

CLIA Clinical Laboratory Personnel Requirements

Laboratories must have one or more individuals who can meet the requirements for each personnel category per the appropriate testing complexity.

◆HIGH COMPLEXITY TESTING◆

LABORATORY DIRECTOR (42 CFR 493.1443)

1. Licensed MD, DO, DPM or DMD and Certified in anatomic, clinical or oral pathology, or
 - ◆ Board eligible or
 - ◆ Certified or eligible for certification by a national accreditation board related to a laboratory specialty or
 - ◆ 2 years directing or supervising high complexity testing or
 - ◆ prior to Feb 28, 1992 qualified under State law to direct a lab in the state a lab is located.
2. Doctoral degree in a lab science and
 - ◆ Board certified after February 23, 2003 or
 - ◆ Prior to Feb 24, 2003 have served/be serving as director of a high complexity lab and have 2 years training plus 2 years directing or supervising high complexity testing.
3. Directed a clinical lab 12 months within 5 years prior to Jan 1, 1970 and
 - ◆ 2 years pertinent lab experience.
4. Prior to Feb. 28, 1992, qualified as a clinical lab director under federal regulations (42 CFR493.1406).

TECHNICAL SUPERVISOR (42 CFR 4931449)

For all specialties/subspecialties except histocompatibility and cytogenetics:

1. Licensed MD or DO, or DPM and
 - ◆ certified in anatomic and clinical pathology.

For subspecialties of **Bacteriology, Mycobacteriology, Mycology, Virology, and Parasitology**:

1. Licensed MD, DO and
 - ◆ 1 year training or experience in high complexity microbiology with at least 6 months in the appropriate subspecialty.
2. Doctoral degree in lab science and
 - ◆ 1 year training or experience in high complexity microbiology with minimum 6 months in the appropriate subspecialty.
3. Master's degree in lab science and
 - ◆ 2 years training or experience in high complexity microbiology with minimum 6 months in the appropriate subspecialty.
4. Bachelor's degree in lab science and
 - ◆ 4 years training or experience in high complexity microbiology with minimum 6 months in the appropriate subspecialty.

For Diagnostic **Immunology, Chemistry, Hematology, and Radiobioassay**:

1. Same education, training or experience requirements as above **EXCEPT** no 6 month subspecialty requirements,

FOR PATHOLOGY AND ITS SUBSPECIALTIES, CYTOLOGY, HISTOPATHOLOGY, CYTOGENETICS, OR IMMUNOHEMATOLOGY:

1. See specific requirements for each specialty/subspecialty in federal regulations under 42 CFR 493.1449.

High Complexity testing personnel (continued)

CLINICAL CONSULTANT (42 CFR 493.1455)

1. Licensed MD, DO, DPM or DMD.
2. Doctoral degree in lab science and
 - ◆ board certified by Dec. 31, 2000.

GENERAL SUPERVISOR (42 CFR 493.1461)

1. Qualified director of high complexity testing.
2. Qualified Technical Supervisor.
3. MD, DO, DPM, doctorate, master's or bachelor's degree in lab science and
 - ◆ 1 year lab training/experience in high complexity testing.
4. Associate degree in lab science or medical laboratory technology and
 - ◆ 2 years lab training/experience in high complexity testing.
5. Previously qualified or could have qualified as general supervisor under federal regulations on or before Feb. 28, 1992 (42 CFR 493.1462).
6. Passed the HHS exam for technologist between March 1, 1986 and Dec 31, 1987 and
 - ◆ prior to Jan 1, 1994, met the requirements of a general supervisor in effect before Feb. 28, 1992.
7. Prior to Sept 1, 1992, served as general supervisor of high complexity testing and
 - ◆ prior to April 24, 1995 graduated from an accredited medical laboratory training program or
 - ◆ high school graduate or equivalent and have completed a 50 week military program of Medical Laboratory Specialist or
 - ◆ 2 years clinical lab training/experience in high complexity testing.
8. Prior to Sept 1, 1992 served as a general lab supervisor of high complexity testing, and
 - ◆ high school graduate or equivalent, and
 - ◆ 10 years of lab training/experience in high complexity testing, including 6 years supervisory experience between Sept 1, 1982 and Sept 1, 1992.

For **Blood Gases**: If not qualified above,

1. Bachelor's degree in respiratory therapy or cardiovascular technology and
 - ◆ 1 year training/experience in blood gas analysis, or,
 - ◆ Associate degree in pulmonary function and
 - ◆ 2 years training/experience in blood gas analysis.

For CYTOLOGY, Refer to 42 CFR 493.1469.

