



EDUCATIONAL RESOURCES



CLINICAL LABORATORY

# Personnel Standards

## Laboratory Personnel Qualifications and Responsibilities



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# Welcome

- So glad you are here!
- As your partner in achieving quality and accuracy in laboratory services, ACHC's intent is to educate and help close gaps in compliance.
- Let's do this workshop!

# Objectives

- Upon completion of the presentation, participants will understand:
  - Where to locate standards related to personnel
  - The CLIA requirements for personnel qualifications and responsibilities for the following types of laboratories:
    - High Complexity
    - Moderate Complexity
    - Provider Performed Microscopy
    - Certificate of Waiver
  - The special personnel requirements related to the performance of Cytology testing

# Location of Personnel Standards/Regulations

- ACHC Accreditation Manual Chapter 2:
  - High Complexity Laboratories §493.1441-§493.1463; §493.1487-§ 493-1495
  - Moderate Complexity Laboratories §493.1403- §493.1425
  
- ACHC Accreditation Manual Chapter 3:
  - Provider Performed Laboratories §493.1353- §493.1365
  
- ACHC Accreditation Manual Chapter 9:
  - Additional High Complexity Cytology Requirements §493.1467- §493.1485

# High and Moderate Complexity Laboratories



# Required Positions

High Complexity Laboratory Required Positions	Moderate Complexity Laboratory Required Positions
<ul style="list-style-type: none"> <li>Laboratory Director</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory Director</li> </ul>
<ul style="list-style-type: none"> <li>Technical <b>Supervisor</b> (Includes Cytology)</li> </ul>	<ul style="list-style-type: none"> <li>Technical <b>Consultant</b></li> </ul>
<ul style="list-style-type: none"> <li>Clinical Consultant</li> </ul>	<ul style="list-style-type: none"> <li>Clinical Consultant</li> </ul>
<ul style="list-style-type: none"> <li>General Supervisor (Includes Cytology)</li> </ul>	
<ul style="list-style-type: none"> <li>Testing Personnel (Includes Cytotechnologists)</li> </ul>	<ul style="list-style-type: none"> <li>Testing Personnel</li> </ul>

# CLIA Position Requirements

- The laboratory must meet all CLIA requirements for each position including qualifications and responsibilities.
- An individual may hold more than one CLIA defined position provided the individual meets the qualifications for each position.
- There can only be one Laboratory Director.
- Each laboratory must define who fills each CLIA required position.



# CLIA Position Deficiencies

- Condition level deficiencies will result when a CLIA-required position is:
  - Not filled;
  - Filled by an individual who does not meet the qualifications; or
  - The required responsibilities are not fulfilled.

# CLIA Position Qualification Requirements



# CLIA Qualification Requirements

## Position Qualification Standard/Regulation:

- 02.01.01 Laboratory Director (§493.1443, §493.1405)
- 02.02.01 Technical Supervisor/Consultant (§493.1449, §493.1411)
  - Defined for each Specialty/Subspecialty
- 02.03.01 Clinical Consultant (§493.1455, §493.1417)
- 02.04.01 General Supervisor (§493.1461(a-d))
  - This position does not exist in a Moderate Complexity Laboratory
- 02.05.01 Testing Personnel (§493.1489(a-b), §493.1423(a-b))

# High Complexity Lab Director Qualifications

**02.02.01** Qualifications include **one** of the following:

- Licensed MD/DO/DPM **and** 1 of the following:
  - Board certified/qualified in anatomic and/or clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology
  - 1 year of lab training during residency/fellowship.
  - 2 years experience directing/supervising high complexity testing **OR**
- Licensed DPM **and** 1 of the following:
  - 1 year of lab training during residency/fellowship.
  - 2 years experience directing/supervising high complexity testing **OR**
- Doctoral degree in a chemical, physical, biological, or clinical laboratory science, **and** current certification from an HHS-approved board **OR**
- Meets “grandfather clause”

§493.1443, §493.1443(b)(6)

# Moderate Complexity Director Qualifications

**02.01.01** Qualifications include **one** of the following:

- Licensed MD/DO/DPM **and** 1 of the following:
  - Board certified/qualified in Anatomic and/or clinical pathology by/for American Board of Pathology or American Osteopathic Board of Pathology
  - 1 year experience directing/supervising non-waived testing or equivalent training during residency/fellowship
  - As of 9/1/1993:≥ 20 CME hours on lab director responsibilities **OR**
- Doctoral degree\* **and** either current certification from an HHS-approved board or 1 year of supervisory lab experience in non-waived testing **OR**
- Master's degree\* **and** 1 year training/experience in non-waived testing AND 1 year of supervisory lab experience in non-waived testing **OR**
- Bachelor's degree\* **and** 2 years training/experience in non-waived testing AND 2 years of supervisory lab experience in non-waived testing.

