount of interpretation
- Calibration and quality control requirements of instruments
- Degree of independent judgment
- Difficulty of calculations
- Examinations, procedures, and methodologies
- Training required to operate the instruments for this particular methodology

The more complicated the test, the more stringent the requirements. The CLIA specifies quality standards for:

- Facility administration
- General laboratory systems
- Personnel qualifications and responsibilities
- Pre-analytic, analytic, and post-analytic systems
- PT
- Quality assessment and control
- Specific cytology provisions for laboratories performing moderate and/or high complexity tests

MEDICARE LABORATORY SERVICES

Medicare covers laboratory services and other diagnostic tests, including materials and the services of technicians, when:

1. The treating physician or a qualified non-physician practitioner orders/refers the services/tests
2. Services are medically reasonable and necessary
3. Services meet all CLIA requirements

For more information about Medicare payment for laboratory services and other diagnostic tests, visit Clinical Labs Center.
## RESOURCES

### Table 2. CLIA and Medicare Laboratory Services Resources

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<th>Resource</th>
<th>Website</th>
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### Table 3. Hyperlink Table

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