



CLIA Required Personnel Qualifications

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Field Director

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Disclaimer

- ▶ This presentation includes some of the more common routes used by laboratories for personnel qualifications for the CLIA required roles
- ▶ For a complete listing of qualifications and role responsibilities see subpart M of the CLIA regulations.

http://wwwn.cdc.gov/clia/regs/subpart_m.aspx

Waived Testing

- ▶ No federally defined qualifications
- ▶ Anyone can be the Laboratory Director
 - The Joint Commission recommends that the individual at least meet the minimum qualifications defined in CLIA for moderate complexity testing personnel
- ▶ Anyone can perform testing

Provider-Performed Microscopy

- ▶ To qualify as PPM the test is performed by the provider during the patient visit in the context of a physical examination
- ▶ The Laboratory Director must meet one of the following requirements:
 - Be a physician
 - Be a midlevel practitioner (Nurse Practitioner, Nurse midwife, Physician Assistant)
 - Be a dentist

Moderate Complexity Testing

- ▶ Laboratory Director (LD)
- ▶ Technical Consultant (TC) – per specialty
- ▶ Clinical Consultant (CC)
- ▶ Testing Personnel (TP)

NOTE: A Medical Doctor (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM), or PhD with the appropriate experience can fill all four of the required positions

Moderate Complexity – Laboratory Director

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- ▶ MD, DO or DPM with current medical license in state of lab's location **AND** laboratory training/experience consisting of (only one required)
 - 1 year directing or supervising non-waived tests
 - 20 CME credit hours in laboratory practice commensurate with director responsibilities (effective 08/02/1993)
 - Equivalent laboratory training (20 CMEs) obtained during medical residency
- ▶ PhD in chemical, physical biological or clinical laboratory science **AND** certification by ABMM, ACBB, ABB, ABMLI

Moderate Complexity – Laboratory Director continued

- ▶ PhD in chemical, physical, biological or clinical laboratory science **AND** 1 year directing or supervising non-waived testing
- ▶ Masters in clinical laboratory science, medical technology or chemical, physical or biological science **AND** 1 year laboratory training/experience **AND** 1 year supervisory experience in a laboratory
- ▶ Bachelors in medical technology or chemical, physical or biological science **AND** 2 years laboratory training/experience **AND** 2 years supervisory experience in a laboratory
- ▶ **ON OR BEFORE 02/28/1992:** Qualified or could have qualified as a director under the laboratory regulations published March 14, 1990
- ▶ **ON OR BEFORE 02/28/1992:** Qualified as a director by the State in which the laboratory is located

Moderate Complexity – Technical Consultant

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- ▶ MD, DO, or DPM with current medical license in state of lab's location **AND** 1 year laboratory training/experience in the designated specialty/subspecialty or responsibility
- ▶ PhD in chemical, physical, biological or clinical laboratory science or medical technology **AND** 1 year laboratory training/experience in the designated specialty/subspecialty of responsibility
- ▶ Masters in chemical, physical, biological or clinical laboratory science or medical technology **AND** 1 year laboratory training/experience in the designated specialty/subspecialty of responsibility
- ▶ Bachelors in chemical physical, biological or clinical laboratory science or medical technology **AND** 2 years laboratory training/experience in the designated specialty/subspecialty of responsibility

Moderate Complexity – Clinical Consultant

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** laboratory training/experience consisting of (only one):
 - 1 year directing or supervising non-waived tests
 - 20 CME credit hours in laboratory practice commensurate with director responsibilities (effective 08/02/1993)
 - Equivalent laboratory training (20 CMEs) obtained during medical residency
- ▶ PhD in chemical, physical, biological or clinical laboratory science **AND** certification by ABMM, ABCC, ABB, ABMLI
- ▶ MD, DO, DPM with current medical license in state of lab's location

Moderate Complexity – Testing Personnel

- ▶ MD, DO, DPM with current medical license in state of lab's location
- ▶ PhD in laboratory science, chemical, physical, or biological science
- ▶ Masters in medical technology, laboratory science, chemical, physical, or biological science
- ▶ Bachelors in medical technology, laboratory science, chemical, physical, or biological science
- ▶ Associate degree in chemical, physical or biological science or medical laboratory technology
- ▶ High school graduate or equivalent and successfully completed military training of 50 or more weeks and served as a medical laboratory specialist
- ▶ High school diploma or equivalent and appropriate training/experience.

