

17-Personnel requirements and Job Description

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ANNUAL REVIEW:

REVIEWED <u>Sanford N. Bailey, M.D</u>	<u>July-16-2025</u>
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SUPERSEDES: Procedure titled _____**Policy:**

CLIA has specific requirements for personnel, depending on the complexity of testing performed. Laboratory testing is classified in three different categories: waived, moderate, and high.

1. Laboratories performing only waived testing have no personnel requirements, according to CLIA.
2. Laboratories performing Moderate complexity testing requires the laboratory to have

Laboratory Director: The Laboratory Director (and there may only be one) is responsible for all the operations of the laboratory and must have at least a Bachelor Degree in Medical Technology, or a chemical, physical, or biological science, must have at least two years laboratory experience, and must have at least two years supervisory experience in a laboratory setting. The laboratory director may be a licensed physician, however not all licensed physicians qualify to be a laboratory director. In order for a physician to qualify as a laboratory director for a moderately complex lab, the physician must either be a pathologist, or must have 20 continuing medical education (CME) credit hours in laboratory practice prior to performing duties as a laboratory director.

Clinical Consultant: may perform certain duties, as delegated by the laboratory director in a job description. In order to qualify as a Clinical Consultant, an individual must either be a licensed physician or must have a PhD in laboratory science, or another chemical, physical, biological science and must be certified by ABMM, ABCC, ABB, or ABMLI.

Technical Consultant: may also perform certain duties which are delegated by the laboratory director through a job description. To qualify as a Technical Consultant, an individual must have a minimum of a Bachelor Degree in a chemical, physical, or biological science and must have at least two years laboratory experience in the specialty or subspecialty for which they are responsible.

Testing Personnel: Must have an academic high school diploma, or equivalent. CLIA requires demonstration of all qualifications in a moderately complex lab through a copy of a diploma or transcript. It is important to note that laboratories holding a CLIA Certificate of Provider Performed Microscopy Procedures (PPMP) must comply with the personnel requirements of a moderately complex laboratory.

3. Laboratories performing Highly complexity testing requires the laboratory to have:

Laboratory Director: The Laboratory Director in a highly complex laboratory is responsible for the overall operations of the laboratory and must have a minimum of a PhD in laboratory science or another chemical, physical, or biochemical science and be certified by ABMM, ABCC, ABB, or ABMLI. A physician who is the laboratory director of a highly complex lab must either be a pathologist, or must have experience or training in directing highly complex laboratories.

Clinical Consultant: may perform certain duties delegated by the laboratory director through a job description and must be either a licensed physician, or must have a PhD in

laboratory science or a chemical, physical, or biological science and certification by ABMM, ABCC, ABB, or ABMLI.

Technical Supervisors: may also perform certain delegated duties and must be either a pathologist or must have a minimum of a Bachelor degree in medical technology or a chemical, physical, or biological science and have at least four years' experience in the specialty or subspecialty for which they are responsible.

General Supervisor: may perform certain duties, as delegated, and must have at least an Associate Degree in medical laboratory technology or a laboratory science and have a minimum of two years laboratory experience.

Testing Personnel: in a highly complex laboratory must have a minimum of an Associate Degree in medical laboratory technology or a laboratory science. However, personnel who were performing laboratory testing prior to February 28, 1992 may fall under CLIA's "grandfather clause" if they have been performing high complexity testing continuously since then. Once an individual who was "grandfathered" breaks employment (i.e. leaves the laboratory for two years to care for a family member), then they must meet the regular CLIA requirements to return to the clinical laboratory (i.e. a minimum of an Associate degree).

Job Description:

Laboratory director:

Verify that all of the following responsibilities are properly performed even if delegated.

- Must be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide a safe environment from physical, chemical, and biological hazards.
- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing.
- Ensure test methods selected have the capability of providing quality results.
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- Ensure that reports of test results include pertinent information required for interpretation.
- Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.
- Ensure that an approved procedure manual is available to all personnel.
- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.
- Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency to:
 - Process specimens
 - Perform test procedures
- Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills
- Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting; and whether consultant or director review is required prior to reporting patient test results.
- Ensure that a general supervisor provides on-site supervision of high complexity test performance by certain testing personnel
- Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program
- Ensure that PT samples are tested in the same manner as patient samples
- Ensure that PT results are returned on time to the PT program
- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory
- Ensure that PT samples are performed according to COLA and CLIA regulations prohibiting referral of specimens and communication of results.
- Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Patient test results are reported only when the system is functioning properly.

Clinical Consultant (Test Complexity: Moderate and High)

The Clinical Consultant renders opinions concerning the diagnosis, treatment, and management of patient care, and:

- Is available to provide consultation to the laboratory's clients
- Is available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations
- Is available for consultation and communication with the laboratory's clients on matters related to the quality of test results reported and their interpretation concerning specific patient conditions
- Ensures that reports of test results include pertinent information required for specific patient interpretation
- Fulfills certain responsibilities if delegated by the lab director as per guidelines and regulations

Position: Technical Supervisor (Test Complexity: High)

The Technical Consultant or Technical Supervisor is responsible for technical and scientific oversight of the laboratory. This person is not required to be on-site at all times, but must be available to provide consultation either on-site, by telephone, or electronically. In addition, the technical consultant/supervisor:

- Selects test methodologies appropriate for the clinical use of the test menu
- Verifies test procedures performed and establishes the laboratory's performance criteria, including accuracy and precision of each test and test system
- Enrolls the laboratory in an approved PT program commensurate with services offered
- Establishes a quality control program appropriate for the testing performed
- Establishes the acceptable levels of analytic performance, and ensures these levels are maintained throughout the testing process
- Resolves technical problems and ensures remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
- Ensures patient test results are not reported until all corrective action has been taken and the test system is functioning properly
- Identifies training needs and ensures testing personnel receive regular in-service training
- Evaluates the competency of all testing personnel on an ongoing basis
- Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be re-evaluated for the new test methodology or instrumentation.
- Fulfills certain responsibilities if delegated by the lab following guidelines and regulations

Position: General Supervisor (Test Complexity: High)

- Is accessible to testing personnel at all times testing is performed to provide on-site, telephone, or electronic support
- Provides day-to-day supervision of personnel performing high complexity testing
- Must be on-site to provide direct supervision when high complexity testing is performed by certain individuals
- Monitors test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained
- Fulfills certain responsibilities if delegated by the lab director or technical supervisor, such as:
 - Resolving technical problems and ensuring remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
 - Ensuring patient test results are not reported until all corrective action has been taken and the test system is functioning properly
 - Providing orientation to all testing personnel

- Annually evaluating and documenting the performance/competency of all testing personnel

Position: Testing Personnel (Test Complexity: Moderate and High)

Testing personnel are responsible for specimen processing, test performance, and for reporting test results, and should only perform those tests that are authorized by the laboratory director and that are within the individual's skill level as determined by education, training or experience, and technical abilities. Testing personnel must:

- Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient results, manually/electronically.
- Maintain records which demonstrate that proficiency testing samples are tested in the same manner as patient specimens
- Adhere to the laboratory's quality control policies and documenting all QC activities, instrument and procedural calibrations, and instrument maintenance
- Follow the laboratory's policies whenever test systems are not within the laboratory's established acceptable levels of performance
- Be able to identify problems that may adversely affect test performance or reporting of test results and either correct the problem or notify the appropriate supervisor
- Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications
- Only perform high complexity testing under the on-site direct supervision of a general supervisor, if required by personnel qualification requirements
- Follow and adhere to laboratory policy of safety and patient confidentiality

Reference:

COLA laboratory accreditation manual-2020