

# CLIA Corner

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- **Laboratory Director Delegation of Responsibilities**

## LABORATORY DIRECTOR - DELEGATION OF RESPONSIBILITIES

Did you know that the laboratory director may delegate some of their responsibilities to qualified personnel? In this issue of the CLIA Corner we will list the specific responsibilities and the personnel to whom these responsibilities may be delegated to. The personnel who may qualify vary depending on the complexity of testing performed by the laboratory. The responsibilities that can be delegated by the laboratory director are located in the Interpretative Guidelines of the CLIA regulations at D6005 §493.1407(c) for moderate complexity testing laboratories and D6082 §493.1407(e) for high complexity testing laboratories. If the laboratory director chooses to delegate any of these responsibilities, the delegation must be done **IN WRITING**.

The CLIA regulations and interpretive guidelines referenced in this article are in Appendix C-Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/App-C\\_Survey-Procedures-IGs-for-Labs-Labs-Svcs-Final.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/App-C_Survey-Procedures-IGs-for-Labs-Labs-Svcs-Final.pdf).

Laboratory director of a **Moderate Complexity** testing laboratory may delegate the following to:

### **Technical Consultant**      [§493.1407(e)(3)-(7) and (11)-(13)]

- (3) (i) Ensure the test methodologies selected have the capability of providing the quality of results required for patient care;
- (ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and
- (iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.
- (4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that --
  - (i) The proficiency testing samples are tested as required under subpart H of the CLIA regulations;
  - (ii) The results are returned with the timeframes established by the proficiency testing program;
  - (iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and
  - (iv) An approved corrective action plan is followed when any proficiency testing results are

- found to be unacceptable or unsatisfactory.
- (5) Ensure that quality control and quality assessment programs are established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur.
  - (6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
  - (7) Ensure that 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 test system is functioning properly.
  - (11) Ensure that 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.
  - (12) Ensure that policies and procedure are established for monitoring individuals who conduct preanalytical, analytical and postanalytical 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.
  - (13) Ensure that an approved procedures manual is available to all personnel responsible for any aspect of the testing process.

**Clinical Consultant [§493.1407(e)(8)-(9)]**

- (8) Ensure that test reports of test results include pertinent information required for interpretation.
- (9) 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.

**Laboratory director of a High Complexity testing laboratory may delegate the following to:**

**Technical Supervisor[§493.1445(e)(3)-(7) and (12)-(14)]**

- (3) (i) Ensure the test methodologies selected have the capability of providing the quality of results required for patient care;  
(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and  
(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.
- (4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that:  
(i) The proficiency testing samples are tested as required under subpart H of the CLIA regulations;  
(ii) The results are returned with the timeframes established by the proficiency testing program;  
(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and  
(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.
- (5) Ensure that quality control and quality assessment programs are established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur.
- (6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
- (7) Ensure that 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 test system is functioning properly.
- (11) Ensure that 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.

- (12) Ensure that policies and procedure are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical 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.
- (13) Ensure that an approved procedures manual is available to all personnel responsible for any aspect of the testing process.

#### **Clinical Consultant [§493.1445(e)(8)-(9)]**

- (8) Ensure that test reports of test results include pertinent information required for interpretation.
- (9) 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.

#### **General Supervisor [§493.1463(b)(1)-(4)]**

The only responsibilities that the laboratory director may delegate to the general supervisor are the ones listed at the CLIA regulations for general supervisor responsibilities:

- (1) Assure that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.
- (2) Ensure that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.
- (3) Provide orientation to all testing personnel.
- (4) Annually evaluate and document the performance of all testing personnel.

#### **Laboratory director responsibilities that can NOT be delegated:**

- All laboratory procedures including manufacturers' operator manuals and package inserts and any changes or modifications to procedures must be approved, signed and dated by the current laboratory director before use.
- Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance.
- Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.
- Provide a safe environment in which employees are protected from physical, chemical and biological hazards.
- 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.
- Specify, in writing, the responsibilities and duties of each consultant, supervisor and testing personnel, identify which examination and procedures each individual is authorized to perform and whether supervision is required and whether supervisory review is required prior to reporting patient test results.

#### **Conclusion**

CLIA does allow the laboratory director to delegate responsibilities as previously outlined. However, it is the laboratory director's responsibility to specify, **in writing**, the delegated responsibilities and duties of each consultant and each supervisor. This will ensure that laboratory personnel understand their specific duties and responsibilities as well as maintain the reporting of accurate and reliable test results.