

## CLIA-Waived Certificate PERSONNEL QUALIFICATION REQUIREMENTS

Laboratory Director	Testing Personnel	
<p><b>Option 1-</b> Illinois licensed MD/DO/DPM or doctoral, master, bachelor, AA degree <b>or</b> managerial professional WITH current employment status at the facility and responsible for the quality assessment and monitoring of tests performed.</p>	<p><b>Option 1-</b>MD/DO/DPM with Illinois license OR doctoral, master, bachelor, AA degree, high school, GED AND documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p><b>NOTE:</b> A certificate of CLIA waived allows the facility to perform only tests categorized as CLIA waived.</p>	<p><b>Before submitting your application the CDC web-based training Ready? Set? Test! available at the following link <a href="http://cdc.train.org">cdc.train.org</a> is recommended.</b> The goal of this course is to promote reliable and high quality testing to enhance patient safety. The training will provide an explanation of the waived testing process and prepare you to be able to perform quality laboratory work. Once you visit the CDC website and complete the registration process, print your certificate of completion and fax to the Illinois Department of Public Health CLIA Laboratory Certification Program at 217-782-0382. The training will be added your CLIA certificate files.</p>

## CLIA-PPM (Provider Performed Microscopy) Certificate PERSONNEL QUALIFICATION REQUIREMENTS

Laboratory Director	Testing Personnel	
<p><b>Option 1-</b> Illinois licensed MD/DO/DPM/ or dentist.</p> <p><b>Option 2-</b> A “midlevel practitioner” nurse midwife, nurse practitioner, or physician assistant, licensed by the state of Illinois.</p>	<p><b>Option 1-</b> Illinois licensed MD/DO/DPM/ or dentist.</p> <p><b>Option 2-</b> A “midlevel practitioner” nurse midwife, nurse practitioner or physician assistant.</p> <p><b>NOTE:</b> A certificate of CLIA PPM (Provider Performed Microscopy) allows the facility to perform only tests categorized as CLIA waived or PPM.</p>	<p><b>Dear PPM Certificate applicant,</b> Please feel free to visit the CDC web site <a href="http://wwwn.cdc.gov/clia/Resources/PPMP">http://wwwn.cdc.gov/clia/Resources/PPMP</a> where additional and valuable information can be found. The CDC site is highly recommended and provides information about the importance of the PPM testing, the process, the regulatory requirements, and additional laboratory practices to assist you with the performance of quality laboratory work.</p>

## CLIA Certificate - Moderate Complexity Laboratory - PERSONNEL QUALIFICATION REQUIREMENTS

Laboratory Director	Clinical Consultant	Technical Consultant	Testing Personnel
<p>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.</p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM AND board certification in anatomical or clinical pathology.</p> <p><b>Option 2-</b> Illinois licensed MD/DO/DPM AND one year lab training or experience directing or supervising a CLIA moderate or high complexity laboratory.</p> <p><b>Option 3-</b> 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.</p> <p><b>Option 4-</b> Doctoral degree in chemical, physical, biological or clinical lab science with <b>board certification*</b> or doctoral degree and one-year experience directing/supervising a CLIA-certified moderate complexity laboratory.</p> <p><b>Option 5-</b> Master degree in lab science AND proof of one-year lab training or experience supervising a CLIA-certified moderate or high complexity laboratory.</p> <p><b>Option 6-</b> Bachelor degree in lab science AND two-years lab training and experience and two- years supervising a CLIA-certified moderate or high complexity laboratory.</p> <p><b>Option 7-</b> On or before February 28, 1992, qualified under Illinois law to direct a laboratory.</p>	<p>As specified in §493.1417, the designated individual must meet one or more of the qualifying options listed below to be eligible for the position.</p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM.</p> <p><b>Option 2-</b> Doctoral degree in chemical physical, biological or clinical lab science <b>AND board certified*</b> in specialty or subspecialty of service.</p> <p style="text-align: center;"><b>*HHS Approved Boards</b></p> <ol style="list-style-type: none"> <li>1. ABB-American Board of Bioanalysis.</li> <li>2. ABB- Public Health Microbiology Certification.</li> <li>3. ABCC- American Board of Clinical Chemistry.</li> <li>4. ABCC- 24mo Commission of Accreditation in Clinical Chem (COMACC) Accredited Program.</li> <li>5. ABFT- American Board of Forensic Toxicology.</li> <li>6. ABHI-American Board of Histocompatibility and Immunogenetics.</li> <li>7. ABMGG-American Board of Medical Genetics and Genomics.</li> <li>8. ABMLI-American Board of Medical Laboratory Immunology.</li> <li>9. ABMM-American Board of Medical Microbiology.</li> <li>10. NRCC- National Registry of Cert Chemists.</li> </ol> <p><b>NOTE: <i>The laboratory director, if qualified, may perform the duties and occupy the positions of the <u>technical consultant</u>, <u>clinical consultant</u> and <u>testing personnel</u>, or delegate these responsibilities to qualified laboratory employees.</i></b></p> <p><i>Clinical Laboratory Improvement Amendments (CLIA) of 1988, and the CLIA regulations at 42 CFR Part 493 as specified in §493.1537, §493.1363, §493.1363, §493.1405, §493.1417, §493.1411 and §493.1423.</i></p> <p><b>UPDATED: 05/11/2018</b></p>	<p>As specified in §493.1411, the designated individual must meet one or more of the qualifying options listed below to be eligible for the position.</p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM AND board certified in anatomical or clinical pathology.</p> <p><b>Option 2-</b> Illinois Licensed MD/DO/DPM AND one-year lab training or experience in non-waived testing in the designated specialty or subspecialty of responsibility.</p> <p><b>Option 3-</b> Doctoral or master degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> one-year of lab training or experience in non-waived testing in the designated specialty or subspecialty of responsibility.</p> <p><b>Option 4-</b> Bachelor degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> two-years of laboratory training or experience in the designated specialty or subspecialty of responsibility</p>	<p>As specified in §493.1423, the designated individuals must meet one of the qualifying options listed below to be eligible for the position.</p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM.</p> <p><b>Option 2-</b> Doctoral, master’s or bachelor’s degree in a chemical, physical, biological or clinical lab science or medical technology.</p> <p><b>Option 3-</b> Associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution.</p> <p><b>Option 4-</b> High school graduate or equivalent <b>AND</b> documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p>

