



Moderate Complexity Testing Clinical Consultant Qualifications § 493.1417

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. [ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M](https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493/subpart-M)
2. CMS Quality Safety & Oversight memoranda, guidance, clarifications, and instructions. [cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos/policy-memos-states-regions](https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/policy-memos/policy-memos-states-regions)
3. CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. [cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines-laboratories](https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/guidelines-laboratories)

or



(a) Be qualified as a laboratory director under § 493.1405(b)(1), (2), or (3), which includes the following pathways:

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.

or

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 have had laboratory training or experience consisting of at least 1 year directing or supervising nonwaived laboratory testing and have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in CLIA § 493.1407 for moderate complexity testing.

or

Hold an earned doctoral degree in a chemical, biological, clinical, or medical laboratory science or medical technology from an accredited institution and have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in CLIA § 493.1407 for moderate complexity testing and be certified and continue to be certified by an HHS-approved board and have had at least 1 year of experience directing or supervising nonwaived laboratory testing.

or

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 have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in CLIA § 493.1407 for moderate complexity testing and be certified and continue to be certified by an HHS-approved board and have had at least 1 year of experience directing or supervising nonwaived laboratory testing.

or

Hold an earned doctoral degree and 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 have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in CLIA § 493.1407 for moderate complexity testing and be certified and continue to be certified by an HHS-approved board and have had at least 1 year of experience directing or supervising nonwaived testing.



(b) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the state in which the laboratory is located.