


Name of Policy: CLIA '88 Testing Personnel Requirements		 Effective date: 01/04/2025 Original effective date: 05/20/1995	
Policy Number: 3364-107-201			
Approving Officer: Medical Director, Clinical Pathology			
Responsible Agent: Director, Clinical Pathology Administrative Director, Lab			
Scope: Pathology Laboratory University of Toledo Medical Center			
Key words: CLIA 88, testing personnel, qualifications, high complexity testing, general supervisor			
<input type="checkbox"/>	New policy proposal	<input type="checkbox"/>	Minor/technical revision of existing policy
<input type="checkbox"/>	Major revision of existing policy	<input checked="" type="checkbox"/>	Reaffirmation of existing policy

(A) Policy statement

All staff must be qualified according to CLIA '88 testing personnel requirements.

(B) Purpose of policy

To define testing personnel qualifications for high complexity testing.

(C) Procedure

Individuals employed to perform high complexity testing must be classified as UTMC Lab Tech III or UTMC Lab Sr. Tech IV and qualify by one of the following routes:

- ❖ Master's in medical technology, clinical laboratory science, chemical, physical, or biological science or 60 semester hours including either 24 hours of medical technology or 16 hours of chemistry and 8 hours of biology and requiring either 1 year of clinical laboratory training including each of the laboratory specialties or 3 months of training in each specialty in which the individual performs high-complexity testing and certified by ASCP as MLS, C, H, BB or I, or eligible for such certifications OR
- ❖ Bachelor's in medical technology, clinical laboratory science, chemical, physical or biological science or 60 semester hours including either 24 hours of medical technology or 16 hours of chemistry and 8 hours of biology and requiring either 1 year of clinical laboratory training including each of the laboratory specialties or 3 months of training in each specialty in which the individual performs high-complexity testing and certified by ASCP as MLS, C, H, BB or I, or eligible for such certifications OR

- ❖ Associate degree in chemical, physical or biological science or medical laboratory technology science or 60 semester hours including either 24 hours of medical technology or 16 hours of chemistry and 8 hours of biology and requiring either 1 year of clinical laboratory training including each of the laboratory specialties or 3 months of training in each specialty in which the individual performs high complexity testing OR
- ❖ Education and training equivalent to an associate degree in a laboratory science or medical laboratory technology or associate degree in medical laboratory technology or completion of military training program (Medical Laboratory Specialist from the US Military, 50-week course prior to April 25, 1995).
- ❖ Anyone hired after April 24, 1995, must have an associate degree at minimum.

Individuals qualified as General Supervisor under CLIA may verify competency and review policy and procedure at UTMC:

- ❖ Master's in clinical laboratory science, medical technology or chemical, physical, or biological science and 1-year training and experience in high-complexity testing; OR
- ❖ Bachelor's in clinical laboratory science, medical technology or chemical, physical, or biological science and 1-year training and experience in high-complexity testing; OR
- ❖ Associate degree in medical laboratory technology (or pulmonary function) and 2 years' laboratory (or blood gas analysis) training or experience, or both, in high-complexity testing.

The CAP testing personnel roster is reviewed annually for accuracy and updated as needed prior to interim self-inspection and on-site inspection.

<p>Approved by:</p> <p><u>/s/</u> Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology</p> <p><u>1/10/2025</u> Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Joshua Otiso, Administrative Director, Lab</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none">• <i>P-01</i> <p>Initial effective date: 05/20/1995</p> <p>Review/Revision Date: 01/04/2025</p> <p>Next review date: 01/04/2027</p>
--	---