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KNOWLEDGE • RESOURCES • TRAINING

PRINT-FRIENDLY VERSION

CLIA PROGRAM AND MEDICARE LABORATORY SERVICES

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

Learn about these laboratory services topics:

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

CLIA PROGRAM OVERVIEW

The Centers for Medicare & Medicaid Services (CMS) oversees all laboratory testing (except research) done 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.

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

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
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CLIA RESEARCH

CLIA regulates research testing when patient-specific results are returned. CLIA does not apply when a statistical research center maintains patient-specific test results for possible use by investigators, and the entity does not report patient-specific 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 Code of Federal Regulations [CFR] § 493.2).

CLIA mandates nearly all laboratories, including those in physician offices, meet applicable Federal requirements and have a current CLIA certificate. CLIA applies to all entities furnishing 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	• Approves and/or reapproves private accreditation organizations that do inspections • Approves State exemptions • Collects user fees • Conducts inspections and enforces regulatory compliance • Issues laboratory certificates • Monitors laboratory Proficiency Testing (PT) performance and approves PT programs • Develops, implements, and publishes CLIA rules and regulations
FDA	• Categorizes tests based on complexity • Reviews Application Waiver requests • Develops CLIA complexity categorization rules and guidance
CDC	• 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 • Gives analysis, research, and technical help

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

GETTING CLIA CERTIFICATION

To get 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 certification type. For moderate and high complexity laboratories, additional fees are based on annual testing volume and scope of testing.
3. Be surveyed, if applicable.
4. Meet CLIA certification standards.

You can find the certification application 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 laboratory services claims.

INTERNATIONAL LABORATORIES

If your laboratory is outside the United States, or is not in 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 (PPM)
3. Certificate of Registration (CoR)
4. Certificate of Compliance (CoC)
5. Certificate of Accreditation (CoA)

Below we describe each type of laboratory certificate.

DID YOU KNOW?

Tests categorized by the FDA as waived are simple tests that have low risk for an incorrect result or pose no reasonable risk of harm. Laboratories that have a Certificate for PPM, CoR, CoC, or CoA can do waived tests without getting a separate CoW.

CoW

The CoW allows laboratories to do tests categorized by the FDA as waived tests. Examples include:

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

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

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

Laboratories with a CoW do not receive routine biennial surveys. Laboratories are surveyed if there is a complaint, the testing is beyond the certificate's scope, there is risk of harm due to inaccurate testing, or to collect information about waived tests.

For more information about CLIA-waived tests, refer to the Categorization of Tests webpage. The Downloads section includes a list of waived tests.

PPM Certificate

- The PPM Certificate is a subset of the moderate complexity tests, and a unique laboratory classification and certification where a physician, mid-level practitioner, or dentist furnishes **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 do the procedure on specimens taken during the visit.

Laboratories with a PPM Certificate do not require routine biennial surveys. Laboratories are surveyed if there is a complaint, to determine if the testing is beyond the certificate's scope, if there is risk of harm due to inaccurate testing, or to collect information about provider-performed microscopy procedures.

CoR

- Laboratories applying for a CoC or CoA initially get a CoR.
- A CoR is temporary and permits the laboratory to perform moderate and high complexity tests until the laboratory is surveyed and found in compliance with 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 gets verification of accreditation approval.
- The CoR is valid for no more than 2 years.

CoC

Laboratories get a CoC after an on-site survey finds they comply with all applicable CLIA regulations. Surveys occur every 2 years at CoC laboratories doing 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 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 (AO) approved by CMS get a CoA.
- A non-profit accreditation organization's requirements must meet or exceed CLIA Program requirements to get 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 on a sample of accredited laboratories within 90 days of the AO's inspection.
- CMS completes an annual review of each accreditation organization's performance through validation surveys.

For a list of approved accreditation organizations, refer to Accreditation Organizations/Exempt States webpage.

CLIA PT

Laboratories performing 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.

DID YOU KNOW?

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

A CMS-approved PT program sends laboratories a set of PT samples approximately three times a year. Laboratories must 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 laboratories so they know how accurately they tested. PT programs undergo an annual CMS reapproval. For more information about PT programs, refer to Proficiency Testing Programs webpage.

TEST CATEGORIZATION

The FDA categorizes and grades each test based on test complexity. To search the CLIA database by test system name, analyst name, complexity, specialty, and date of categorization, refer to the Public Databases webpage.

The FDA categorizes tests into three levels of complexity:

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

When categorizing a test, the FDA considers:

- Knowledge needed to do the test
- Training and experience needed to do the test
- Reagents and materials preparation
- Operational steps characteristics
- 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 and/or 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, refer to Clinical Labs Center webpage.

RESOURCES

Table 2. CLIA and Medicare Laboratory Services Resources

Resource	Website
CLIA	CMS.gov/Regulations-and-Guidance/Legislation/CLIA
CLIA Brochures	CMS.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures
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
CLIA Waived Tests	CMS.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4336CP.pdf
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
Clinical Labs Center	CMS.gov/Center/Provider-Type/Clinical-Labs-Center
FAQs, Abbott i-STAT	CMS.gov/files/document/frequently-asked-questions-faqs-abbott-i-stat.pdf
Lab National Coverage Determinations	CMS.gov/medicare-coverage-database/indexes/lab-ncd-index.aspx
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

Table 3. Hyperlink Table

Embedded Hyperlink	Complete URL
42 Code of Federal Regulations [CFR] § 493.2	https://www.ecfr.gov/cgi-bin/text-idx?SID=deb3949c1699033d506918f63c5b2b06&mc=true&node=pt42.5.493&rgn=div5#se42.5.493_12
CMS	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
FDA	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CDC	https://wwwn.cdc.gov/clia
Form CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf
State Agency	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.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
Categorization of Tests	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests
Accreditation Organizations/Exempt States	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Accreditation_Organizations_and_Exempt_States
Proficiency Testing Programs	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers
Public Databases	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/public-databases
Clinical Labs Center	https://www.cms.gov/Center/Provider-Type/Clinical-Labs-Center