High Complexity Testing Laboratory Director Qualifications § 493.1443



(a) The laboratory director must possess a current license (and) (b) The laboratory as a laboratory director issued by the state in which the laboratory is located, if such licensing is required;



director must













(1)(i) Be a doctor of medicine or osteopathy licensed to practice in the state in which the laboratory is located.

and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.

(2)(i) Be a doctor of medicine, a doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located.

and

or

(ii) Have at least 2 years of experience directing or supervising high complexity testing.

and

(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445.

or

(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution.

(3)(i)(B) Hold an earned doctoral degree.

and

or

- (1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS).
- (2) Have an approved thesis or research project in biology/ chemistry/MT/CLS/ MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a **CLIA-certified laboratory** as of December 28, 2024, and have done so continuously since December 28, 2024.

(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology. American Board of Pathology, or the American Osteopathic Board of Pathology.

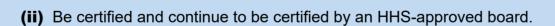
or



Resources 1. Code of Federal Regulations. Title 42, Part 493 Subpart M- Personnel for Nonwaived Testing

- 2. CMS Quality Safety & Oversight memoranda, guidance, clarifications, and instructions. Policy & Memos to States and CMS Locations | CMS
- 3. CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. Interpretive Guidelines for Laboratories | CMS





and

(iii) Have at least 2 years of:

(A) Laboratory training or

and (B) Laboratory experience directing or supervising

and

and

(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in § 493.1445.

