STATE OF MICHIGAN

Department of Licensing & Regulatory Affairs
Bureau of Survey & Certification

Laboratory Director Qualification

CLIA regulations specify qualifications for laboratory directors to oversee non-waived testing. The documentation required for director qualification is dependent on the type of certificate being requested:

Certificate Type	Qualification Requirements
Waiver	No additional documentation required
PPMP	A copy of the proposed director's active MI state license
Compliance & Accreditation	o A copy of the proposed director's active MI state license; ***and*** o **ONE** of the following based on the complexity of the testing to be performed **Moderate Complexity Testing:** o Documentation of at least one (1) year directing or supervising non-waived testing; ***or*** o Completion of 20 CME credit hours from one (1) of the CME courses for Laboratory Directors of Moderate Complexity Laboratories listed on the CMS web site; ***or*** o Documentation of lab training equivalent to 20 CME credit hours in lab practice during medical residency.

	Additional routes of qualification (PhD, Master's degree, Bachelor's degree, etc.) are detailed at §493.1405 of the Code of Federal Regulations (hyperlink to link #1 below in document) **High Complexity Testing:** o Documentation of board certification in Anatomic and/or Clinical Pathology; ***or*** o Documentation of one (1) year of high complexity lab experience during residency; ***or*** o Documentation of two (2) years directing or supervising high complexity lab testing. Additional routes of qualification (PhD, Master's degree, Bachelor's degree, etc.) are detailed at §493.1443 of the Code of Federal Regulations (hyperlink to link #2 below) **For PhD Applicants –** In lieu of a state license the following documentation is required:

	• A doctoral degree (in a chemical, physical, biological, or clinical laboratory science) indicating specialty; *or* • A copy of transcripts indicating specialty; ***and*** • A copy of a current board certification approved by HHS. **For Mohs applicants** – Per the regs at 493.1443(b)(2), an individual must: (i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (ii) Have at least 2 years of experience directing or supervising high complexity testing To meet (i) (medical residency), provide documentation that verifies that the residency program provided the knowledge in principles and theories of laboratory practice including: quality control and quality assessment, proficiency testing, the phase of the total process (i.e., preanalytic, analytic and postanalytic), as well as general laboratory systems, facility administration,

	and development and implementation of personnel policy and procedure manuals. This training should also include hands-on laboratory testing. This can be accomplished by providing documentation of participation in a residency program as well as a detailed syllabus/program schedule of the medical residency. To meet (ii) (at least 2 years of experience directing/supervising), provide documentation demonstrating this experience. Documents such as delegation of laboratory director responsibilities, verification of having supervised High Complexity testing such as serving as Technical or General Supervisor, or having been the laboratory director of another CLIA-certified laboratory could help to meet this requirement. ***A resume or CV is not acceptable evidence of experience***

Link #1 http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5

Link #2 http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5