Clinical Laboratory Improvement Amendments (CLIA)

ASSESSING PERSONNEL COMPETENCY

Assessing laboratory personnel competency, or the ability to correctly apply their skill, knowledge, training, and experience to their laboratory duties, is an important part of complying with CLIA requirements. This brochure describes key procedures for a laboratory competency assessment and explains how to assess and document laboratory personnel competency by personnel roles and test complexity.

GENERAL INFORMATION

What's a laboratory competency assessment?

A laboratory competency assessment is a way for laboratories to assess whether personnel can adequately perform their duties. CLIA requires that moderate and high complexity laboratories demonstrate and document competency for all personnel who perform laboratory testing. For laboratories only performing waived testing, CLIA does not require a competency assessment for Testing Personnel (TP), however, it is good laboratory practice. All TP should be properly trained to follow all manufacturers' instructions.

Important: Training and personnel evaluations **differ** from competency assessments and do not satisfy the CLIA requirement for a documented laboratory competency assessment. More specifically:

- Training is a process that develops laboratory personnel's knowledge, skills, and behaviors **before** they begin testing. After training, a competency assessment evaluates whether they're following laboratory policies and procedures and doing the testing correctly.
- Personnel evaluations rate laboratory personnel behaviors and attributes related to the position, job, or role.

What are the required competency assessment procedures?

A competency assessment includes six required procedures that apply to all personnel who perform moderate or high complexity laboratory testing and for every test performed (even when multiple tests are part of a single testing platform). The six procedures of a competency assessment include:

1. Directly observing routine test performance, including patient preparation and, if applicable, specimen handling, processing, and testing.
2. Monitoring the recording and reporting of test results.
3. Reviewing intermediate test results or worksheets, quality control (QC) records, proficiency testing (PT) results, and preventive maintenance records.
4. Directly observing instrument performance, maintenance, and function checks.
   Note: This procedure does not apply to a competency assessment for Provider-performed Microscopy (PPM) procedures.
5. Assessing test performance using previously analyzed test specimens, internal blind testing samples, or external PT samples.
6. Assessing problem-solving skills.

How often should our laboratory perform a competency assessment?

You must perform a competency assessment for all personnel who perform laboratory testing **at least once a year**. All six procedures must be documented for each of these personnel each year. However, you must perform a competency assessment **at least two times** (semi-annually) during the first year that laboratory personnel test patient specimens in your laboratory.

If the laboratory acquires new analyzers or changes methodology, TP should be trained and competent before reporting patient results.

***Tip**: Competency assessment can be done **throughout the entire year** by coordinating it with routine laboratory practices and procedures to minimize impact on workload.*

Is competency assessment the same as PT?

A competency assessment confirms that TP can adequately perform their laboratory duties, but it is not the same as PT. While you can use PT performance as part of your competency assessment, it's insufficient to meet all six procedures and **does not** satisfy the CLIA requirement for a documented laboratory competency assessment. Refer to the Proficiency Testing and PT Referral Brochure on the CLIA Brochures page for more information.

PERSONNEL & TEST COMPLEXITY

Does a laboratory director need a documented competency assessment?

If the Laboratory Director (LD) is the only individual testing and reporting test results, they must establish and document a minimum proficiency level that shows they maintain the required competency to perform and report accurate and reliable test results. This could be accomplished through testing PT samples or having another entity review their work for accuracy. They'll also be evaluated during a survey to ensure they're meeting their regulatory responsibilities.

Who must have a documented competency assessment?

A documented competency assessment is required for laboratory personnel in the following roles:

- Clinical Consultant (CC)
- Technical Consultant (TC)
- Technical Supervisor (TS)
- General Supervisor (GS)
- Testing Personnel (TP)

The CC, TC, TS, and GS must have a competency assessment that's based on their federal regulatory responsibilities outlined in Subpart M of the CLIA regulations at 42 CFR Part 493.

All TP and any CC, TC, TS, and GS that also perform testing must have the six procedures for testing included in their competency assessment.

Who is responsible for performing a competency assessment?

The LD is ultimately responsible for ensuring that the laboratory completes all competency assessments, and that TP are competent so they consistently perform and report accurate and reliable test results.

LDs of Certificate of Compliance laboratories can only delegate competency assessment responsibilities to personnel who meet the regulatory qualifications belonging to a TC, TS, or GS, since these personnel are qualified to perform competency assessments for TP.

LDs of Certificate of Accreditation laboratories should contact their accreditation organization for more information.

The personnel who can perform a competency assessment **will depend** on the test complexity performed in your laboratory. Specifically, in laboratories that perform:

- **Waived testing:** CLIA does not require a competency assessment for TP. However, you must ensure they are trained properly and follow all manufacturers' instructions to perform the test(s) correctly and get accurate results.

- **Moderate complexity testing**: The TC performs and documents competency assessments for TP. However, other personnel who meet the TC regulatory qualification requirements can also perform competency assessments.

- **Provider-Performed Microscopy (PPM) testing:** The LD is responsible for evaluating the competency assessment for all TP who are midlevel practitioners, doctors and dentists by the definition of PPM. However, the LD may delegate the responsibility of individual procedures of competency, in writing, to other qualified PPM TP.

  Remember, PPM competency assessments only need to include five of the six procedures in a competency assessment. Directly observing instrument performance, maintenance, and function checks **don't** apply.

