COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 16

Personnel Training and Competency Assessment

●Overview ●

Effective training and meaningful competency assessments are essential for a quality laboratory.

Training provides personnel with the knowledge and skills to perform laboratory tasks effectively and helps standardize processes, enabling personnel to produce accurate and reliable results.

Competency assessments are a quality measure that confirms the training was effective. They evaluate the ongoing ability of personnel to perform tasks per procedure, as well as reinforce understanding and skills along with providing an opportunity for improvement when necessary.

●Training●

All laboratory personnel must be trained before they begin patient testing. General Supervisors, Technical Consultants and competent, experienced testing personnel are considered qualified laboratory personnel who may administer training. The training should be specific and documented. At the completion of training, the documentation must be evaluated and signed by the personnel, the trainer and the Laboratory Director (or designee).

Read, Observe, Perform, Review

A comprehensive training approach involves:

- Reading laboratory policies and procedures (including manufacturer's instructions and package inserts)
- Observing the preanalytic, analytic and postanalytic phases of testing
- Performing laboratory processes under competent supervision
- A review of documentation and training

Initial Training

A standardized training checklist helps guide and document initial training and should include:

- Required policies and training
  - FDA medical device alert
  - OSHA and blood-borne pathogens
  - Incident management reporting
  - HIPAA guidelines
  - Laboratory and facility safety procedures
- Computer/EMR functions, including test ordering and result reporting
- Quality Control (QC) processes
  - Storage, preparation and labeling of reagents and controls
  - QC acceptability and rejection criteria
  - Corrective action to take before testing patients
- Instrument maintenance (where applicable)
  - Function checks
  - Calibrations and calibration verifications

© 11/2026 COLA

- Testing
  - Test name, purpose, equipment and supplies needed
  - Specimen collection, handling and processing (both for in-house testing and send-outs for reference laboratory testing)
  - Step-by-step instructions for each test performed
  - Interpretation and reporting of patient test results
  - Critical values
- Quality Assessment (QA) plan and documentation

Updated training

Retraining is required with:

- New instruments or methodology changes
- Changes to existing procedures

●Competency Assessment●

The Laboratory Director is responsible for establishing policies and procedures for the competency assessment of personnel responsible for testing, supervision and consultation.

For testing personnel, competencies assess actual performance in the preanalytic, analytic and postanalytic phases of testing. The focus is on the testing personnel's ability to perform testing according to a defined process and procedure to ensure accurate and reliable laboratory results.

For supervisory personnel, competencies assess fulfillment of the duties and responsibilities of their position.

Frequency

Personnel in each CLIA-defined position in the laboratory must have competency assessments performed semi-annually for the first year and annually thereafter.

Who Can Perform Competency Assessments?

Only qualified laboratory personnel can perform competency assessments.

In a *Moderate Complexity* laboratory, the Technical Consultant is responsible for conducting, evaluating and signing off on the competency assessments. Note that the required qualifications for Technical Consultant are updated as of December 28, 2024, to include an associate's level laboratory technician with four years of qualifying experience.

In a *High Complexity* laboratory, competency assessments are the responsibility of the Technical Supervisor.

However, the responsibility for performing competency assessments may be delegated to any other individual, provided that they meet the qualifications of a Technical Consultant in a moderate complexity laboratory or a Technical Supervisor or General Supervisor in a high complexity laboratory. The qualified General Supervisor may perform competency for both

© 11/2026 COLA

moderate and high complexity testing. The Laboratory Director should delegate this responsibility in writing.

Refer to COLA Primer 4: *Personnel Requirements in a Non-Waived Laboratory* for information on the qualifications for the CLIA-required positions of Technical Consultant, Technical Supervisor and General Supervisor.

Competency Assessments for Testing Personnel

The competency for testing personnel must include the six methods of assessment required by CLIA regulations. .

1. Direct observation of routine patient test performance, including patient preparation (if applicable), specimen handling, processing and testing
2. Monitoring the recording and reporting of test results
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously-analyzed specimens, internal blind sample testing or external proficiency testing samples
6. Assessment of problem solving skills

Note: Testing personnel who "float" to different laboratories in a multi-site system are required to have training and competency assessments documented at each location they cover.

Competency Assessments for Consultants and Supervisors

Supervisory and consulting positions include Clinical Consultants, Technical Consultants, Technical Supervisors and General Supervisors. The competencies for supervisory and consulting personnel assess fulfillment of the duties and responsibilities of their position and must be documented and signed by the Laboratory Director for each laboratory they oversee. This requirement applies to individuals internal and external to the laboratory organization. If these individuals also perform patient testing, they also must have documented testing personnel competency assessments as outlined in the section above.

Provider Performed Microscopy (PPM)

Competency assessment is required for PPM testing. However, since most laboratories have microscope maintenance performed by another department or a contracted vendor, the requirement for direct observation of instrument maintenance does not apply to tests in this category. Providers that perform PPM testing, as well as non-providers who perform these same microscopic exams, must undergo competency assessment at the frequency described above.

Resources

Competency assessment templates and examples are available on COLAcentral. The template for Testing Personnel documents the six methods of assessment and the example demonstrates how to fill out the form. Templates are also available for the competency assessments for the Clinical Consultant, the General Supervisor and the Technical Supervisor/Technical Consultant.

© 11/2026 COLA

See: *COLAcentral>Document Center>Solutions Library>Personnel.*

●Continuing Education●

Continuing education (CE) is an investment in the personnel's knowledge and engagement in the laboratory and is required for laboratory personnel to stay current with laboratory practices, new testing methods and topics of disease.

COLA requires some form of laboratory-related CE to be documented for all laboratory personnel. In addition, some states require that laboratory personnel complete a specific number of continuing education credits per year or per license renewal cycle.

Continuing education opportunities are widely available. CE credits may be obtained through (but not limited to) the following sources:

- Laboratory magazines (online and print)
- Proficiency testing providers
- Podcasts
- Webinars produced by organizations such as Lab Roots, Whitehat Communications or the CDC
- Courses on COLA Academy

© 11/2026 COLA