



CLIA PROGRAM AND MEDICARE LABORATORY SERVICES

The Clinical Laboratory Improvement Amendments (CLIA) program regulates laboratories that test human specimens and ensures laboratories produce accurate, reliable, and timely patient test results regardless of where the test is performed.

Learn about these laboratory services topics:

- CLIA Program overview
- Obtaining CLIA certification
- Types of laboratory certificates
- CLIA Proficiency Testing (PT)
- Test categorization
- Medicare laboratory services
- Resources



Target Audience: Medicare Fee-For-Service Providers

The Hyperlink Table, at the end of this document, provides the complete URL for each hyperlink.

CLIA PROGRAM OVERVIEW

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA. Congress passed CLIA in 1988 to establish quality standards, strengthen Federal oversight of clinical laboratories, and ensure the accuracy and reliability of patient test results.

CLIA applies to all laboratories that examine “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.” ([42 U.S.C. § 263a\(a\)](#)).

CLIA Research

CLIA is responsible for research testing when patient-specific results are returned. CLIA does not apply when patient-specific test results are maintained by a statistical research center for possible use by investigators, and the entity does not report patient-specific results.

CLIA mandates nearly all laboratories, including those in physician offices, must meet applicable Federal requirements and have a current CLIA certificate. CLIA applies to all entities providing clinical laboratory services including those that do not file Medicare test claims. Laboratories billing Medicare have additional responsibilities and requirements discussed in the “Medicare Laboratory Services” section.

Table 1. CLIA Agency Administration Responsibilities

Federal Agency	Responsibilities
CMS	<ul style="list-style-type: none"> • Approves private accreditation organizations that perform inspections • Approves State exemptions • Collects user fees • Conducts inspections and enforces regulatory compliance • Issues laboratory certificates • Monitors laboratory performance on PT and approves PT programs • Publishes CLIA rules and regulations
FDA	<ul style="list-style-type: none"> • Categorizes tests based on complexity • Develops rules and guidance for CLIA complexity categorization
CDC	<ul style="list-style-type: none"> • Conducts laboratory quality improvement studies • Develops and distributes professional information and educational resources • Develops technical standards and laboratory practice guidelines, including cytology guidelines • Manages the Clinical Laboratory Improvement Advisory Committee (CLIAC) • Monitors PT practices • Provides analysis, research, and technical assistance

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

OBTAINING CLIA CERTIFICATION

To obtain CLIA certification, laboratories must:

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

You can find the application for certification at the [How to Apply for a CLIA Certificate, Including International Laboratories](#) webpage. Contact the appropriate State agency for help enrolling.

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

International Laboratories

If your laboratory is outside the United States, or is not one of the territories of the United States and is seeking CLIA certification before completing a CMS-116, contact CLIA-IOIntake@cms.hhs.gov.

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)

Each type of laboratory certificate is described on pages 4 and 5.

Did You Know?

Laboratories that have a Certificate for PPMP, COR, COC, or COA, can perform waived tests without obtaining a separate CoW.



CoW

The CoW permits laboratories to perform waived tests, considered 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

Laboratories with a CoW do not require routine biennial surveys unless there is a complaint, the testing is 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 these links: [Certificate of Waiver Laboratory Project](#) and [Categorization of Tests](#). The Downloads section includes a list of waived tests.

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 during a patient's visit. A provider-performed microscopy procedure is a moderately complex test using a bright-field or phase-contrast microscope (for example, urine sediment examinations or potassium hydroxide [KOH] preparations). The physician, mid-level practitioner (under supervision if required by the State), or dentist must personally perform the procedure on specimens obtained during the visit.

Laboratories with a PPMP Certificate do not require routine biennial surveys. Laboratories may be part of a routine survey for non-waived tests or if there is a complaint. A CLIA certificate is required and the laboratory must meet the CLIA quality standards for moderate complexity testing.

COR

Laboratories applying for a COC or COA initially receive a COR. A COR is temporary and permits the laboratory to conduct moderate and high complexity tests until the laboratory is surveyed and is in compliance with the CLIA regulations. For laboratories applying for a COA, a COR indicates the laboratory is registered with CMS and permits the laboratory to operate until CMS receives verification of accreditation approval. The COR is valid for no more than 2 years.