§ 493.1405

# Technical Supervisor Qualifications

**02.02.01** A **high complexity** lab may test in all specialties/subspecialties (except histocompatibility and clinical cytogenetics) provided **both** of the following are met:

- A licensed MD/DO **and**
- Board certified/qualified in both anatomic & clinical pathology by/for the American Board of Pathology or American Osteopathic Board of Pathology.

**NOTE:** If both requirements are not met, the technical supervisor(s) must meet the specific qualifications required for each specialty/subspecialty.

§493.1449 (a-q)



# Technical Consultant Qualifications

**02.02.01** A **moderate complexity** laboratory's technical consultant must meet **one** of the following:

- A licensed MD/DO/DPM **and** certification in anatomic or clinical pathology with 1 year of lab training/experience in the non-waived specialty/subspecialty
- Doctoral or master's degree in a chemical, physical, biological, or clinical laboratory science **and** 1 year of lab training/experience in the non-waived specialty/subspecialty
- Bachelor's degree in a chemical, physical, biological, or clinical laboratory science **and** 2 years of lab training/experience in the non-waived specialty/subspecialty

§493.1411(a-b)

# Clinical Consultant Qualifications

**02.03.01** Must be qualified to consult with and render opinions concerning diagnosis, treatment, & management of patient care.

Qualifications include **one** of the following:

- A licensed MD/DO/DPM
- A doctoral degree in chemical, physical, biological, or clinical laboratory sciences **and** is board certified in the specialty/subspecialty

§493.1455, §493.1417



# General Supervisor Qualifications

**02.04.01** A **high complexity** lab must have general supervisor(s) who provide day-to-day supervision of testing personnel & test result reporting.

Qualifications include **one** of the following:

- Qualified as high complexity director or technical supervisor
- Doctoral, master's, or bachelor's degree in a chemical, physical, biological, or clinical laboratory science **and** 1 year of lab training/experience in high complexity testing
- Associate degree in medical laboratory technology **and** 2 years of lab training/experience in high complexity testing
- Qualified or could have qualified prior to 2/28/1992

§493.1461(a-d)

# Cytology General Supervisor Qualifications

**09.03.02** Must be state licensed, if required, and must meet **one** of the following:

- Be qualified as a technical supervisor (MD/DO & board certified/qualified)
- Be qualified as a cytotechnologist **and** have at least three (3) years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

§493.1467, §493.1469

# Cytologist Qualifications

**09.03.04** Must be state licensed, if required, and meet **one** of the following:

- Graduate from accredited cytotechnology (CT) school approved by HHS
- Certified CT by HHS-approved agency (e.g., ASCP)
- Before 9/1/1992 meets **one** of the following:
  - Completed 2 years (12 semester science hrs. with 8 in biology) **and** 12 months in CT school **OR** 6 months CT school training & 6 months full time (FT) experience.
  - Satisfactory grade in an HHS CT proficiency test
- Before 9/1/1994: 2 yrs. FT pathologist-supervised experience within prior 5 years reading slides and before 1/1/1969, a HS graduate with 6 months CT training in physician-directed lab and 2 yrs. FT supervised CT experience
- On or before 9/1/1994, 2 yrs. FT experience within prior 5 yrs. in the US and, on or before 9/1/1995 graduated CAHEA-approved school or be certified as CT

§493.1481, §493.1483

# High Complexity Testing Personnel

**02.05.01** Must possess a current state license, if required, and meet **one** of the following:

- Licensed MD/DO/DPM
- Doctoral, master's, or bachelor's degree in a chemical, physical, biological, or clinical laboratory science/medical technology from an accredited institution.
- Associate degree in laboratory science or medical laboratory technology, or equivalent education and training.
- Individuals performing high complexity testing on or before April 24, 1995, with a high school diploma or equivalent with documented training may continue to perform testing only on those tests for which training was documented prior to September 1, 1997 (refer to CLIA regulation 42 CFR 493.1489(b) for details on required training).
- Previously qualified or could have qualified as a technologist under CFR §493.1489 and CFR §493.1491 on or before February 28, 1992.