## CLIA Certificate - High Complexity Laboratory - PERSONNEL QUALIFICATION REQUIREMENTS

Laboratory Director	Clinical Consultant	Technical Supervisor	General Supervisor	Testing Personnel
As specified in §493.1443, candidate must meet one or more options	As specified in §493.1455, candidate must meet one or more options	As specified in §493.1449, the candidate must meet one or more specific option qualifications under each specialty or subspecialty of service below.	As specified in §493.1461, the candidate must meet one or more specific options	As specified in §493.1489, candidate must meet one or more options
<p><b>Option 1-</b> Illinois licensed MD/DO <b>AND</b> board certification in anatomical or clinical pathology.</p> <p><b>Option 2-</b> Illinois licensed MD/DO/DPM <b>AND</b> one- year of laboratory training during medical residency.</p> <p><b>Option 3-</b> Illinois licensed MD/DO/DPM <b>AND</b> at least two-years experience directing or supervising a high complexity CLIA-certified lab. (Note: type of experience required is <b>clinical</b>).</p> <p><b>Option 4-</b> Doctoral degree in a chemical, physical, biological or clinical lab science with current <b>board certification*</b>.</p> <p><b>Option 5-</b> 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 high complexity lab.</p> <p><b>Option 6-</b> On or before February 28, 1992, qualified under Illinois law to direct a laboratory.</p> <p><b>Option 7- For the Subspecialty of Oral Pathology,</b> 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.</p>	<p><b>Option 1-</b> Illinois licensed MD/DO/DPM.</p> <p><b>Option 2-</b> Doctoral degree in chemical, physical, biological or clinical lab science <b>AND board certified*</b> in specialty or subspecialty of service.</p> <p style="text-align: center;"><b>*HHS Approved Boards</b></p> <ol style="list-style-type: none"> <li>1. ABB- American Board of Bioanalysis.</li> <li>2. ABB- Public Health Microbiology Certification.</li> <li>3. ABCC- American Board of Clinical Chemistry.</li> <li>4. ABCC- 24mo Commission of Accreditation in Clinical Chemistry (COMACC) Accredited Program.</li> <li>5. ABFT- American Board of Forensic Toxicology.</li> <li>6. ABHI- American Board of Histocompatibility and Immunogenetics.</li> <li>7. ABMGG- American Board of Medical Genetics and Genomics.</li> <li>8. ABMLI- American Board of Medical Laboratory Immunology.</li> <li>9. ABMM- American Board of Medical Microbiology.</li> <li>10. NRCC- National Registry of Certified Chemists.</li> </ol>	<p><b>For Microbiology Subspecialties: bacteriology, mycobacteriology, mycology, virology and parasitology.</b></p> <p><b>Option 1-</b> 1 Illinois licensed MD/DO <b>AND</b> board certified in clinical pathology.</p> <p><b>Option 2-</b> IL Illinois licensed MD/DO/DPM/PhD in lab science <b>AND</b> one- year of laboratory training or experience in microbiology high complexity and six- months in subspecialty of testing.</p> <p><b>Option 3-</b> Master's degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> two-years lab training or experience in microbiology high complexity and six- months in subspecialty of testing.</p> <p><b>Option 4-</b> Bachelor's degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> four-years lab training or experience in microbiology high complexity and six-months in subspecialty of testing.</p> <p><b>For Specialties: Immunology, Chemistry, Hematology and Radiobioassay.</b></p> <p><b>Option 1-</b> Illinois licensed MD/DO <b>AND</b> board certified in clinical pathology.</p> <p><b>Option 2-</b> Illinois licensed MD/DO/DPM/PhD in lab science <b>AND</b> one-year lab training or experience in high complexity specialty of testing.</p> <p><b>Option 3-</b> Master's degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> two-years lab training or experience in high complexity specialty of testing.</p> <p><b>Option 4-</b> Bachelor's degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> four-years lab training or experience in high complexity specialty of testing.</p> <p><b>For the Specialty: Immunohematology</b></p> <p><b>Option 1-</b> Illinois licensed MD/DO <b>AND</b> board certified in clinical pathology.</p> <p><b>Option 2-</b> Illinois licensed MD/DO/DPM <b>AND</b> one-year laboratory training or experience in high complexity immunohematology testing.