COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 4

Personnel Requirements in a Non-Waived Laboratory

● Introduction ●

A clinical laboratory must employ sufficient personnel with adequate education and experience to accurately perform laboratory testing, to supervise and oversee laboratory operations, and to consult on both technical and clinical matters. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) require that certain laboratory personnel positions be filled in a non-waived laboratory, and they also define the specific minimum qualifications required to hold each position. These personnel requirements vary depending on the complexity of testing performed in the laboratory. Remember that if even one test performed in your laboratory is designated High Complexity by the FDA[1], your laboratory will be required to meet high complexity personnel requirements.

Moderate Complexity Laboratory	High Complexity Laboratory
Laboratory Director	Laboratory Director
Clinical Consultant	Clinical Consultant
Technical Consultant	Technical Supervisor
Testing Personnel	General Supervisor
	Testing Personnel

A person who fills any of the roles in the table above will have specific laboratory-related responsibilities, as defined by the CLIA regulations. A person may hold more than one position in this list if they meet all of the educational and experience requirements for each position and are able to fulfill all of the responsibilities involved for each position. In a larger laboratory, it is also possible to have more than one person in each of the roles; for example, a laboratory may have different Technical Consultants to oversee different testing specialties. The exception to this is the Laboratory Director: only one person may be designated as a laboratory's Director, even if some of their responsibilities are delegated to others.

● Laboratory Director Responsibilities ●

The Laboratory Director holds responsibility for the operation and administration of the laboratory, which includes several areas of oversight. The following is an overview of these responsibilities; they are described in more detail in COLA's Accreditation Manual under the "LDR" criteria in the Laboratory Director Responsibilities section. Please note that while some responsibilities may be delegated to other qualified personnel, the Laboratory Director is still ultimately responsible for the laboratory's compliance and so must verify that all delegated duties are being properly performed.

[1] Test complexity information can be obtained from the manufacturer or can be looked up in the FDA's searchable database.

Laboratory Director General Responsibilities

- Remain accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed.
- Conduct onsite visits at least twice per year, spaced a minimum of four months apart, with documented evidence of tasks related to Laboratory Director responsibilities completed during the visits.
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed and provide a safe environment, free of physical, chemical, and biological hazards.
- Ensure that the laboratory remains compliant with all applicable federal, state, and local regulations.

Laboratory Director Procedural Responsibilities

- Ensure that testing systems provide quality laboratory services across the path of workflow (for all phases of testing: pre-analytic, analytic, and post-analytic phases).
- Ensure that the test methods selected have the capability of providing quality results, and that test result reports include pertinent information required for interpretation.
- Ensure that verification procedures are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method.
- 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, and that laboratory personnel are performing the test methods as required to obtain accurate and reliable results.

Laboratory Director Personnel Management Responsibilities

- Employ sufficient laboratory personnel with appropriate education, experience and/or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.
- Ensure that all personnel have the appropriate education and experience prior to testing patient specimens, receive 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 verifying ongoing competency in all staff who conduct pre-analytical, analytical, and post-analytical phases of testing.
- 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.
- In a high complexity laboratory, ensure that a general supervisor provides on-site supervision of certain testing personnel who perform high complexity testing.

Proficiency Testing Responsibilities

- Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program, and that PT results are returned by the submission deadline.
- Ensure that the laboratory's PT policies and procedures state that samples are to be tested in the same manner as patient samples and prohibit referral of specimens and sharing of or communication about results.
- Ensure that PT results are reviewed by the appropriate staff, and corrective action is documented when PT results are found to be unsatisfactory.

Quality Control & Quality Assessment Responsibilities

- 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 corrective actions are taken and documented, whenever significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly.

● Clinical Consultant Responsibilities ●

The clinical consultant renders opinions concerning the diagnosis, treatment, and management of patient care and:

- Is available to assist the laboratory's clients in ensuring that the ordered tests are appropriate to meet the clinical expectations.
- Is available for consultation and communication with the laboratory's clients on matters related to the quality of reported test results and their interpretation concerning specific patient conditions.
- Ensures that reports of test results include pertinent information required for specific patient interpretation.

● Technical Consultant / Technical Supervisor Responsibilities●

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 and 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.
- Evaluates the competency of all testing personnel on an ongoing basis, and identifies training needs and ensures testing personnel receive regular in-service training.
- 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 reevaluated for the new test methodology or instrumentation.

