

**CLIA
LABORATORY DIRECTOR QUALIFICATION REQUIREMENTS**

**CLIA-WAIVED CERTIFICATE
Laboratory Director Qualification Requirements**

NOTE: A CLIA Certificate of Waived allows the facility to perform ONLY tests categorized as CLIA waived.

Option 1- (ID-Identification) Of Illinois licensed MD/DO/DPM or doctoral, master, bachelor, AA degree or managerial position WITH current employment status at the facility and responsible for the quality assessment and monitoring of CLIA Waived tests performed.

**CLIA-PPM CERTIFICATE (Provider Performed Microscopy)
Laboratory Director Qualification Requirements**

CLIA PPM Laboratory Director

CLIA PPM Testing Personnel

NOTE: A CLIA Certificate of PPM allows the facility to perform ONLY tests categorized as CLIA waived and PPM.

Option 1- Illinois licensed MD/DO/DPM/ or dentist.

Option 2- A “midlevel practitioner” nurse midwife, nurse practitioner, or state licensed physician assistant.

Option 1- Illinois licensed MD/DO/DPM/ or dentist.

Option 2- A “midlevel practitioner” nurse midwife, nurse practitioner or state licensed physician assistant.

**MODERATE COMPLEXITY CERTIFICATES OF COMPLIANCE OR ACCREDITED
Laboratory Director Qualification Requirements**

As specified in §493.1405, the designated individual must meet one or more of the qualifying options listed below to be eligible for the position.

Option 1- Illinois licensed MD/DO/DPM AND board certification in anatomical or clinical pathology.

Option 2- Illinois Licensed MD/DO/DPM AND one year lab training or experience directing or supervising a CLIA moderate or high complexity laboratory.

Option 3- Illinois licensed MD/DO/DPM AND 20 CME credit hours related to lab directors practice or equivalent 20 CMEs for lab practice during medical residency.

Option 4- Doctoral degree in chemical, physical, biological or clinical lab science with board certification or doctoral degree and one year experience directing/supervising a CLIA-certified moderate or high complexity laboratory.

Option 5- Master degree in lab science AND proof of one-year lab training or experience supervising a CLIA-certified moderate or high complexity laboratory.

Option 6- Bachelor degree in lab science AND two years lab training and experience and two- years supervising a CLIA-certified moderate or high complexity laboratory.

Option 7- On or before February 28, 1992, qualified under state law to direct a moderate or high complexity laboratory.

NOTE: For additional qualifications please refer to CLIA regulations at 42CFR Part 493.1405 or contact your state CLIA Program.

**HIGH COMPLEXITY CERTIFICATES OF COMPLIANCE OR ACCREDITED
Laboratory Director Qualification Requirements**

As specified in §493.1443, the designated individual must meet one or more of the qualifying options listed below to be eligible for the position.

Option 1- Illinois licensed MD/DO AND board certification in anatomical or clinical pathology.

Option 2- Illinois licensed MD/DO/DPM AND one- year of laboratory training during medical residency. (**Note: type of experience required is clinical**)

Option 3- Illinois licensed MD/DO/DPM AND at least two years’ experience directing or supervising a high complexity CLIA-certified laboratory.

Option 4- Doctoral degree in a chemical, physical, biological or clinical lab science with current board certification.

Option 5- Doctoral degree in chemical, physical, biological or clinical lab science and before February 24, 2003, must have served or be serving as director of a high complexity lab with two years lab training/experience and two years’ experience directing or supervising a CLIA certified high complexity laboratory.

Option 6- On or before February 28, 1992, qualified under state law to direct a high complexity laboratory.

Option 7- 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 possess qualifications that are equivalent to those required for certification.

NOTE: For additional qualifications please refer to CLIA regulations at 42CFR Part 493.1443 or contact your state CLIA Program Dph.Clia@Illinois.gov