CLIA Personnel Duties, Responsibilities, and Requirements

Purpose

This document describes the duties, responsibilities, and requirements of laboratory personnel under CLIA.

Scope

This document is intended for all personnel who participate in any phase of the preanalytic, analytic, and post analytic testing process.

Policy

- CLIA requires that laboratory personnel meet defined requirements and fulfill expected duties and responsibilities.
- The following table lists the required laboratory personnel roles for non-waived testing:

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

- When a laboratory performs even one high complexity test, all of the CLIA personnel requirements (qualifications and responsibilities) for high complexity testing must be met.

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Duties and Responsibilities by Role

Laboratory Director is responsible for the overall operation and administration of the lab, and must ensure the competency of all laboratory personnel.	• Verify that all delegated duties are properly performed. Refer to the local policy for delegation of CLIA Director responsibilities. • Must be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed. • May direct no more than five labs. • 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 testing systems provide quality laboratory services across the path of workflow (for all phases of testing: pre-analytic, analytic, and post-analytic phases). • Ensure test methods selected have the capability of providing quality results. • Ensure verification procedures are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method. • Ensure that test result reports 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 to obtain accurate and reliable results. • Employ a sufficient number of laboratory personnel with appropriate education, experience and/or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.

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Duties and Responsibilities by Role, Cont.		• 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 monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency: o To process specimens, o Perform test procedures, o Report test results promptly and proficiently, and o Whenever necessary, identify remedial training and/or continuing education needs to improve skills. • Have a written list of responsibilities of each individual in the laboratory that specifies: o The level of activity each is authorized to perform, o Whether supervision is required for specimen processing, test performance or results reporting, and o Whether consultant or director review is required prior to reporting patient test results. • Ensure that a general supervisor provides on-site supervision of certain testing personnel who perform high complexity testing. • 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 samples are tested in compliance with regulations that prohibit referral of specimens and sharing of or communication about results.

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Duties and Responsibilities by Role, Cont.

	• 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 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 renders opinions concerning patient diagnosis and treatment, management of patient care.	• Is available to provide consultation to the laboratory's clients. • 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.

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Duties and Responsibilities by Role, Cont.

Technical Consultant (Moderate Complexity) / **Technical Supervisor** (High Complexity) is responsible for technical and scientific oversight. This person is not required to be on-site at all times, but must be available to provide needed consultation either on-site, by telephone, or electronically.	• Selects test methodology appropriate for the clinical use of the test menu. • Verifies procedures for testing 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 corrective 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 Testing Personnel's performance within six months and twelve months during the first year of employment and yearly thereafter. Performance is reevaluated (prior to reporting patient test results) if test methodology or instrumentation changes. The evaluation must include the use of the new test methodology or instrumentation.

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Duties and Responsibilities by Role, Cont.

General Supervisor (High Complexity)	• 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 examination to ensure that acceptable levels of analytic performance are maintained.
	• Fulfills certain responsibilities as delegated by the Lab Director and/or Technical Supervisor. These may include:
	  ○ Resolving technical problems and ensuring corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications.
	  ○ Ensuring patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.
	  ○ Providing orientation to all testing personnel.
	  ○ Evaluating and documenting the performance of all testing personnel as required.

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Duties and Responsibilities by Role, Cont.

Testing Personnel are responsible for specimen processing, test performance, and reporting test results. They 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.	• Following the laboratory's procedures for specimen handling and processing, test analyses, reporting, and maintaining records of patient results. • Maintaining records which demonstrate that proficiency testing samples are tested in the same manner as patient specimens. • Adhering to the laboratory's Quality Control policies and documenting all Quality Control activities, instrument and procedural calibrations, and instrument maintenance. • Following the laboratory's policies, including taking and documenting corrective actions, whenever test systems are not within the laboratory's established acceptable levels of performance. • Being able to identify problems that may adversely affect test performance or test result reporting and correcting the problem or notifying the appropriate supervisor. • Documenting all corrective actions taken when test systems deviate from the laboratory's established performance specifications. • If required by route of qualification, performing high complexity testing only under the on-site direct supervision of a General Supervisor.

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Personnel Requirements

NOTE: *All individuals must have all required state licenses for all positions held – pertains to the state where the lab is located*

	MODERATE COMPLEXITY	
DIRECTOR 1. Licensed MD/DO/DPM, **AND** certified in anatomic or clinical pathology, **OR** lab training or experience consisting of 1 year directing or supervising non-waived tests, **OR** Beginning 09/01/1993, have earned at least 20 CME credits in laboratory practice addressing director responsibilities, **OR** training equivalent to 20 CME credits obtained during medical residency. 2. Doctoral degree in a laboratory science* **AND** certified by an HHS-approved Board, **OR** have 1 year experience directing or supervising non-waived testing. 3. Master's degree in laboratory science* **AND** 1 year lab training or experience **AND** 1 year of experience supervising non-waived testing. 4. Bachelor's degree in laboratory science* **AND** 2 years lab training or experience **AND** 2 years experience supervising non-waived testing. 5. Prior to 02/28/1992, qualified as Director under state law or Medicare lab regulations.	**TECHNICAL CONSULTANT** 1. Licensed MD/DO/DPM **AND** certified in anatomic or clinical pathology **OR** 1 year lab training or experience in non-waived specialty/subspecialty of service. 2. Doctoral or Master's degree in laboratory science* **AND** 1 year lab training or experience in the non-waived specialty / subspecialty of service. 3. Bachelor's degree in laboratory science* **AND** 2 years lab training or experience in the non-waived specialty / subspecialty of service **NOTE:** "Training or experience" in specialties and subspecialties can be acquired concurrently.	**CLINICAL CONSULTANT** 1. Licensed MD/DO/DPM. 2. Doctoral degree in laboratory science* **AND** board certified in specialty/subspecialty of service. **TESTING PERSONNEL** 1. Licensed MD/DO/DPM 2. Doctoral, Master's, Bachelor's, or Associate's degree in laboratory science* 3. High School graduate or equivalent **AND** completed military Medical Lab Specialist (50 week) course. 4. High School graduate or equivalent **AND** documentation of training at the present facility for testing performed.

