Clinical Laboratory Improvement Amendments (CLIA)

LABORATORY DIRECTOR RESPONSIBILITIES

This brochure focuses on laboratory director roles & responsibilities for moderate and high complexity laboratories.

If you're interested in becoming a laboratory director, you'll need certain qualifications that are dependent on test complexity. Learn more about the qualifications you need to become a laboratory director in the CLIA regulations and interpretive guidelines, specifically 42 CFR 493.1443 for high complexity testing and 42 CFR 493.1405 for moderate complexity testing.

For Provider Performed Microscopy (PPM) Procedures: *Review CLIA regulations and interpretive guidelines, specifically 42 CFR 493.1357 and 42 CFR 493.1359 for information about updated requirements for laboratory director qualifications and responsibilities to perform PPM testing.*

LABORATORY DIRECTOR RESPONSIBILITIES

What are my overall responsibilities?

A laboratory director is responsible for the overall operation and administration of the entire laboratory, which includes employing qualified personnel who are competent to perform their duties. While you have the option to delegate some of your responsibilities, you're ultimately responsible for the laboratory and must ensure it meets all applicable CLIA regulations. Additionally, you're responsible for developing and applying a quality system approach to laboratory testing that provides accurate and reliable patient test results.

What is a quality system approach?

Under this approach, the laboratory applies comprehensive and coordinated efforts to achieve high-quality, consistent, accurate, reliable, and timely testing services in all your laboratory's policies, processes, procedures, and resources. More specifically, for each test system, proficiency testing (PT), training, and competency assessments, your laboratory must apply an effective quality system approach to its quality assessment (QA) plan and documentation, which includes:

- Policies and procedures to monitor, assess, and correct identified problems, and
- Documenting ongoing assessment activities, such as:
    - Reviewing the effectiveness of corrective actions taken
    - Revising policies and procedures to prevent recurring problems
    - Addressing complaints
    - Assessing staff and providing competency assessment reviews

What are my specific duties?

A laboratory director must personally oversee and ensure that:

- Testing systems in your laboratory are appropriate for your patient population and provide quality laboratory services for all aspects of test performance, i.e., preanalytic, analytic, and postanalytic phases of testing.
- Physical and environmental laboratory conditions are appropriate for the testing your laboratory performs.
- The laboratory environment is safe from physical, chemical, and biological hazards, and your laboratory meets safety and biohazard requirements.
- Your laboratory employs a sufficient number of educated, experienced, trained, and competent personnel.
- Ensure policies and procedures are reviewed, signed, dated, and approved.
- All employee responsibilities and duties are specified in writing.
- You're onsite at least once every 6 months, with at least 4 months between the minimum 2 onsite visits. Laboratory directors:
    - May choose to be onsite more frequently.
    - Must be accessible for consultation, either by telephone or electronically, as needed.
    - Must document their visits and include evidence that they performed activities that fall under their laboratory director responsibilities.

Notes:
The onsite requirement is a new requirement under laboratory director responsibilities.

Laboratory directors cannot delegate any of these duties to other laboratory staff or personnel.

What are the required positions in laboratories that perform nonwaived testing?

In addition to the laboratory director, CLIA requires specific laboratory positions depending on the testing type and complexity. PPM, high, and moderate complexity testing laboratories each require personnel in the following positions:

Position	High Complexity	Moderate Complexity	PPM
Clinical consultant	✓	✓	
Technical supervisor	✓		
General supervisor	✓		
Technical consultant		✓	
Testing personnel	✓	✓	✓

Note: *Personnel **qualifications** for these positions may **differ** in PPM and high complexity testing laboratories because they need staff with specialized education, training and/or experience. As the laboratory director, you may assume the responsibilities for any, or all, of these positions, if you're qualified and meet all educational, training, and experience requirements.*

Do I need to designate different individuals for each laboratory position?

No. You can either:

1. Fill each position with different individuals, or
2. Have the same individual serve in multiple positions, as long as they can fulfill position responsibilities and meet personnel qualifications for that position.

Which responsibilities may I delegate and to whom?

As laboratory director, you may share dual responsibilities with personnel in certain positions (Clinical Consultant, Technical Consultant, Technical Supervisor, and General Supervisor). You must indicate, in writing, which responsibilities you will delegate to personnel in these positions. The table below highlights the responsibilities you may delegate by position title.