High Complexity Testing

- ▶ Includes any modified FDA-cleared or approved tests as well as laboratory developed tests
- ▶ Laboratory Director (LD)
- ▶ Technical Supervisor (TS) – per specialty
- ▶ Clinical Consultant (CC)
- ▶ General Supervisor (GS)
- ▶ Testing Personnel (TP)

NOTE: A Medical Doctor (MD), Doctor of Osteopathy (DO), Doctor of Podiatric Medicine (DPM), or PhD with the appropriate experience can fill all five of the required positions

High Complexity – Laboratory Director

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP, AOBP, or equivalent qualifications
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** 1 year laboratory training during medical residency
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** 2 years experience in directing/supervising high complexity testing
- ▶ PhD in chemical, physical, biological or clinical laboratory science **AND** certification by the HHS-approved boards (effective 02/24/2003)

High Complexity – Laboratory Director continued

- ▶ Hold an earned PhD in chemical, physical, biological, or clinical laboratory science from an accredited institution **AND** until 12/31/2002 must have served or be serving as director of a laboratory performing high complexity testing **AND** must have at least 2 years of laboratory training or experience or both **AND** 2 years of experience directing or supervising high complexity testing. (Directors meeting this qualification will be “grandfathered” in by CMS)
- ▶ **ON OR BEFORE 02/28/1992:** Serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under laboratory regulations published 03/14/1990
- ▶ **ON OR BEFORE 02/28/1992:** Qualified as director by the state in which the laboratory is located

High Complexity – Technical Supervisor

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP, AOBP, or equivalent qualifications
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** certified in clinical pathology by ABP, AOBP, or equivalent
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** 1 year training/experience in high complexity testing in the respective specialty
- ▶ PhD in clinical laboratory science, chemical, physical, biological science **AND** 1 year training/experience in high complexity testing in the respective specialty
- ▶ Masters in medical technology, clinical laboratory science, chemical, physical, or biological science **AND** 2 years training/experience in high complexity testing in the respective specialty
- ▶ Bachelors in medical technology, chemical, physical, or biological science **AND** 4 years training/experience in high complexity testing in the respective specialty

High Complexity – Clinical Consultant

- ▶ MD, DO with current medical license in state of lab's location **AND** certified in anatomic and/or clinical pathology by ABP or AOBP or equivalent qualifications
- ▶ MD, DO, or DPM with current medical license in state of lab's location **AND** 1 year laboratory training during medical residency
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** 2 years experience in directing/supervising high complexity testing
- ▶ PhD in chemical, physical, biological or clinical laboratory science **AND** certification by ABMM, ABCC, ABB, ABMLI, or other board deemed comparable by HHS
- ▶ MD, DO, DPM with current medical license in state of lab's location

High Complexity – General Supervisor

- ▶ Qualify as laboratory director of high complexity testing
- ▶ Qualify as technical supervisor of high complexity testing
- ▶ MD, DO, DPM with current medical license in state of lab's location **AND** 1 year training in high complexity testing
- ▶ PhD in clinical laboratory science or chemical, physical, biological science **AND** 1 year training/experience in high complexity testing
- ▶ Masters in clinical laboratory science, medical technology, or chemical, physical, biological science **AND** 1 year training/experience in high complexity testing
- ▶ Bachelors in medical technology or chemical, physical, biological science **AND** 1 year training/experience in high complexity testing