- **High complexity testing**: The TS performs and documents competency assessments for all TP. However, a TS may delegate the responsibility, in writing, to a GS if they meet the regulatory qualification requirements.

Remember, an LD may share dual responsibilities with laboratory personnel in certain positions. In situations when an LD performs duties belonging to a TC, TS, and/or GS, they're responsible for performing competency assessments for all TP. Refer to the Laboratory Director Responsibilities Brochure on the CLIA Brochures page for more information.

Important: *Personnel who don't meet the regulatory qualifications of a TC, TS, or GS* ***cannot*** *perform or be designated to perform competency assessments.*

What should I consider in a competency assessment?

The following table highlights items you should consider when assessing personnel competency by role, including delegated responsibilities.

Delegated Responsibility	CC	TC	TS	GS	TP
Available to assist the laboratory's clients to ensure the appropriate tests to meet clinical expectations are ordered.	✓				
Ensures that test result reports include relevant information that patients can understand and interpret.	✓				
Available to provide clinical consultation to the laboratory's clients, particularly about test result report quality and their ability to understand their condition(s). **Tip:** Consider laboratory client feedback and satisfaction.	✓				
Available to provide consultation to the laboratory.		✓	✓		
Selects test methods appropriate to the laboratory's patient population.		✓	✓		
Assures performance specifications are established or verified for necessary tests.		✓	✓		
Ensures that the laboratory is enrolled and participating in an HHS-approved PT program for each test that requires PT. **Tip:** Consider how well the laboratory performs PT and whether they conduct the appropriate reviews after receiving PT results.		✓	✓		
Ensures that a QC program is in effect and is adequate for the laboratory's testing performance.		✓	✓		
Resolves technical problems and ensures remedial actions are taken when there's a test system failure.		✓	✓	✓	
Identifies training needs and assures that TP get regular in-service training and education appropriate to the tests they perform.		✓	✓		
Evaluates TP competency and ensures they maintain their competency to perform and report accurate, reliable, and timely test results.		✓	✓	✓	
Uses techniques that the laboratory determines appropriate for evaluating TP competency.		✓	✓		
Ensures that patient test results are reported after taking all corrective actions and confirming the test system functions properly.		✓	✓	✓	
Is accessible to TP whenever they perform testing.				✓	
Provides day-to-day supervision.				✓	
Monitors test analyses and specimen examinations to ensure analytic performance maintains acceptable levels.				✓	
Makes sure all TP are oriented and trained.				✓	
Correctly processes the specimen used in testing.					✓

Understands the test report and completes it correctly, using the appropriate measurement units.					✓
Performs the test correctly, e.g., adds the proper amount of testing solutions/reagents in the appropriate order, collects sufficient patient specimens and correctly adds them to the test system, uses test solutions/reagents from the same test kit & lot number, and reviews expiration date.					✓
Maintains patient testing result records.					✓
Treats PT samples the same as patient specimens and maintains records indicating such.					✓
Adheres to the laboratory's policies and documents QC activities.					✓
Adheres to the laboratory's policies for instrument calibration and maintenance.					✓
Follows the laboratory's corrective action policies and procedures when a test system fails to meet the laboratory's acceptable performance level.					✓
Identifies problems that may affect test performance or reporting results. Either corrects the problem or notifies the TC or LD.					✓
Documents corrective action(s) taken when there's a test system failure.					✓

What should I consider in a PPM competency assessment?

When you're completing a PPM competency assessment, you may want to consider the following questions in addition to the five required procedures:

- Is the test performed during the patient's visit?
- Is the correct microscope type used (limited to brightfield or phase/contrast)?
- Is the patient specimen processed correctly and timely?
- Do all TP perform the test according to the laboratory's procedure?
- Do all TP report the test using the using the correct units/terminology and in a timely manner?

Do I need to perform a competency assessment on every analyte?

CLIA requires that laboratories perform a competency assessment that include the specific test procedures performed by TP. Your laboratory should assess tests with unique aspects, problems, or procedures (e.g., ammonia received on ice or similar) to ensure that TP maintain their competency to perform and report accurate, reliable, and timely test results.

Do I need to perform competency assessments for other types of personnel?

Whether you perform competency assessments for other personnel in your laboratory will depend on their roles and responsibilities. For example, a competency assessment **isn't** required by regulation for non-testing personnel, but it's considered good laboratory practice and a good quality assurance measure. These individuals may include:

- Individuals who only draw blood
- Individuals who only label or process samples
- Phlebotomists, **unless** they perform bleeding times, which are categorized as a moderate complexity test
- Accessioning personnel

Ultimately, the LD is responsible for ensuring that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training.

WHERE CAN I FIND MORE INFORMATION?

For more information and resources about the CLIA program and regulations, visit:

Resource	Website
CMS CLIA Website	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
CDC CLIA Website	https://www.cdc.gov/clia/php/about/index.html
FDA CLIA Website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CLIA State Agency Contact List	https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf
CLIA Regulations 42 CFR 493	https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493
PPM Booklet	https://www.cdc.gov/lab-quality/docs/PMP_Booklet_7252019.pdf

You can also email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

Note: *This brochure presents information about personnel competency. It's not intended to replace or substitute CLIA regulatory requirements. Note that state, local, and accreditation requirements may be more stringent.*

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Congress passed the **Clinical Laboratory Improvement Amendments (CLIA) in 1988,** establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. The information provided in this brochure is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This brochure summarizes current policy and operations as of the date it was published. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.