● General Supervisor Responsibilities ●

The general supervisor in a high complexity laboratory must be accessible to testing personnel at all times testing is performed to provide on-site, telephone, or electronic support, and provides day-to-day supervision of personnel performing high complexity testing. They must also:

- Provide direct on-site supervision when high complexity testing is performed by certain individuals.
- Monitor test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.
- With delegation from the Technical Supervisor, evaluate the competency of high and moderate complexity testing personnel.

● Testing Personnel Responsibilities ●

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.
- 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.

● Personnel Qualifications ●

All personnel employed in a non-waived laboratory must be qualified for the roles that they hold. This can include documentation of education, documentation of previous laboratory experience, and, in some cases, documentation of relevant licensure or certification by a state or national professional body.

For documentation of an individual's education, diplomas or transcripts are required, and they must clearly show a **graduation date** and the individual's **field of study**. Examples include a high school diploma, an Associate's degree, a Bachelor's degree, or higher. A completion certificate for a training program in an allied health field is not generally sufficient for documentation of an individual's education. Any individuals educated outside of the United States **must** have degrees and transcripts evaluated by a reputable credential evaluation organization; a translation is not sufficient to show that the degree is equivalent to one earned in the United States.

Résumés or CVs alone are not sufficient for documenting experience. Additional documentation is required to substantiate the experience, including applicable responsibilities and the complexity of testing performed and/or supervised. Examples of additional documentation from a current or previous employer might include:

- Letters of attestation on letterhead with a detailed job description and responsibilities
- Competency assessments
- Comprehensive list of job responsibilities signed by the employer

Experience either directing, supervising, performing, or having received training to perform non-waived patient testing must have occurred in a laboratory with a valid CLIA certificate.

When used to describe the experience for a CLIA-defined position in the laboratory, the resume must include a high level of detail regarding the type and complexity of testing that was performed and/or supervised. It must also include details about specific job duties for which the individual was responsible, and in the case of supervisory work must include higher-level duties such as training of new personnel, evaluation of new test systems, and the review of quality control or quality assurance data.

Any required licenses or board certifications must be current and specific to the state in which the laboratory is located, if applicable.

The tables on the following pages can be used as a quick reference for the various pathways by which an individual can qualify for the different positions in a non-waived clinical laboratory.

Note: An individual who was qualified and serving in a CLIA position as of Dec 27, 2024, remains qualified in that position on/after Dec 28, 2024, as long as they continuously serve in that position in a CLIA laboratory, with no more than a six month break in service.

MODERATE COMPLEXITY PERSONNEL REQUIREMENTS

***NOTE**: When required, state licenses for all positions pertain to the state where the laboratory is located*

LABORATORY DIRECTOR

Refer to CLIA Regulation § 493.1405 for complete details

1. Licensed MD/DO/DPM, **AND** certified in anatomic or clinical pathology

   OR laboratory training or experience consisting of 1 year directing or supervising non-waived tests

   OR have earned at least 20 CE credit hours in laboratory practice addressing director responsibilities
2. Doctoral degree in a laboratory science* **AND** currently certified by an HHS-approved board**

   AND have 1 year experience directing or supervising non-waived testing
3. Master's degree in a laboratory science* **AND** 1 year non-waived laboratory training or experience **AND** 1 year of experience supervising non-waived testing.
4. Bachelor's degree in a laboratory science* **AND** 2 years of non-waived laboratory training or experience **AND** 2 years experience supervising non-waived testing.

TECHNICAL CONSULTANT

Refer to CLIA Regulation § 493.1411 for complete details

1. Licensed MD/DO/DPM **AND** certified in anatomic or clinical pathology

   OR 1 year hands-on laboratory training or experience in non-waived specialty/subspecialty of service
2. Doctoral or Master's degree in a laboratory science* **AND** 1 year of training or experience in the non-waived specialty/subspecialty of service
3. Bachelor's degree in a laboratory science* **AND** 2 years laboratory training or experience in the non-waived specialty/subspecialty of service
4. Associate's degree in medical technology, medical laboratory science or clinical laboratory science **AND h**ave at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service
5. **For Blood Gases, if not qualified under subsections 1, 2, or 3 above:**

   Bachelor's degree in respiratory therapy or cardiovascular technology **AND** have at least 2 years of laboratory training or experience, or both, in blood gas analysis

CLINICAL CONSULTANT

Refer to CLIA Regulation § 493.1417 for complete details

1. Licensed MD/DO/DPM
2. Doctoral degree in a laboratory science* **AND** meets the qualification requirements for Laboratory Director

