



RESPONSIBILITIES OF THE LABORATORY DIRECTOR



The laboratory director is responsible for the overall operation and administration of the laboratory. Perhaps most importantly, the director must select and employ laboratory personnel competent to perform

testing, and accurately and proficiently record and report test results.

Simply appointing yourself as the director of the laboratory because you have the necessary education and/or training is not sufficient. The Centers for Medicare and Medicaid Services (CMS) has asked local health departments to make certain the laboratory director is providing effective direction of the laboratory.

This is accomplished by evaluating the director's role in every aspect of the laboratory's day-to-day operation. CLIA requires the laboratory director to:

1. Ensure test systems provide quality services.
2. Ensure the physical laboratory is safe for personnel and they are protected from physical, chemical, or biological hazards.
3. Ensure test methods used in the laboratory provide appropriate results required for patient care; that these test procedures are regularly checked for accuracy, precision, and other pertinent performance characteristics; and that lab personnel are performing the tests as required.
4. Ensure the laboratory is enrolled in a CMS approved proficiency testing program.
5. Ensure proficiency testing samples are tested and reported as required by CLIA.
6. Review and evaluate proficiency testing (PT) results and check with staff on any corrective actions which may be needed if PT results are unsatisfactory.
7. Ensure quality control (QC) and quality assessment (QA) programs are established and maintained to ensure quality of laboratory services and to identify failures in quality as they occur.
8. Establish and maintain acceptable levels of performance for each test system.
9. Ensure all necessary remedial actions are taken and documented whenever problems are identified, and patient results are reported only when the system is functioning properly.
10. Ensure test reports include information required for interpretation.
11. Ensure consultation is available to patients on matters relating to the quality of test results reported and their interpretation.
12. Employ a sufficient number of laboratory personnel and, prior to testing, ensure employees have the appropriate education, experience, or training to provide appropriate consultation and supervision and to accurately perform tests and report results.
13. Ensure policies and procedures are established to monitor personnel performing tests to ensure they are competent to process specimens, perform test procedures, and report test results promptly and proficiently. When necessary, these policies and procedures should identify the need for remedial training or continuing education.

14. Ensure an approved procedure manual is available to all personnel responsible for any aspect of testing.
15. Specify, in writing, the responsibilities and duties of each person engaged in the testing process and identify which examinations and procedures each individual is authorized to perform, whether supervision is required, and whether consultant or director review is required prior to the reporting of test results.

Some of these responsibilities may be delegated to qualified laboratory personnel. For example, responsibilities 3-9 and 13-15 may be delegated to a qualified technical consultant or technical supervisor.

Responsibilities 10-11 may be performed by the qualified clinical consultant if that individual is someone other than the laboratory director. Should the laboratory director delegate these responsibilities, he or she is still ultimately accountable to ensure they are accomplished.

Ways to document attention to these responsibilities include:

- Document the laboratory director's review of QC records on a regular basis, including proficiency testing reports;
- Provide the staff with written instructions for collecting and handling specimens, and proper labeling and tracking of specimens
- Document the laboratory director review of policies and procedures in the procedure manual.