eBook

CLIA Moderate Complexity Testing

POCT U

As of 2021, almost half of all tests listed in the FDA CLIA database are classified as moderately complex.[1]

CLIA Moderate Complexity Testing:

A Reference Guide

This guide provides summary information and helpful links to assist you in navigating the CLIA requirements for performing moderate complexity tests.

Note: This brochure is not a legal document and does not replace the official CLIA requirements. It is the responsibility of every lab to ensure compliance with the official CLIA requirements as described in the Code of Federal Regulations, Title 42; Chapter IV; Subchapter G; Part 4932.

The information contained in this brochure was accurate as of June 2021.

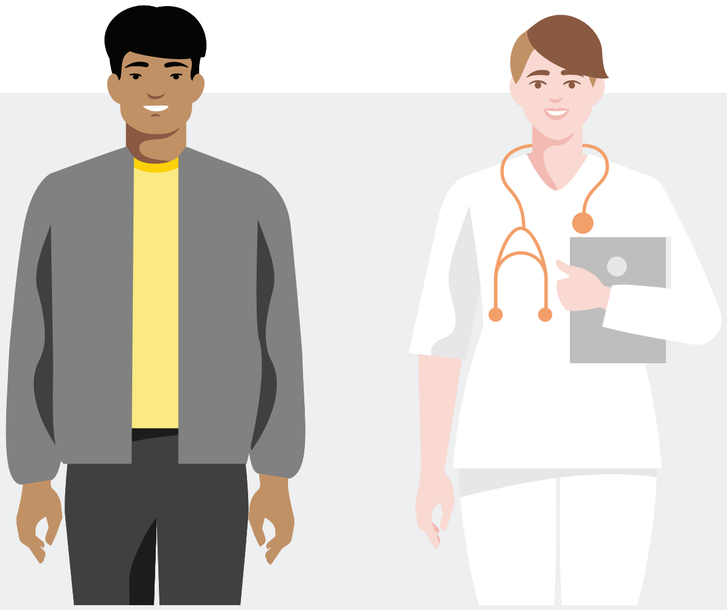
Contents

Introduction

Point-of-care testing (POCT) enables testing at or near the site of patient care, providing fast and actionable results that can lead to better patient outcomes.

Point-of-care instruments are generally designed to provide convenient, user-friendly, portable testing platforms to clinicians across a variety of care settings and require minimal sample volume, operator training, and maintenance.[2]

As with all laboratory testing, sites performing POCT must obtain Clinical Laboratory Improvement Amendments of 1988 (CLIA) certification prior to testing.[3]



Contents

What is CLIA?[3,4]

CLIA is a federal program for certification and oversight of clinical laboratory testing.

CLIA stands for Clinical Laboratory Improvement Amendments of 1988.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing performed on humans, whether for health assessment or to diagnose, treat, or prevent disease, through CLIA.

CLIA regulations include quality standards for **all laboratory testing** to ensure the accuracy, reliability, and timeliness of patient test results, **regardless of where the test was performed**.

Contents

CLIA certification[3]

Certification

All laboratories are required to obtain CLIA certification prior to testing.

Additionally, laboratories must meet any requirements imposed by state law.

The type of certification required, and associated process, depend on test complexity.

Test categorization

Tests are classified in two general categories depending on test complexity:

Waived

Nonwaived

- Moderate complexity
- High complexity
  - Specialized scientific knowledge and training are required.

To determine test complexity, refer to the:

↗ CLIA-Clinical Laboratory Improvement Amendments database

Contents

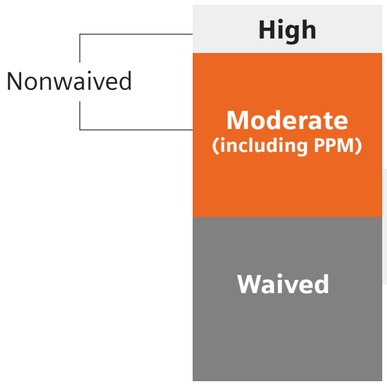
CLIA moderately complex testing[3]

Moderate complexity tests are tests requiring basic lab knowledge and training for personnel performing the test.

To perform moderate complexity testing, labs must:

- Have a CLIA certificate.
- Be inspected.
- Meet specific CLIA quality requirements.

These laboratories also require a CLIA Certificate of Compliance (CoC) or Certificate of Accreditation (CoA).