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Personnel Requirements, Cont.

	HIGH COMPLEXITY LABORATORIES	
DIRECTOR 1. Licensed MD/DO/DPM **AND** certified in anatomic or clinical pathology **OR** 1 year of lab training during medical residency **OR** 2 years experience directing or supervising high complexity testing. 2. Doctoral degree in a laboratory science* **AND** certified by an HHS-approved board **OR** prior to 02/24/2003, served as Lab Director **AND** 2 years lab training or experience **AND** 2 years experience supervising or directing high complexity testing. 3. Prior to 02/28/1992, qualified as Lab Director under state law or Medicare lab regulations. **TESTING PERSONNEL** 1. Licensed MD/DO/DPM. 2. Doctoral, Master's, Bachelor's or Associate's degree in 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. 4. Prior to 04/24/1995, High School graduate or equivalent **AND** graduated from an **HHS**-approved lab training program **OR** completed military Medical Lab Specialist (50 week) course. 5. Prior to 04/24/1995, High School graduate or equivalent **AND** documentation of training for high complexity testing **AND** if training before 01/19/1993, on-site supervision is required when high complexity testing is performed. **NOTE:** Must also provide documentation of training at the present facility for testing personnel **For Blood Gases:** If not qualified above: Bachelor's or Associate's degree in respiratory therapy, pulmonary	**TECHNICAL SUPERVISOR** Specific qualifications are required for each specialty or subspecialty. **For Microbiology subspecialties – bacteriology, mycobacteriology, mycology, virology, and parasitology:** 1. Licensed MD/DO/DPM or PhD **AND** certified in clinical pathology **OR** 1 year lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service. 2. Master's degree in laboratory science* **AND** 2 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service. 3. Bachelor's degree in laboratory science* **AND** 4 years lab training or experience in high complexity microbiology with a minimum of 6 months in subspecialty of service. **For Immunology, Chemistry, Hematology, or Radiobioassy: **** 1. Licensed MD/DO.DPM or PhD **AND** certified in clinical pathology **OR** 1 year lab training or experience in the high complexity testing specialties performed 2. Master's degree in laboratory science* **AND** 2 years lab training or experience in the high complexity testing specialties performed. 3. Bachelor's degree in laboratory science* **AND** 4 years lab training or experience in the high complexity testing specialties performed. **For Immunohematology:** Licensed MD/DO/DPM **AND** certified in clinical pathology **OR** 1 year lab training or experience in immunohematology testing. **CLINICAL CONSULTANT** 1. Licensed MD/DO/DPM. 2. Doctoral degree in laboratory science* **AND** board certified in specialty/subspecialty of service.	**GENERAL SUPERVISOR** 1. Qualified as Lab Director or Technical Supervisor of high complexity testing. 2. Licensed MD/DO/DPM, or have a Doctoral, Master's, or Bachelor's degree in laboratory science* **AND** 1 year lab training or experience in high complexity testing. 3. Qualified as Testing Personnel for high complexity testing **AND** at least 2 years lab training or experience in high complexity testing. 4. Previously qualified as General Supervisor on or before 02/28/1992. 5. Prior to 09/01/1992, served as General Supervisor of high complexity testing **AND** prior to 04/24/1995 completed military Medical Lab Specialist (50 week course) **AND** had at least 2 years lab training or experience in high complexity testing **OR** graduated from an HHS-approved lab training program **AND** had at least 2 years lab training or experience in high complexity testing 6. Prior to 09/01/1992, served as General Supervisor of high complexity testing **AND** have a high school diploma or equivalent **AND** more than 10 years' experience in high complexity testing including at least 6 years supervisory experience from 09/01/1982 to 09/01/1992. 7. Prior to 09/01/1992, served as General Supervisor of high complexity testing and prior to 01/01/1994: passed an HHS approved technical proficiency exam given between 03/01/1986 and 12/31/1987 **AND** have 6 years lab training or experience with 2 years in high complexity testing specialties. **For Blood Gases**: if not qualified above: 1. BA/BS in respiratory therapy, or cardiovascular technology **AND** 1 year training or experience 2. AA/AS related to pulmonary function **AND** 2 years training or experience.

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Non-Controlled Documents

The following non-controlled documents support this procedure.

- CLIA Requirements, 42 CFR, Part 493, Subpart M
- COLA LabGuide 4, Revision Feb. 2015
- College of American Pathologists Laboratory General Checklist

Controlled Documents

The following controlled documents support this procedure.

Policy

Form
Task Authorization Grid

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Reviewed and approved by (for Medical Center Area Approval Only):

SIGNATURE	DATE
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HISTORY PAGE

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CLIA Personnel

Initial Approval

Name/Signature	Title	Date	Meaning/Reason
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Darryl Palmer-Toy (T188420)	SCPMG Laboratory Sys Med Dir	12 Sep 2016, 04:19:48 PM	Approved
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	19 Sep 2016, 11:23:35 AM	Approved

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