

Clinical Laboratory Personnel Requirements

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

Laboratory Compliance Section
PO Box 275 Portland, OR 97207-0275
Ph: 503-693-4125 Fax: 503-693-5602
www.healthoregon.org/II

High Complexity testing

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 2/28/92 qualified under State law to direct a lab in the state lab is located.
2. Doctoral degree in a lab science **and**
 - board certified after 2/23/03 **or**
 - Prior to 2/24/03 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 1/1/70 **and**
 - 2 years pertinent lab experience.
4. Prior to 2/28/92 qualified as clinical lab director under 42 CFR 493.1406.

Technical Supervisor (42 CFR 493.1449)

For all specialties/subspecialties except histocompatibility and cytogenetics:

1. Licensed MD or DO, or DPM **and**
 - certified in anatomic & 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, radiobiology:

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.

Clinical Consultant (42 CFR 493.1455)

1. Licensed MD, DO, DPM or DMD.
2. Doctoral degree in lab science **and**
 - board certified by 12/31/00.

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 lab technology or equivalent (see *Testing Personnel*, #3. of this section) **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 2/28/92 (42 CFR 493.1462).
6. Passed the HHS exam for technologist between 3/1/86 and 12/31/87 **and**
 - prior to 1/1/94, met the requirements of a general supervisor in effect before 2/28/92.
7. Prior to 9/1/92 served as general supervisor of high complexity testing **and**
 - prior to 4/24/95 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 9/1/92 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 9/1/82 & 9/1/92.

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, see 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

High Complexity testing *(continued)*

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 2/28/92 (42 CFR 493.1491).
5. After 9/1/97 personnel with a high school degree and documented training of high complexity testing **prior to**:
 - 4/24/95 — may continue under direct supervision of a qualified supervisor
 - 1/19/93— 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 4/25/95.

For blood gases: meet the requirements above **or**

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

For histopathology: tissue exams must be performed by an individual who meets the qualifications of 493.1449(b) or (l).

For cytology, see 42 CFR 493.1483

Provider Performed Microscopy Procedures (PPMP) testing

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

Testing Personnel

Same as PPMP Director.

Moderate Complexity Testing

Director (42CFR 493.1405)

1. Qualified to direct a high complexity lab.
2. Licensed MD, DO, OD or DPM in Oregon **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.

Waived testing

Director Individual taking legal responsibility for laboratory testing.

Testing Personnel— No specific requirements.

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.

Clinical Consultant (42 CFR 493.1417)

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

Testing Personnel (42 CFR 493.1423)

1. Qualify to perform high complexity testing.
2. Licensed MD, DO or DPM in Oregon.
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 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 go on-line to:

<http://wwwn.cdc.gov/clia/regs/toc.aspx>

Health Screen Testing (HST)

Refer to HST Synopsis for Personnel Requirements; OAR 333-024-0390.