COC

Laboratories receive a COC after an on-site survey finds they comply with all applicable CLIA regulations. Surveys occur every 2 years at laboratories with a COC performing moderate and high complexity tests. The surveys:

- Help laboratories improve patient care through education and emphasize standards directly impacting their quality test performance
- Determine laboratories' regulatory compliance

The surveyor determines whether laboratories meet CLIA regulations 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 receive a COA. A non-profit accreditation organization's requirements must equal or exceed CLIA program requirements to receive CMS approval. Every 6 years or sooner, each organization reapplies for continued deeming authority to ensure its requirements are equivalent to, or more stringent than CLIA.

An accreditation organization inspects laboratories once every 2 years. CMS performs a validation survey of those laboratories within 90 days of the AO's inspection. CMS performs an annual review of the accreditation organization's performance through validation surveys.

For a list of approved accreditation organizations, visit the [Accreditation Organizations/Exempt States](#) webpage.

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 accuracy and reliability.

A CMS-approved PT program sends laboratories a set of PT samples approximately three times a year. Laboratories must test the PT samples in the same manner as patient specimens and report the results to the PT program. The PT program grades the results and returns the scores to laboratories so they know how accurately they performed testing. PT programs undergo an annual reapproval by CMS. For more information about PT programs, visit the [Proficiency Testing Programs](#) webpage.

Did You Know?

Even if it is the protocol for patient specimens, do not refer PT samples to another laboratory for analysis.

TEST CATEGORIZATION

The FDA categorizes and grades each test based on the complexity of the test. To search the CLIA database by test system name, analyst name, complexity, specialty, and date of categorization, visit the [Public Databases](#) webpage.

The FDA categorizes tests into three levels of complexity:

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

When categorizing a test, the FDA considers:

- Knowledge needed to perform the test
- Training and experience required to perform the test
- Reagents and materials preparation
- Characteristics of operational steps
- Calibration, quality control, and proficiency testing materials
- Test system troubleshooting and equipment maintenance
- Amount of interpretation and judgment

The more complicated the test, the more stringent the specific CLIA quality standards requirements are for personnel qualifications and responsibilities.

MEDICARE LABORATORY SERVICES

Medicare covers laboratory services and other diagnostic tests, including materials and technician services, 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 regulations

For more information about Medicare laboratory services payment and other diagnostic tests, visit the [Clinical Labs Center](#) webpage.

RESOURCES

Table 2. CLIA and Medicare Laboratory Services Resources

Resource	Website
CLIA	CMS.gov/Regulations-and-Guidance/Legislation/CLIA
CLIA Frequently Asked Questions	CMS.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/cliaback.pdf
CLIA Regulations	CMS.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html
CLIA Brochures	CMS.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html
Medicare Laboratory Policy and Procedures	Chapter 15, Sections 80.1 and 280 of the Medicare Benefit Policy Manual CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf Chapters 16 and 18 of the Medicare Claims Processing Manual CMS.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html
Clinical Laboratory Fee Schedule	CMS.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243659.html
Clinical Labs Center	CMS.gov/Center/Provider-Type/Clinical-Labs-Center.html
Medicare Enrollment for Providers Who Solely Order or Certify	CMS.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1247538.html
Lab National Coverage Determinations	CMS.gov/Medicare/Coverage/CoverageGenInfo/LabNCDs.html
Medicare Coverage Database – Local Coverage Determinations	CMS.gov/medicare-coverage-database/overview-and-quick-search.aspx

Table 3. Hyperlink Table

Embedded Hyperlink	Complete URL
42 U.S.C. § 263a(a)	https://www.govinfo.gov/content/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap6A-subchapII-partF-subpart2-sec263a.pdf
Accreditation Organizations/ Exempt States	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States.html
Categorization of Tests	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests.html
CDC	https://wwwn.cdc.gov/clia
Certificate of Waiver Laboratory Project	https://www.cms.gov/regulations-and-guidance/legislation/clia/certificate_of_waiver_laboratory_project.html
Clinical Labs Center	https://www.cms.gov/Center/Provider-Type/Clinical-Labs-Center.html
CMS	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
FDA	https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm
Form CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
How to Apply for a CLIA Certificate, Including International Laboratories	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html
Proficiency Testing Programs	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html
Public Databases	https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm393285.htm
State Agency	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

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