

CLIA Applications
Supporting Documents for Nonwaived Laboratory Director Qualification
West Virginia Office of Laboratory Services
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Laboratory Director qualification documents are required to be submitted with CLIA applications in the following circumstances:

- With all initial applications for PPMP, Compliance, or Accreditation certificates
- With PPMP, Compliance, or Accreditation laboratory director changes*
 - Laboratories must notify our office of a change in director within 30 days.

Waived laboratories do not need to provide documentation for director qualification.

The type of document(s) needed is determined by the regulatory qualifications on the next page.

CLIA Laboratory Personnel Documentation and Qualifications			
Type	Requirement	Acceptable Documents	Unacceptable Documents
Education	Diploma or college degree	<ul style="list-style-type: none"> ● Copy of degree, diploma, or transcript (includes foreign equivalency evaluation) ● Primary source verification (PSV) ● WV laboratory practitioner license (for testing personnel only) 	<ul style="list-style-type: none"> ● CV, resume ● College certificates ● Degrees not listing concentration ● Documents not in English ● Other professional licenses (nursing, respiratory, etc.)
	Medical license (doctor)	<ul style="list-style-type: none"> ● Copy of license ● PSV 	<ul style="list-style-type: none"> ● CV, resume ● License from state other than WV
	Board certification	<ul style="list-style-type: none"> ● Copy of certificate ● PSV 	<ul style="list-style-type: none"> ● CV, resume
	Continuing education	<ul style="list-style-type: none"> ● Copy of certificate(s) ● PSV 	<ul style="list-style-type: none"> ● CV, resume
Experience	Experience/training*	<ul style="list-style-type: none"> ● Verifiable proof of employment and job duties ● Signed procedure manuals/worksheets ● Signed competency assessment ● Verifiable MLT or MLS program instruction ● Medical residency syllabus 	<ul style="list-style-type: none"> ● CV, resume ● Job description alone <p>*Ordering and/or interpreting test results does <u>not</u> qualify as experience for moderate or high complexity testing</p>

Laboratory Director Qualifications
[CLIA Regulations: 42 CFR 493](#)

493.1405: Moderate complexity testing

1. MD or DO board certified in pathology and licensed to practice medicine in WV*
2. MD, DO, or DPM licensed to practice medicine/podiatry in WV, and
 - a. Has at least one year of experience directing or supervising nonwaived testing, or
 - b. Has at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in § 493.1407, or
 - c. Received relevant laboratory training during medical residency
3. Doctorate in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and
 - a. Has board certification from the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or
 - b. Has at least one year of experience directing or supervising nonwaived testing
4. Master's degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and
 - a. Has at least one year of training or experience in nonwaived testing, and
 - b. Has at least one year of supervisory experience in nonwaived testing
5. Bachelor's degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and
 - a. Has at least two years of training or experience in nonwaived testing, and
 - b. Has at least two years of supervisory experience in nonwaived testing
6. Grandfather provision for laboratory director qualification under federal law prior to 2/28/1992
7. Grandfather provision for laboratory director qualification under state laws prior to 2/28/1992

493.1443: High complexity testing

1. MD or DO board certified in pathology and licensed to practice medicine in WV*
2. MD, DO, or DPM licensed to practice medicine/podiatry in WV, and
 - a. Has at least one year of laboratory training during medical residency, or
 - b. Has at least two years of experience directing or supervising high complexity testing
3. Doctorate in a chemical, physical, biological, or clinical laboratory science from an accredited institution, and
 - a. Certified by a board approved by HHS**, or
 - b. Grandfather provision for directing laboratory prior to 2/24/2003 (see regulations)
4. Grandfather provision for laboratory director qualification under federal law prior to 2/28/1992
5. Grandfather provision for laboratory director qualification under state laws prior to 2/28/1992

*Specific board certification options for directors of oral pathology

** American Board of Bioanalysis (ABB), ABB Public Health Microbiology Certification, American Board of Clinical Chemistry (ABCC), American Board of Forensic Toxicology (ABFT [limited to doctoral degree Fellows]), American Board of Medical Genetics and Genomics (ABMGG), American Board of Medical Laboratory Immunology (ABMLI), American Board of Medical Microbiology (ABMM), American College of Histocompatibility and Immunogenetics (ACHI), National Registry of Certified Chemists (NRCC [limited to doctoral degree])