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FACT SHEET
KNOWLEDGE • RESOURCES • TRAINING

CLIA Program & Medicare Lab Services

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

What's Changed?

- CMS has a tool to help labs fill out the CMS-116 (page 4)
- Labs must report SARS-CoV-2 test results during the COVID-19 Public Health Emergency (PHE) (page 7)

You'll find substantive content updates in dark red font.

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.

Together we can advance health equity and help eliminate health disparities for all minority and underserved groups. Find resources and more from the CMS Office of Minority Health:

- Health Equity Technical Assistance Program
- Disparities Impact Statement

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 42 CFR 493.2, 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 meet applicable federal requirements and have a current CLIA certificate, including those 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
CDC	• Performs lab quality improvement studies • Develops and distributes professional information and educational resources • Develops technical standards and lab practice guidelines, including cytology guidelines • Manages 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 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 certification-type fees. 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's 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 How to Apply for a CLIA Certificate, Including International Laboratories webpage. Contact your state agency for help enrolling.

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

Lab Certificates

The CLIA Program grants 5 types of lab certificates.

Certificate of Waiver (CoW)

The 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 **only** do waived testing must:

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

What are Waived Tests?

FDA waives 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.

Labs with a CoW don't get surveyed every 2 years. Lab surveys happen if there's a complaint, to decide if the testing is beyond the certificate's scope, if there's risk of harm from inaccurate testing, or to collect waived tests information.

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

Provider-Performed Microscopy (PPM) Procedures Certificate

- The PPM 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 PPM procedure is a moderate complexity test using a bright-field or phase-contrast microscope (for example, urine sediment exams or potassium hydroxide [KOH] preparations)
- The physician, mid-level practitioner (under supervision if state required), or dentist must personally perform the specimen procedures taken during the visit

Labs with a PPM certificate don't get surveyed every 2 years. Lab surveys happen if there's a complaint, to decide if the testing is beyond the certificate's scope, if there's risk of harm from inaccurate testing, or to collect PPM procedure information.

Certificate of Registration (CoR)

- Labs applying for a Certificate of Compliance (CoC) or Certificate of Accreditation (CoA) first get a CoR
- A CoR is temporary and allows labs to perform moderate and high complexity tests until it gets surveyed to verify it meets CLIA regulations
- If a lab's 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 only valid for 2 years

Certificate of Compliance (CoC)

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 (CoA)

- CoAs are given to labs that do moderate and high complexity tests and 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 validation survey 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

Accreditation Organizations/Exempt States webpage lists approved AOs.

CLIA Proficiency Testing (PT)

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. 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

FDA categorizes each test based on complexity. Use the Public Databases webpage to search the CLIA database by test system name, analyte name, complexity, specialty, and date of categorization.

The FDA categorizes tests into these complexity levels:

- Waived complexity
- Moderate complexity, including the PPM 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 proficiency testing materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment needed

During the COVID-19 Public Health Emergency (PHE), each lab performing tests to detect SARS-CoV-2 or diagnose a case of COVID-19 must report results in such form, manner, and timing as we prescribe.

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

Find waived or nonwaived (moderate or high complexity) categorized tests at FDA CLIA Database.

Medicare Lab Services

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

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

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

Resources

- CDC CLIA
- CLIA Brochures
- CLIA FAQs
- CLIA Regulations
- Clinical Laboratory Fee Schedule
- Lab National Coverage Determinations
- Medicare Claims Processing Manual