COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 3

Laboratory Director Responsibilities

●Choose a Qualified Laboratory Director●

Ensure the laboratory obtains the services of a laboratory director that has the qualifications to hold the position. With minimal exception, the laboratory responsibilities will remain the same with any type of laboratory.

The requirements for choosing a qualified laboratory director are based on the complexity of the test and not the type of laboratory where the testing is performed. The following are laboratory complexity types to consider when choosing a qualified laboratory director.

- **Waived**
- **Non-Waived**
  - **Moderate Complexity**
  - **(PPM) Provider Performed Microscopy**
  - **High Complexity**
    - **Modified FDA-Approved**
    - **(LDT) Laboratory Developed Tests**

● General Responsibilities ●

- **Overall operation and administration of the laboratory and assurance of compliance with all applicable regulations.**
- **If qualified, the laboratory director may perform the duties of the technical consultant/supervisor, clinical consultant, general supervisor, and testing personnel.**
  - **May delegate some responsibilities to personnel meeting the qualifications; however, he or she remains responsible for ensuring all duties are properly performed. This delegation of authority must be in writing.**
- **Must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.**
- **Each individual may direct no more than five non-waived laboratories.**
- ***Be aware that some states have more stringent requirements for the number of laboratories that a Laboratory Director may direct.* The physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.**
- **Effective December 28, 2024, Laboratory Directors laboratories must visit (on-site) each non-waived laboratory they direct a *minimum* of twice annually, at intervals of no less than four months. The on-site visits must be documented in detail to include evidence of tasks performed that are related to laboratory director responsibilities.**

Procedural Responsibilities

- Testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the pre-analytic, analytic, and post-analytic phases of testing.
- Test methodologies selected have the capability of providing the quality of results required for patient care.
- Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.
- Policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.
- An approved procedure manual is available to all personnel responsible for any aspect of the testing process.
- Specify, in writing, the responsibilities and duties of all personnel engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether technical supervisor/consultant or laboratory director review is required prior to reporting patient test results.
- Specify, in writing, the responsibilities and duties of the laboratory director, clinical consultant, technical supervisor/consultant, and general supervisor.
- All new laboratory directors sign each and every policy and procedure within thirty days.
  - May not be delegated
- All new policies and procedures are signed by the laboratory director prior to go live date.
  - May not be delegated
- All changes to a policy or procedure must be signed by the laboratory director prior to go live date.
  - May not be delegated
- Policy and procedures are signed every two years.
  - May be delegated to qualified designee in writing
  - May sign a cover page if desired

• Personnel Management Responsibilities •

- Employ personnel who are competent to perform test procedures record and report test results promptly, accurately, and proficiently.
- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, accurately perform tests, and report test results.
- Ensure prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Current and appropriate license are required for some states.
- Laboratory personnel are performing the test methods as required for accurate and reliable results.
- Ensure a general supervisor provides on-site supervision of high complexity test performance by minimally qualified testing personnel.
- Ensure the clinical consultant has reviewed that all reports of tests results include pertinent information required for interpretation.
- Ensure the clinical consultant is available for consultation to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

• Proficiency Testing Responsibilities•

- The laboratory is enrolled in an HHS (U.S. Department of Health and Human Services) approved proficiency testing program for all testing performed.
- When PT is not available, and for non-regulated analytes not enrolled in PT, establish an alternate quality evaluation program, such as split specimen testing, and establish acceptability criteria.
- The laboratory has a policy stating that proficiency testing is performed in compliance with regulations prohibiting the referral of specimens and communication or sharing of results before the cutoff date. All proficiency testing is rotated among testing personnel.
- All personnel who participate in a proficiency testing event sign the attestation, along with the laboratory director or qualified designee.
- All personnel who participate in a proficiency testing event sign the graded results, along with the laboratory director or qualified designee.
- The laboratory director or qualified designee review, sign, and date the graded proficiency testing results within thirty days.
- Corrective action is documented for any graded proficiency testing results that score less than 100% and personnel is educated if warranted.

- Self-grading is documented for any artificial proficiency testing scores.
- All directions from COLA's Regulatory Team are followed, including but not limited to, cease testing.
- All proficiency testing records, to include but not limited to, test records, instrument tapes, logs, attestations, and corrective action are retained by the laboratory for two years (three years for California laboratories, and 10 years for transfusion related PT records).

● Quality Control and Quality Assessment Responsibilities ●

- The quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.
- All necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and patient test results are reported only when the system is functioning properly.

● Tips for Laboratory Directors ●

- It is important to remember that the laboratory director is ultimately responsible for all aspects of the laboratory. This includes any testing performed out of the laboratory but under the laboratory CLIA ID.
- If the laboratory director is not on-site every day, it is highly recommended that he or she visit the lab at least monthly. Effective December 28, 2024, laboratory directors must visit the laboratory a minimum of twice annually, at intervals of no less than four months.
- All quality control is to be signed and dated monthly by the laboratory director.
  - May be delegated to a qualified designee in writing
  - Remember to review all waived quality control data
- All quantitative quality control is to be reviewed weekly or every five to seven data points.
  - May be delegated to a qualified designee in writing
- If a laboratory director performs any testing, to include waived testing, he or she must have the same competency assessment performed as testing personnel.
- It is not required, but it is recommended that the laboratory director attend the survey, or minimally the summation portion of the survey. Attendance at the summation allows the laboratory director to interact with the surveyor and often can reduce any confusion that may arise when the survey report is received.