

Personnel Qualification Requirements

Determine if your lab performs moderate or high complexity testing. Only complete the section that is appropriate for the complexity level of your MTS.

Moderate Complexity Testing

Director (check only one and **provide a copy of evidence of credentials with application submission**)

- 1. Pathologist w/State license
- 2. MD, DO, DPM with State license and 1 year directing or supervising non-waived testing:
Which lab _____ Dates _____
- 3. MD, DO, DPM with State license and 20 CMEs in laboratory practice:
Which program _____ Dates _____
- 4. MD, DO, DPM with State license and lab training during residency equivalent to 20 CMEs:
Which program _____ Dates _____
- 5. Doctor of Optometry performing testing only within their scope of practice.
- 6. PhD in science
+ board certification (ABB, ABMM, ABCC, ABMLI)
- 7. PhD in science (choosing this option requires a clinical consultant)
+ 1 yr directing or supervising non-waived testing
- 8. Master in science (choosing this option requires a clinical consultant)
+ 1 yrs lab training and/or experience and
1 yrs laboratory supervisory experience
- 9. Bachelor in science (choosing this option requires a clinical consultant)
+ 2 yrs lab training and/or experience and
2 yrs laboratory supervisory experience

Clinical Consultant (check only one and **provide a copy of evidence of credentials with application submission**)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
- 3. PhD in science
+ board certification (ABB, ABMM, ABCC, ABMLI)

Technical Consultant (check only one)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
+ 1 yr training and/or exper. in the laboratory specialty
- 3. PhD or Master in science
+ 1 yr training and/or exper. in the laboratory specialty
- 4. Bachelor in science
+ 2 yr training and/or exper. in the laboratory specialty
- 5. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements

Testing Personnel (include total # of personnel performing testing in front of appropriate categories)

- 1. MD, DO, DPM, PhD, master or bachelor degree in science, or associate degree in science or medical lab technology
- 2. H.S. graduate or equivalent
+ 50 week military medical laboratory procedures course
- 3. H.S. graduate or equivalent with documented training for testing performed

High Complexity Testing

Director (check only one and **provide a copy of evidence of credentials with application submission**)

- 1. Pathologist w/ State license
- 2. MD, DO, DPM with State license and 1 year lab training in medical residency:
Which program _____ Dates _____
- 3. MD, DO, DPM with State license and 2 years directing or supervising high complexity testing:
Which lab _____ Dates _____
- 4. PhD in science
+ board certification by HHS approved board; or served as high complexity testing director before 2/24/03
- 5. For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology (dentists), American Board of Pathology, or American Osteopathic Board of Pathology or equivalent

High Complexity Test (continued)

Clinical Consultant (check only one and provide a copy of evidence of credentials with application submission)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
- 3. PhD in science
+ board certification (ABB, ABMM, ABCC, ABMLI)
- 4. DDS certified in oral pathology (ABOP, ABP, AOBP)

Technical Supervisor Qualifications:

Chemistry, Hematology, Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology and Diagnostic Immunology (include total # of personnel performing duties in front of appropriate categories)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
+ 1 yr training and/or experience in high complexity testing in laboratory specialty
- 3. PhD in science
+ 1 yr training and/or experience in high complexity testing in laboratory specialty
- 4. Master in science
+ 2 yrs training and/or experience in high complexity testing in laboratory specialty
- 5. Bachelor in science
+ 4 yrs training and/or experience in high complexity testing in laboratory specialty

Technical Supervisor Qualifications:

Histocompatibility, Cytogenetics, Immunohematology and Pathology (include total # of personnel performing testing in front of appropriate categories)

Histocompatibility

- 1. MD, DO, DPM w/State license or PhD
+ 4 yrs of training and/or experience in histocompatibility; or 2 yr in general immunology + 2 yr in histocompatibility

Cytogenetics

- 1. MD, DO, DPM w/State license or PhD
+ 4 yrs of training and/or experience in genetics, 2 of which have been in clinical cytogenetics