TESTING PERSONNEL (42 CFR 493.1489)

1. Licensed MD, DO or DPM.
2. Doctorate, master's, or bachelor's in laboratory science.
3. Associate degree in laboratory science or
 - ◆ 60 semester hours including 24 semester hrs of medical lab technology; or,
 - ◆ 60 semester hrs including 24 hrs of science that includes 6 hrs chemistry, 6 hrs biology, and 12 hrs chemistry, biology or, medical lab tech in any combination and laboratory training that includes either:
 - ◆ completion of a clinical lab training program or
 - ◆ 3 months training in each specialty in which high complexity testing is performed,
4. Previously qualified or could have qualified as a technologist under federal regulations prior to February 28, 1992 (42 CFR 493.1491).

High Complexity testing personnel (continued)

5. After September 1, 1997, personnel with a high school degree and documented training of high complexity testing prior to:

- ◆ April 25, 1995 — may continue under direct supervision of a qualified supervisor
- ◆ January 19, 1993 — may continue testing but unsupervised work must be reviewed within 24 hours by a qualified supervisor
- ◆ Medical Laboratory Specialist from the US Military, 50 week course prior to April 25, 1995.

For **Blood Gases** meets the requirements above or

- ◆ BS in respiratory therapy or cardiovascular technology, or
- ◆ Associate degree related to pulmonary function.

For **Histopathology**: tissue examinations must be performed by an individual who meets the qualifications of 493.1449(b) or (I).

For **Cytology**, see 42 CFR 493.1483(k)

◆ MODERATE COMPLEXITY TESTING ◆

LABORATORY DIRECTOR (42CFR 493 1405)

1. Qualified to direct a high complexity lab.
2. Licensed MD, DO, OD or DPM in and
 - ◆ lab training or experience consisting of one year directing or supervising non-waived lab or
 - ◆ 20 continuing medical education credit hours in laboratory practice or
 - ◆ 1 year lab training in non-waived testing during medical residency (ex. hematology or oncology).
3. Doctoral degree in lab science and
 - ◆ board certified or
 - ◆ 1 year directing or supervising non-waived testing.
4. Master's degree in lab science and
 - ◆ 1 year lab training or experience and
 - ◆ 1 year of supervisory experience in non-waived testing.
5. Bachelor's degree in lab science and
 - ◆ 2 years lab training or experience and
 - ◆ 2 years of supervisory experience in non-waived testing.

TECHNICAL CONSULTANT (42 CFR 493.1411)

1. Licensed MD, DO or DPM and
 - ◆ Certified in anatomic or clinical pathology or both or
 - ◆ 1 year laboratory training or experience in non-waived testing in designated specialty/subspecialty.
2. Doctoral or master's degree in lab science and
 - ◆ 1 year lab training or experience in non-waived testing, in designated specialty /subspecialty.
3. Bachelor's degree in lab science and

- ◆ 2 years laboratory training or experience in non-waived testing, in designated specialty/subspecialty.

Note: Training or experience can be acquired concurrently in specialties and subspecialties.

Moderate Complexity testing personnel (continued)

CLINICAL CONSULTANT (42 CFR 493.1417)

1. Licensed MD, DO or DPM..
2. Doctoral degree in laboratory science and Board certified.

TESTING PERSONNEL (42 CFR 493 1423)

1. Qualified to perform high complexity testing.
2. Licensed MD, DO or DPM.
3. Doctorate, master's, bachelor's or associate's degree in laboratory science.
4. High school graduate or equivalent and
 - ◆ 50 week military training as Medical Lab Specialist, or
 - ◆ Documentation of training appropriate to testing performed. Training must assure skills for:
 - ▶ specimen collection, labeling, preparation, etc.
 - ▶ implementing laboratory procedures
 - ▶ performing assigned tests
 - ▶ conducting preventative maintenance, troubleshooting, calibration
 - ▶ knowledge of reagent stability and storage
 - ▶ implementing quality control (QC) procedures
 - ▶ knowledge of factors influencing test results
 - ▶ validating patient test results with QC before reporting.

Note: This guide is abbreviated from CFR Part 493, Subpart M. To view the complete text on-line, link to the following CDC website address: <http://www.cdc.gov/clia/regs/toc.aspx>.

◆ PPMP (PROVIDER PERFORMED MICROSCOPY PROCEDURES) ◆

DIRECTOR (42 CFR 493.1357) ◆ MD, DO, DPM, Dentist, or licensed physician assistant, nurse practitioner or nurse midwife.

TESTING PERSONNEL - Same as PPMP Director for performance of PPMP tests.

◆ WAIVED TESTING ◆

DIRECTOR - Individual taking legal responsibility for laboratory testing.

TESTING PERSONNEL - No specific requirements.