TESTING PERSONNEL

Refer to CLIA Regulation § 493.1423 for complete details

1. Licensed MD/DO
2. Doctoral, Master's, Bachelor's, or Associate's degree in a laboratory science*
3. Doctoral, Master's, Bachelor's, or Associate's degree in nursing
4. High School graduate or equivalent **AND** documentation of training at the present facility for testing performed
5. **For Blood Gases, if not qualified above:**

   a. Bachelor's degree in respiratory therapy or cardiovascular technology **AND** have at least 1 year of laboratory training or experience in blood gas analysis
   b. Associate's degree related to pulmonary function **AND** have at least 2 years of laboratory training or experience in blood gas analysis

* Acceptable degrees are biological, chemical or laboratory science degrees. In some cases, COLA may request transcripts to evaluate the curriculum. For degrees other than biology, chemistry or laboratory science, specific semester hours of applicable coursework or an approved thesis or research project related to laboratory science is required.
**See Certification Boards for Laboratory Directors of High Complexity Testing | CMS for a list of HHS-approved boards.

HIGH COMPLEXITY PERSONNEL REQUIREMENTS

***NOTE**: When required, state licenses for all positions pertain to the state where the laboratory is located*

LABORATORY DIRECTOR

Refer to CLIA Regulation § 493.1443 for complete details

1. Licensed MD/DO/DPM **AND** certified in anatomic or clinical pathology

   OR 2 years experience directing or supervising high complexity testing

2. Doctoral degree in a laboratory science* **AND** currently certified by an HHS-approved board**

   AND have at least 2 years of laboratory training or experience, or both **AND** 2 years of laboratory experience directing or supervising high complexity testing

CLINICAL CONSULTANT

Refer to CLIA Regulation § 493.1445 for complete details

1. Licensed MD/DO/DPM

2. Doctoral degree in a laboratory science* **AND** meets the qualification requirements for Laboratory Director

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GENERAL SUPERVISOR

Refer to CLIA Regulation § 493.1461 for complete details

1. Qualified Laboratory Director or Technical Supervisor of high complexity testing

2. Licensed MD/DO/DPM, or have a Doctoral, Master's, or Bachelor's degree in a laboratory science* **AND** 1 year laboratory training or experience in high complexity testing

3. Qualified as Testing Personnel for high complexity testing **AND** at least 2 years laboratory training or experience in high complexity testing

For Blood Gases, if not qualified above:

1. Bachelor's degree in respiratory therapy, or cardiovascular technology **AND** 1 year training or experience in blood gas analysis

2. Associate's degree related to pulmonary function **AND** 2 years training or experience in blood gas analysis

TESTING PERSONNEL

Refer to CLIA Regulation § 493.1489 for complete details

1. Licensed MD/DO/DPM

2. Doctoral, Master's, Bachelor's or Associate's degree in a laboratory science*

3. Have education or experience equivalent to an Associate's degree **AND** graduated from a clinical laboratory training program

   OR have 3 months experience in each specialty of high complexity testing performed

For Blood Gases, if not qualified above:

1. Bachelor's or Associate's degree in respiratory therapy, pulmonary function, or cardiovascular technology

TECHNICAL SUPERVISOR

Refer to CLIA Regulation § 493.1449 for complete details

Specific qualifications are required for each specialty or subspecialty.

For Microbiology subspecialties:

1. Licensed MD/DO/DPM **AND** certified in clinical pathology

   OR 1 year laboratory training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service

2. Doctoral degree in a laboratory science***AND** 1 year laboratory training or experience in the high complexity microbiology with a minimum of 6 months in subspecialty of service

3. Master's degree in a laboratory science***AND** 2 years laboratory training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service

4. Bachelor's degree in a laboratory science***AND** 4 years laboratory training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service

For Immunohematology, Immunology, Chemistry, Hematology:

1. Licensed MD/DO/DPM **AND** certified in clinical pathology

   OR 1 year laboratory training or experience in the high complexity testing specialties performed

2. Doctoral degree in a laboratory science***AND** 1 year laboratory training or experience in the high complexity testing specialties performed

3. Master's degree in a laboratory science***AND** 2 years laboratory training or experience in the high complexity testing specialties performed

4. Bachelor's degree in a laboratory science***AND** 4 years laboratory training or experience in the high complexity testing specialties performed

*Acceptable degrees are biological, chemical or laboratory science degrees. In some cases, COLA may request transcripts to evaluate the curriculum. For degrees other than biology, chemistry or laboratory science, specific semester hours of applicable coursework or an approved thesis or research project related to laboratory science is required.

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