# Moderate Complexity Testing Personnel

**02.05.01** Must possess a current state license, if required, and meet **one** of the following:

- Licensed MD/DO/DPM.
- Doctoral, master's, bachelor's, or associate degree in a chemical, physical, biological, or clinical laboratory science, or medical technology from an accredited institution.
- High school graduate or equivalent AND completed military Medical Lab Specialist (50 week) course.
- High school graduate or equivalent AND have documentation of training at the present facility for testing performed.

§493.1423(a-b)

# Blood Gas Testing Personnel

**02.05.01** Individuals performing **high** complexity Blood Gas Analysis when high complexity testing qualifications are not met must have **one** of the following:

- Bachelor's degree in respiratory therapy or cardiovascular technology
- Associate degree related to pulmonary function from an accredited institution

# CLIA Position Responsibilities



# Laboratory Director Responsibilities

## 02.01.02 Laboratory Director (LD)

*The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.*

§493.1445, §493.1407



# Laboratory Director Duty Delegation

## 02.01.03 Delegation of Responsibilities

*The laboratory director, if qualified, may perform the duties of the technical supervisor or consultant, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications.*

**This delegation must be in writing.**

§493.1445(a-b), §493.1407(a-b)

# Duties and Responsibilities Assignment

## 02.01.15 Assigned Duties and Responsibilities

*The laboratory director must specify, **in writing**, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing, and **identify which examinations and procedures each individual is authorized to perform**, whether supervision is required for specimen processing, test performance or results reporting, and whether supervisory or director review is required prior to reporting patient test results.*

§493.1445(e)(15), §493.1407(e)(14)

# Director Duties That May Not be Delegated

Responsibilities that may **NOT** be delegated:

- 02.01.03 *Ensure delegated duties are properly performed*
- 02.01.04 *Ensure accessibility (onsite, telephone, electronic)*
- 02.01.06 *Ensure quality test systems and services for all aspects*
- 02.01.07 *Ensure a safe environment*
- 02.01.14 *Ensure Director-approved procedures are available to staff*
- 02.01.15/02.05.03 *Authorize duties and responsibilities for all positions*
- 02.01.12 *Ensures onsite supervision of High Complexity testing by personnel qualified under 493.1489(4)*

High Complexity §493.1445(a-c)(e)(1,2,14,15), §493.1495(a), §493.1445 (e)(10)

Moderate Complexity §493.1407(a-c)(e)(1,2,13,14), §493.1425(a)

# Duties Delegated to Clinical Consultant

Responsibilities that **may** be delegated to a qualified Clinical Consultant:

## **02.01.11** *Test result Information and Consultation:*

- Test reports include pertinent information for interpretation
- Consultation is available to the laboratory's clients related to the quality of results and their interpretation for specific patient conditions

§493.1445(e)(8-9), §493.1407(e)(8-9)

# Duties Delegated to Technical Supervisor/Consultant

Director responsibilities that **may** be delegated to Technical Supervisor/Technical Consultant:

- 02.01.08 *Select and verify the performance of test methods*
- 02.01.09 *Proficiency Testing enrollment, testing, and remedial action*
- 02.01.10 *QC and QA programs for all areas and test phases*
- 02.10.13 *Employ sufficient staff with appropriate education/training*
- 02.10.13 *Establish Performance monitoring and identify training needs*
- 02.02.04 *Semi-annual 1<sup>st</sup> year testing personnel competency assessment*

§493.1445(e)(3)(i-iii)(4)(i-iv)(5-9)(11-13); §493.1407(e)(4)(i-iv)(5-12)

# Delegation to Technical Supervisor/ Consultant or General Supervisor

**02.04.03** Responsibilities that **may** be delegated to the Technical Supervisor/Technical Consultant or the General Supervisor:

- Orientation and training for Testing Personnel
- Annual competency assessment of Testing Personnel
- Ensure remedial actions are taken to resolve technical problems and no patient results are reported until corrected.