Immunohematology

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license
+ 1 yr of training and/or experience in high complexity immunohematology

Pathology

- 1. For histopathology, anatomic pathologist*;
- 2. For dermatopathology, anatomic pathologist, dermatopathologist, or dermatologist certified by American Board of dermatology*
- 3. For oral pathology, anatomic pathologist or oral path.*
- 4. For ophthalmic pathology, anatomic pathologist or certified by American Board of Ophthalmology*

- 5. For cytology, anatomic pathologist or MD/DO certified by American Society of Cytology**

* Can delegate responsibility for examination and interpretation to a resident

** Can delegate some responsibilities to resident in final year of full-time training

General Supervisor (include total # of personnel performing duties in front of appropriate categories)

- 1. Pathologist w/State license
- 2. MD, DO, DPM w/State license + 1 yr of training and/or experience in high complexity testing
- 3. PhD, master or bachelor in science
+ 1 yr training and/or exper. in high complexity testing
- 4. AS/AA in lab science or medical technology + 2 yr training and/or exper. in high complexity testing
- 5. Education equivalent to AA degree (60 semester hrs) in lab science + documented lab training program (at least 3 mos); + 2 yr T/or E in high complex testing

General supervisor: Blood Gas Analysis (include total # of personnel performing duties in front of appropriate categories)

- 1. Qualify as a general supervisor of high complexity testing listed above
- 2. Bachelor degree in respiratory therapy or cardiovascular technology + 1 yr training and/or exper. in blood gases
- 3. Associate degree related to pulmonary function
+ 2 yrs training and/or experience in blood gas analysis

Testing Personnel (include total # of personnel performing testing in front of appropriate categories)

- 1. MD, DO, DPM w/State license, PhD, master, or bachelor degree in science
- 2. Associate degree in lab science or medical lab technology or 60 semester hrs in science + approved lab training program
- 3. On 2/28/92, previously qualified or could have qualified as a technologist under previous Medicare/CLIA independent lab personnel requirements
- 4. On 4/24/95, H.S. graduate performing high complexity testing + completed med lab clinical training program or 50 week US military program
- 5. On 4/24/95, H.S. graduate performing high complexity testing + appropriate training
- 6. Until 9/1/97, H.S. graduate or equivalent with documented training for the testing performed (if hired before 1/19/93, no direct on-site supervision if results reviewed by general supervisor within 24 hours)
- 7. For blood gas analysis, qualify under 1, 2, 3, 4, 5, 6; or bachelor in resp. therapy or cardiovascular technology; or associate degree in pulmonary function

High Complexity Test (continued)

Cytology General Supervisor

- ___ 1. Qualify as a technical supervisor in cytology
- ___ 2. Qualify as a cytotechnologist + 3 yrs full time (2080 hrs/yr) experience within preceding 10 yrs

Cytotechnologist (include total # of personnel performing testing in front of appropriate categories)

- ___ 1. Anatomic pathologist or cytopathologist or resident
- ___ 2. Graduate from an accredited school of cytotechnology
- ___ 3. Certified in cytotechnology by an approved agency
- ___ 4. Prior to 9/1/92:
 - 2 yrs of college (12 semester hrs in science, 8 of which are biology, + 12 mos training in an approved school of cytotechnology
 - 6 mos of formal training in an approved school of cytotechnology + 6 mos FT experience in cytotechnology in lab acceptable to pathologist who directed training.
 - achieved a satisfactory grade in an HHS proficiency exam for cytotechnologist
- ___ 5. Prior to 9/1/94:
 - 2 yrs FT exp. within preceding 5 yrs examining slide preps under supervision of a TS in cytology and prior to 1/1/69:
 - graduated from high school.
 - completed 6 mos training in cytotechnology directed by a pathologist or other MD providing cytology services.
 - 2 yrs FT supervised experience in cytotechnology
- ___ 6. Prior to 9/1/94:
 - 2 yrs of FT experience under supervision of a TS in cytology in US in past 5 yrs; and by 9/1/95 graduate from an accredited school or be certified by an approved agency