

# Clinical Laboratory Personnel Requirements\*

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

## High Complexity testing

### Director (42 CFR 493.1443)

1. Oregon 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. On or before February 28, 1992 qualified under 42 CFR 493.1415 published March 14, 1990.

### Technical Supervisor (42 CFR 493.1449)

For all specialties/subspecialties except histocompatibility and cytogenetics:

1. Oregon licensed MD or DO, or DPM **and**
  - certified in anatomic & clinical pathology.

For subspecialties of bacteriology, mycobacteriology, mycology, virology, and parasitology:

1. Oregon 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, 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.

### Clinical Consultant (42 CFR 493.1455)

1. Oregon 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. Oregon licensed 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. Oregon 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,

## High Complexity testing (continued)

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**

## 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.
  6. Prior to 2/28/92 qualified as clinical lab director under 42 CFR 493.1406.

### Technical Consultant (42 CFR 493.1411)

1. Oregon 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.

### 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 & storage
      - implementing quality control procedures
      - knowledge of factors influencing test results
      - validating patient test results with QC before reporting.

## Provider Performed Microscopy Procedures (PPMP) testing

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

**Testing Personnel** Same as PPMP Director.

## Waived testing

**Director** Individual taking legal responsibility for laboratory testing.

**Testing Personnel** — No specific requirements.

## Health Screen Testing (HST)

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

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\* Note: this guide is abbreviated from CFR Part 493, Subpart M. View complete text at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/>