

High Complexity Testing and Laboratory Director Qualifications

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests. (CFR 493.1443 and OAR 333-024-021)

The high complexity laboratory director must be licensed to practice medicine or osteopathy in the State of Oregon; *and*

1. Be certified in anatomic or clinical pathology; *or*
2. Have at least one year of laboratory training during medical residency providing knowledge of the principles and theories of laboratory practice including:
 - Quality control and quality assurance
 - Proficiency testing
 - Patient test management
 - Development and implementation of personnel policy and procedure manuals; *or*
3. Have at least 2 years documented experience directing or supervising high complexity testing. This experience must be clinical in nature and include directing or supervising personnel who examine and perform tests on human specimens and may include personally examining and performing tests on patient specimens.

A physician may apprentice to a qualified director of a high complexity laboratory for 2 years to gain the required experience. During this 2 year period the physician must have direct participation in the following activities:

- Selection of methods to assure accurate test results
- Verification of the accuracy and precision of test methods
- Appropriate proficiency testing enrollment
- Review of proficiency test reports and remedial action
- Establishing and maintaining quality control and quality assurance programs
- Monitoring of employee training and competency including annual evaluation of testing personnel
- Establishing and maintaining acceptable levels of analytical performance for each test

Documentation of these activities should be maintained as evidence will be required when the director's qualifications are evaluated. This documentation should include signed procedure manuals, documented review of quality control, instrument maintenance, proficiency testing and remedial action and documented participation in quality assurance activities and monitors.

We strongly recommend participation in a continuing education program in laboratory practice. Contact information for two of the available programs is listed below:

University of Wisconsin and COLA: <http://www.cola.org/labu.html>

University of Iowa: <http://www.medicine.uiowa.edu/cme/clia/>

In accordance with the ADA, this document is available in alternate formats by phoning 503-693-4100.