Clinical Laboratory Personnel Requirements

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 or experience in directing or supervising high complexity testing.

**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 minimum 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 test 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.

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.

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.