



CLIA Testing Personnel Competency Assessment Requirements

Assessment Frequency:

- At least semi-annually (twice in the first year) for new employees performing patient testing.
- Annually thereafter for all testing personnel.

Six Required Competency Assessment Elements:

1. Direct Observation of Routine Testing Procedures
 - a) Ensure personnel correctly follow test protocols and safety procedures.
2. Monitoring Test Result Recording & Reporting
 - a) Assess accurate documentation and interpretation of results.
3. Review of QC, Proficiency Testing, & Preventive Maintenance Records
 - a) Confirm proper handling of quality control (QC) and participation in proficiency testing (PT).
4. Performance of Previously Tested Specimens, Blind Samples, or PT
 - a) Evaluate accuracy using unknown or pre-analyzed samples.
5. Problem-Solving Skills & Corrective Actions
 - a) Assess how personnel troubleshoot QC failures and instrument issues.
6. Assessment of Instrument Maintenance & Calibration
 - a) Verify that personnel correctly perform and document equipment maintenance.

Documentation & Compliance:

Competency assessments must be documented and available for inspection.

The laboratory director or designee is responsible for ensuring compliance.