



# High Complexity Testing Clinical Consultant Qualifications § 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must

## 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](#)



**(a)** Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3) or, for the subspecialty of oral pathology, § 493.1443(b)(5) which includes the following pathways:

or



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

or

or

or

or

or

Be a doctor of medicine or osteopathy licensed to practice in the state in which the laboratory is located, and be certified in anatomic or clinical pathology or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.

Be a doctor of medicine, a doctor of osteopathy, or a doctor of podiatric medicine licensed to practice in the state in which the laboratory is located and have at least 2 years of experience directing or supervising high complexity testing and have 20 continuing education (CE) credit hours in laboratory practice that cover the director responsibilities defined in CLIA for high complexity testing.

Hold an earned doctoral degree in a chemical, biological, clinical, or medical laboratory science from an accredited institution and be certified and continue to be certified by an HHS-approved board and have at least 2 years of laboratory training or experience, or both, and laboratory experience directing or supervising high complexity testing and have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in CLIA for high complexity testing.

Hold an earned doctoral degree and 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) and be certified and continue to be certified by an HHS-approved board and have at least 2 years of laboratory training or experience or both and laboratory experience directing or supervising high complexity testing and have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in CLIA for high complexity testing.

Hold an earned doctoral degree and 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 and be certified and continue to be certified by an HHS-approved board and have at least 2 years of laboratory training or experience, or both, and laboratory experience directing or supervising high complexity testing and have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in CLIA for high complexity testing.

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.