Position	Responsibilities that the laboratory director may delegate
Clinical Consultant	• Ensuring test result reports include pertinent information to support interpretation. • Being available to consult on test results and interpreting those results as they relate to specific patient conditions.
Technical Consultant (moderate complexity) or Technical Supervisor (high complexity)	General laboratory testing responsibilities: • Selecting the appropriate test method • Verifying the adequate test method to determine test accuracy and precision • Establishing and maintaining QA and quality control (QC) programs • Establishing and maintaining acceptable analytical test performance for each test system. • Taking remedial action and documenting actions when there are significant deviations from the laboratory's established performance characteristics. Reporting patient test results only when the test system properly functions. PT-specific responsibilities: • Enrolling the laboratory in a CMS-approved PT program for the appropriate tests your laboratory performs. • Testing PT samples following CLIA requirements • Returning PT results within the time frames set by the PT program • Ensuring the appropriate staff reviews PT result reports • Following corrective action plans when PT results are unacceptable or unsatisfactory

	Personnel-focused responsibilities: • Ensuring personnel are appropriately trained and demonstrate competency before they test patient specimens • Assuring ongoing competency for all individuals who perform testing • Establishing policies and procedures for monitoring personnel competency in all test phases (preanalytic, analytic, and postanalytic) • Identifying remedial training or continuing education needs and providing training • Providing an approved procedure manual to all personnel
General Supervisor (high complexity) ***Note:*** *For high complexity testing, the laboratory director or technical supervisor may delegate, in writing, these responsibilities to a* ***general supervisor****.*	• Ensuring the laboratory takes remedial action when test systems deviate from the laboratory's established performance specifications • Assuring patient test results aren't reported until all corrective actions have been taken and the test system functions properly • Making sure that all testing personnel receive orientation and training. • Evaluating and documenting the competency of all testing personnel

How can I be sure that personnel appropriately perform the responsibilities I delegate?

Remaining actively involved in laboratory operations is the best way to ensure that personnel appropriately perform the duties you delegate to them. Here are some actions you can take to ensure personnel are meeting position expectations:

General actions:

- Routinely review QC and QA activities to ensure you identify and correct problems that occur in the laboratory. Additionally, corrections should be monitored to ensure future effectiveness.
- If your laboratory hasn't identified problems through its routine QA or QC assessments, you should investigate whether you need a more stringent QA plan. For example, your laboratory's current QA plan may not be identifying errors, and it may be necessary to make changes to what you monitor.
- Make certain your laboratory's QA activities include a way to:
    - Resolve and document any complaints your laboratory receives.
    - Address any breakdown in communication within all laboratory activities.
    - Review a sampling of test systems' analytical performance to assess whether they meet your laboratory's acceptance criteria.

PT-specific actions:

- Review PT results to ensure that PT samples are tested in the same manner as patient specimens. As necessary, identify, correct, and document the cause of PT failures.
- Ensure laboratory staff and management are aware of CLIA requirements related to PT referral. More specifically, the requirements that prohibit them from sending PT samples to another laboratory or discussing the results with other laboratories.
- Review a sampling of procedure results and their outcomes to verify test accuracy when PT isn't required.

Personnel-specific actions:

- Establish documentation to enable effective communication among management and laboratory personnel.
- Review policies and procedures for assessing personnel training and competency.
- Review personnel qualifications and competency assessments.

How many laboratories can a laboratory director be in charge of?

A laboratory director may serve as a director of 5 nonwaived CLIA-certified laboratories. However, a laboratory director may serve as clinical consultant, technical supervisor, or technical consultant for any number of laboratories. The maximum limit only applies to laboratories that perform nonwaived tests. If your laboratories only perform waived tests, there is no limit to how many laboratories you can direct (or the number of certificates you can have).

What are the top ten tips I should consider as a laboratory director?

Refer to these tips to help you become a successful laboratory director:

1. Refer to CLIA regulations and interpretive guidelines to understand your responsibilities.
2. Review, evaluate, and acknowledge the laboratory policies, procedures, and processes.
3. Review the documentation in all logs and corresponding corrective actions.
4. Review the laboratory's critical values and determine if they're appropriate for its patient population.
5. Notify your State Agency or Accreditation Organization within 30 days when there's a change in the laboratory director.
6. Review, evaluate, and document the laboratory's QA plan.
7. Review the laboratory's PT, including enrollment, performance evaluation, corrective actions (as necessary), and PT referral.
8. Review and approve the QC and validation protocols for equipment, instruments, and test systems used in the laboratory.
9. Confirm qualifications, training, and competency records for all personnel and ensure the laboratory has an adequate number of personnel.
10. Ensure that the laboratory provides quality, accurate, and reliable test results for its patients.

Note: *The CLIA regulations don't specify the frequency of reviews by the laboratory director. Reviews should be performed at the frequency established by the laboratory's SOP.*

WHERE CAN I FIND MORE INFORMATION?

For more information and resources about the CLIA program and Laboratory Director Responsibilities, visit:

Resource	Website
CMS CLIA Website	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
CDC CLIA Website	https://www.cdc.gov/clia/php/about/index.html
FDA CLIA Website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CLIA State Agency Contacts	https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf
PPM Laboratory Director Qualifications and Responsibilities Sections 493.1357 and 493.1359	https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR9fd4b51b2991285/section-493.1357 https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M/subject-group-ECFR9fd4b51b2991285/section-493.1359
Laboratory Director Qualifications & Responsibilities	https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493#subpart-M

You can also email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

Note: *This brochure presents information about laboratory director requirements and responsibilities. It's not intended to replace or substitute CLIA regulatory requirements. Note that state, local, and accreditation requirements may be more stringent.*

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Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. The information provided in this brochure is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This brochure summarizes current policy and operations as of the date it was published. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.