50%

Almost half of all tests listed in the FDA CLIA database are classified as moderately complex.[1]

Contents

CLIA certification and CMS-approved accreditation[3]

Certificate of Registration (CoR)

Laboratories applying for a CoC or CoA initially get a CoR.

A CoR is temporary and permits the laboratory to perform tests until it is surveyed and found in compliance with CLIA regulations.

Certificate of Compliance (CoC)	Certificate of Accreditation (CoA)
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.	Laboratories that meet the standards of a private, nonprofit accreditation organization (AO) approved by CMS get a CoA. An accreditation organization inspects laboratories once every 2 years.

CMS-approved Accrediting Organizations[5]

American Association of Blood Banks (AABB)

American Association for Laboratory Accreditation (A2LA)

Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP)

American Society for Histocompatibility and Immunogenetics (ASHI)

COLA, Inc.

College of American Pathologists (CAP)

The Joint Commission

Laboratories select the accrediting organization at time of CLIA application.

Note: Some accrediting organizations offer resources to assist in the CLIA application process. Contact the organization for more details.

Contents

CLIA quality standards[6]

In general, CLIA standards center on policies and procedures designed to monitor and evaluate the ongoing and overall quality of the total testing process, including:

- Personnel Requirements: Positions & Qualifications
- Personnel Competency Assessment
- Proficiency Testing Performance
  - Externally validate the quality of the laboratory's performance.
- Verification of Performance Specifications
  - Accuracy, precision, reportable range, reference intervals/range
- Calibration and Calibration Verification
  - Accuracy and performance check
- Quality Control Procedures
  - Monitor and evaluate the testing process to assure accurate and reliable patient results.

Please refer to the Code of Federal Regulations, Title 42; Chapter IV; Subchapter G; Part 493 for details on the requirements for each quality standard.

Contents

Personnel requirements[3]

The CLIA personnel requirements are found in Subpart M of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to have personnel who meet the following qualifications:

Demonstrate knowledge and experience to oversee and perform laboratory testing.

- **Laboratory director:** Responsible for the overall administration of the laboratory.
- **Technical consultant:** Responsible for the technical and scientific oversight of the laboratory and must be available on an as-needed basis.
- **Clinical consultant:** Serves as liaison between the laboratory and its clients in matters related to reporting and interpreting results.
- **Testing personnel:** Responsible for processing the specimens and reporting results.

Resources

CLIA Laboratory Director

CLIA Brochure

↗ Laboratory Director Responsibilities (PDF)

CLIA Lab Director Certification Courses

↗ COLA Laboratory Director Course

↗ University of Iowa Health Care CLIA Lab Director Certification

↗ CRI Lab Director CME Program

CLIA Technical Consultant

↗ COLA

Contents

Personnel competency[3]

The CLIA personnel requirements are found in Subpart K of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to:

Assess the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.

- There are a minimum of six required procedures included in competency assessment.
- Competency assessment for personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens and yearly thereafter.

Resource

CLIA personnel requirements

CLIA Brochure

↗ What Do I Need to Do to Assess Personnel Competency? (PDF)

Contents

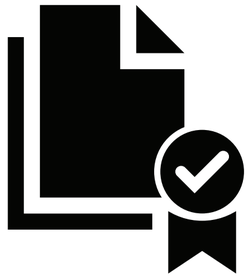
Quality control (QC) procedures[3,7]

The CLIA personnel requirements are found throughout Subpart M of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to:

Follow established written procedures to monitor and evaluate the entire analytical testing process to assure accurate and reliable patient results.

- QC consists of the activities used to detect errors that occur due to test system failure, adverse environmental conditions, and variance in operator performance.
- Laboratories can follow CLIA quality control requirements or can meet CLIA quality requirements with the development and implementation of an Individual Quality Control Plan (IQCP).



Resources

Quality control procedures

CLIA Brochure
↗ CLIA Individualized Quality Control Plan Introduction (PDF)

CLIA Brochure
↗ CLIA IQCP, Considerations When Deciding to Develop an IQCP (PDF)

CLIA Brochure
↗ CLIA IQCP, What is an IQCP? (PDF)

Contents

Proficiency testing (PT)[3]

Proficiency Testing (PT): The CLIA requirements for proficiency testing are found in Subparts H, I, and K of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to:

Externally validate the quality of the laboratory's performance.

- Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS.
- Unknown samples are sent to a laboratory by an approved PT program on a scheduled basis (usually three times per year).
- After testing, the laboratory reports its sample results back to their PT program.
- Results are graded.
- CMS and accreditation organizations routinely monitor their laboratories' performance.

Resources

Proficiency Testing

CLIA Brochure

↗ Proficiency Testing and PT Referral (PDF)

Proficiency Testing Programs

↗ College of American Pathologists (CAP)
CAP 800-323-4040

↗ Wisconsin State Laboratory of Hygiene (WSLH)
800-462-5261

↗ American Proficiency Institute (API)
800-333-0958 ext 3023

Contents

Verification of performance specifications[3]

The CLIA requirements for verification are found in Subparts K and M of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to:

Demonstrate that, in the laboratory, the test system can obtain performance specifications comparable to those established by the manufacturer for the following:

- Accuracy
- Precision
- Reportable Range
- Reference Intervals/Range

Resource

CLIA Brochure

↗ Verification of Performance Specifications (PDF)

Contents

Calibration and calibration verification[3]

The CLIA requirements for verification are found in Subpart K of the Code of Federal Regulations.

In part, a moderate complexity laboratory is required to:

- Substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system.[4]
- Follow the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer.

Resource

CLIA Brochure

↗ Calibration and Calibration Verification (PDF)

Contents

Applying for CLIA certification for moderate complexity testing[3]

Please refer to the CLIA regulations for complete information on CLIA requirements and the application process for moderately complex testing.

All laboratories are required to obtain CLIA certification prior to testing.

Additionally, laboratories must meet any requirements imposed by state law.

It is the responsibility of the laboratory to apply for the appropriate certification based on its desired test menu and respective test complexity and to meet all CLIA requirements and applicable state requirements.

7 Meet CLIA certification standards.

6 Be surveyed, if applicable.

5 Pay appropriate fees.
- Based on annual testing volume and scope of testing
- Source current CLIA Fee Schedule

4 Download and complete Form CMS-116.

3 Have the following information available:
- Verification of State Licensure, as applicable
- Documentation of qualifications:
  - Education (copy of diploma, transcript from accredited institution, CMEs)
  - Credentials
  - Laboratory experience

Note: Proof of laboratory director qualifications must be submitted with the application.

2 Download the Laboratory Quick Start Guide to CMS CLIA Complete General Certification to review required information.

To prepare for application process

1 Prior to applying for CLIA certification you must apply for either a Certificate of Accreditation (COA) or a Certificate of Compliance (COC).

Contents

CLIA: helpful resources

There are many additional resources available that provide details on the CLIA requirements and assist in navigating the path to CLIA certification.

Centers for Medicare & Medicaid Services

How to Apply for a CLIA Certificate

Accreditation Organizations/Exempt States

Categorization of Tests

CLIA Brochures

- How to Obtain a CLIA Certificate (PDF)
- Proficiency Testing and PT Referral (PDF)
- Verification of Performance Specifications (PDF)
- Calibration and Calibration Verification (PDF)
- Laboratory Director Responsibilities (PDF)
- What Do I Need to Do to Assess Personnel Competency? (PDF)
- CLIA Individualized Quality Control Plan Introduction (PDF)
- CLIA IQCP, Considerations When Deciding to Develop an IQCP (PDF)
- CLIA Brochure - CLIA IQCP, What is an IQCP? (PDF)

Laboratory Quick Start Guide To CMS CLIA Certification

Clinical Laboratory Improvement Amendments (CLIA) Application For Certification (Form CMS-116)

Clinical Laboratory Improvement Amendments (CLIA) State Survey Agency Contacts

Resource

CLIA: helpful resource

Code of Federal Regulation

↗ Title 42 → Chapter IV → Subchapter G → Part 493

Note: All links were active as of August 8, 2023

References

1. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/results.cfm Accessed 8-8-23.
2. Gami U. Emerging technologies for point-of-care (POCT) testing: a future outlook for scientists and engineers. 2018 Jan 5.
3. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493 Accessed 8-8-23.
4. https://www.cdc.gov/clia/about.html
5. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf
6. https://www.cdc.gov/mmwr/preview/mmwrhtml/00016177.htm
7. https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf

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POINT OF CARE TESTING UNIVERSITY

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