**Note:** The **General Supervisor** position **applies only to High Complexity** Laboratories

§493.1463(b)(1-2)



# General Supervisor Responsibilities

**02.04.02** A **high complexity** lab general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. The general supervisor:

- Must be accessible to staff when testing is performed to provide on-site, telephone, or electronic consultation to resolve technical problems per policies and procedures established by the laboratory director or technical supervisor.
- Provides day-to-day supervision of staff performing high complexity testing.
- Provides on-site direct supervision when high complexity testing is performed by individuals qualified as trained HS graduates under §493.1489(b)(5).
- Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

§493.1463, §493.1463(a)(1-4)

# Cytologist Responsibilities

**09.03.05** In addition to the responsibilities for high complexity testing personnel, the cytotechnologist is also responsible for documenting:

- The slide interpretation results of each gynecologic and non-gynecologic cytology case he or she examined or reviewed.
- For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer.
- The number of hours spent examining slides in each 24-hour period.
- No more than 100 cytology slides (gynecologic and non-gynecologic) may be examined or reviewed in a 24-hour period.

§493.1485



# Provider Performed Microscopy (PPM) Laboratories



# PPM Laboratory Director Qualifications

**03.01.01** The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures.

The laboratory director must:

- Be state-licensed as a laboratory director, if required.
- Be a physician, a mid-level practitioner, or a dentist.
- Be eligible to operate a lab or testing site within CLIA requirements
- Be authorized to practice independently in the state in which the laboratory or testing site is located.
- Direct no more than five laboratories

§493.1357(a),(b),(1-3)

# PPM Lab Director Responsibilities

**03.01.02** The PPM laboratory director must:

- Ensure PPM procedures are done by individuals who meet qualifications
- Ensure PPM testing is performed according to CLIA requirements:
  - Current procedure manual with director approval and review.
  - Appropriate physical environment for testing.
  - Equipment maintenance procedures with documentation.
  - QC procedures with evidence of compliance.
  - Test report criteria.
  - PT or alternate method of evaluating accuracy twice a year.
  - QA system that covers all phases of the testing process.
  - Retention of all records for at least two years. §493.1359(a),(b)(1-2)

# PPM Testing Personnel Qualifications

**03.01.03** Must possess a current license issued by the state, if required.

PPM Testing Personnel must be **one** of the following:

- A licensed MD/DO/DPM
- A mid-level practitioner (a nurse midwife, nurse practitioner, or physician assistant) under the supervision of a physician or in independent practice if authorized by the state
- A licensed dentist (doctor of dental medicine or doctor of dental surgery)

§493.1361, §493.1363(a)(b)(1-3)

# Certificate of Waiver Laboratories





# Waived Laboratory Supervisor Qualifications

**03.02.01** The laboratory must have a supervisor who provides overall management and direction of the laboratory. The lab supervisor must be qualified to manage and direct the lab personnel and waived test performance.

The waived lab supervisor shall meet **one** of the following qualifications:

- Licensed MD/DO/DPM
- Doctoral, master, bachelor, or associate degree in a chemical, physical, biological, or clinical laboratory science, or medical technology from an accredited institution
- High school graduate or equivalent **and** completed military Medical Lab Specialist (50 week) course.
- High school graduate or equivalent **and** have documentation of training and experience for the testing performed.

# Waived Lab Supervisor Responsibilities

**03.02.02** The laboratory supervisor is responsible for the overall operation and administration of the laboratory, including the oversight of personnel who are competent to perform test procedures, and record and report test results promptly, accurately, and proficiently. The lab supervisor has the responsibility for:

- implementing test procedures with written policies including provisions for appropriate QC and QA monitors.
- ensuring that all policies/procedures are followed.
- initial training and for evaluating the competency of all testing personnel.
- ensuring staff maintain competency and that competency for testing personnel is evaluated at least annually. The director may decide how evaluation of competency is determined.
- reviewing QC data at least monthly

# Waived Testing Personnel Qualifications

**03.02.04** Each individual performing waived testing must possess a current license issued by the state if required.

Testing personnel must meet **one** of the following requirements:

- Licensed MD/DO/DPM.
- Doctoral, master, bachelor, or associate degree in a chemical, physical, biological, or clinical laboratory science, or medical technology from an accredited institution.
- High school graduate or equivalent **and** completed military Medical Lab Specialist (50 week) course.
- High school graduate or equivalent **and** have documentation of training for the testing performed



# Waived Testing Personnel Responsibilities

**03.02.05** The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

Records should indicate who performed the test. Test results may be retained in the patient's medical record.

Testing Personnel must:

- follow the current manufacturer's instructions for all tests performed.
- review the results to determine if results are acceptable prior to reporting patient results.
- follow policies/procedures for recording QC and patient test results.
- know and follow corrective action policy if QC results are not acceptable.



Questions?

The ACHC  
Laboratory Team  
is here to help.





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# Thank you

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