High Complexity – General Supervisor continued

- ▶ Associate Degree in laboratory science or medical laboratory technology **AND** have at least 2 years of laboratory training or experience, or both, in high complexity testing
- ▶ Education and training equivalent to an associates degree in laboratory science or medical laboratory technology **AND** have at least 2 years laboratory training or experience, or both, in high complexity testing
 - Education – 60 semester hours including either 24 semester hours of medical laboratory courses or 24 semester hours of science courses (6 hours chemistry; 6 hours biology; and 12 hours in chemistry, biology, or medical laboratory technology, or any combination
 - Training – either completion of an approved/accredited clinical laboratory or medical laboratory training program, which may be included in the 60 semester hours specified above or three months of documented laboratory training in each specialty in which the individual performs high complexity testing
- ▶ For blood gas analysis, earned an associate degree related to pulmonary function **AND** have at least 2 years of laboratory training or experience, or both, in blood gas analysis

High Complexity – General Supervisor continued

- ▶ **ON OR BEFORE 02/28/1992:** Qualified or could have qualified as a general supervisor under 42 CFR 493.1433 laboratory regulations published 03/14/1990
- ▶ **ON OR BEFORE 09/01/1992:** Served as a general supervisor of high complexity testing **AND** as of 04/24/1996 have at least 2 years of clinical laboratory training or experience, or both, in high complexity testing (either before or after completing the accredited or military medical laboratory training) **AND** meet 1 of the following:
 - Have graduated from an approved or accredited medical laboratory or clinical laboratory program
 - Be a high school graduate or equivalent **AND** have successfully completed at least a 50 week official US military medical laboratory procedures course **AND** have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician)
- ▶ **ON OR BEFORE 09/01/1992:** Served as a general supervisor of high complexity testing **AND**
 - Have a high school diploma or the equivalent **AND**
 - Have at least 10 years of laboratory training or experience, or both in high complexity testing, including at least 6 years of supervisory experience between 09/01/1982 and 09/01/1992

High Complexity – Testing Personnel

- ▶ MD, DO, DPM with current medical license in state of lab's location
- ▶ PhD in clinical laboratory science or chemical, physical, or biological science
- ▶ Master's in medical technology, clinical laboratory science or chemical, physical, or biological science
- ▶ Bachelor's in medical technology, clinical laboratory science or chemical, physical, or biological science
- ▶ Associate degree in laboratory science or medical laboratory technology

High Complexity – Testing Personnel continued

- ▶ Education **AND** training equivalent to an associate degree in laboratory science or medical laboratory technology:
 - Education - 60 semester hours including either 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses (6 hours of chemistry; 6 hours of biology, and 12 hours in chemistry, biology or medical laboratory technology, or any combination)
 - Training – either completion of an approved/accredited clinical laboratory training program, which may be included in the 60 semester hours specified above or at least three months of documented laboratory training in each specialty in which the individual performs high complexity testing
- ▶ **ON OR BEFORE 02/28/1992:** Qualified or could have qualified as a technologist under laboratory regulations published 03/14/1990. **Does not apply after 09/01/1997**

High Complexity – Testing Personnel continued

- ▶ **On OR BEFORE 04/24/1995:** With a high school degree of equivalent **AND** either one below
 - Have graduated from an approved or accredited medical laboratory or clinical laboratory training program
 - Have successfully completed at least a 50 week official US military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician)
- ▶ **AFTER 09/01/1997** the high school diploma route can no longer be used for new employees.

Cytology Testing

- ▶ Cytology General Supervisor (CGS)
- ▶ Cytology Technologist (CT)

Non-Waived POCT

- ▶ **Under their own Moderate Complexity CLIA certificate:** individuals with the proper qualifications must be identified for the positions of director, technical consultant, clinical consultant, and testing personnel
- ▶ **Under their own High Complexity CLIA certificate:** individuals with the proper qualifications must be identified for the positions of director, technical supervisor, clinical consultant, general supervisor, and testing personnel
- ▶ **Under the central laboratory CLIA certificate:** only the requirements for testing personnel usually need to be addressed