</p> <p><b>For the Specialty: Histocompatibility</b></p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM/PhD in lab science <b>AND</b> four-years training or experience within the specialty of histocompatibility or two-years training or experience in both general immunology and histocompatibility testing</p> <p><b>For the Specialty: Cytogenetics</b></p> <p><b>Option 1-</b> Illinois licensed MD/DO/DPM or PhD in lab science <b>AND</b> four-years lab training or experience in genetics with two of them in clinical cytogenetics.</p>	<p><b>Option 1-</b> Qualified as a lab director or technical supervisor of high complexity testing.</p> <p><b>Option 2-</b> Illinois licensed MD/DO/DPM</p> <p><b>Option 3-</b> Doctorate, master's, or bachelor's degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> one-year lab training and experience in high complexity testing.</p> <p><b>Option 4-</b> AA degree in a chemical, physical, biological or clinical lab science or medical technology <b>AND</b> two-years lab training /experience in high comp/testing.</p> <p><b>For Blood Gas Analysis-</b> If the candidate is not qualified under options 1, 2, 3 and 4 above, she/he must meet one of the following options.</p> <p><b>Option 1-</b> Bachelor's degree in respiratory therapy or cardiovascular technology <b>AND</b> one-year training and experience in blood gases analysis.</p> <p><b>Option 2-</b> AA degree related to pulmonary function <b>AND</b> two-years training and experience in blood gas analysis.</p> <p><b>For Histopathology, Oral Pathology, Dermatopathology and Ophthalmic Pathology</b> the general supervisor requirements are met because all tests and examinations must be performed by individuals qualified as technical supervisors and this meets the general supervisor qualifications.</p> <p><b>For Cytology</b></p> <p><b>Option 1-</b> Illinois licensed MD/DO <b>AND</b> board certified in both anatomic and clinical pathology or anatomic and American Society of Cytology.</p> <p><b>Option 2-</b> Qualified as a cytotechnologist by an organization approved by the department of Health and Human Services HHS <b>AND</b> three years full-time experience (2,080 hours/year) as a cytotechnologist within the previous 10 years.</p>	<p><b>Option 1-</b> Illinois licensed MD/DO/DPM</p> <p><b>Option 2-</b> Doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical lab science or medical technology.</p> <p><b>Option 3-</b> Associate's degree in a chemical, physical or biological science or medical lab technology</p> <p><b>Option 4-</b> Have education and training equivalent to <b>Option 3</b> with at least 60 semester hours to include either 24 in medical lab technology or 24 hours with (6-chemistry, 6-biology and 12 hours in chemistry, biology, medical technology in any combination) <b>AND</b> three months documented lab training in high complexity testing by specialty or completion of an approved department of Health and Human Services HHS lab training program (ABHES, CAHEA).</p> <p><b>Option 5-</b> Qualified as a technologist on or before February 28, 1992.</p> <p><b>Option 6-</b> On or before April 24, 1995, high school diploma or GED <b>AND</b> graduated from an HHS approved lab training program (ABHES, CAHEA) or military lab 50-week training course</p> <p><b>For Blood Gas Analysis-</b> If the candidate is not qualified under options 1 through 6 above, she/he must meet one of the following options.</p> <p><b>Option 1-</b> Bachelor's degree in respiratory therapy or cardiovascular technology <b>AND</b> one-year training and experience in blood gases analysis.</p> <p><b>Option 2-</b> AA degree related to pulmonary function <b>AND</b> two-years training and experience in blood gas analysis.</p>
<p><b>NOTE: The Laboratory Director, if qualified, may perform the duties and occupy the positions of the <u>clinical consultant, technical supervisor, general supervisor and testing personnel</u>, or delegate these responsibilities to qualified laboratory employees.</b></p> <p><i>Clinical Laboratory Improvement Amendments (CLIA) of 1988, and the CLIA regulations at 42 CFR Part 493 as specified in §493.1443, §493.1455, §493.1449, §493.1461 and §493.1489.</i></p> <p>Illinois, CLIA Laboratory Certification Program Phone: 217-782-6747 Fax: 217-782-0382</p> <p style="text-align: right;"><b>UPDATED: 05/11/18</b></p>				