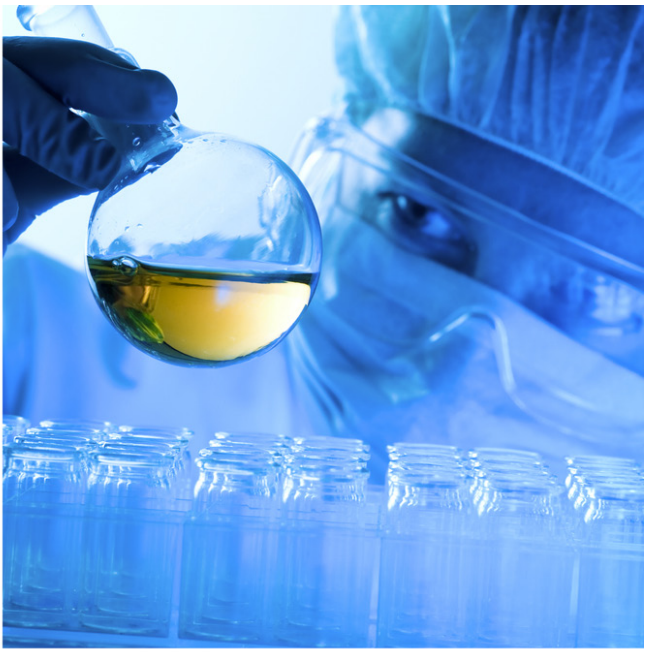
CMS
CENTERS FOR MEDICARE & MEDICAID SERVICE

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

What Do I Need to Do to Assess Personnel Competency?



GENERAL INFORMATION

What is competency and CLIA competency assessment?

Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly. Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.

The following six (6) procedures are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:

1. Direct observations 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 observations of performance of instrument maintenance and function checks;
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Assessment of problem solving skills.

Competency assessment, which includes the six procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform.

Who is required to have a competency assessment?

Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities.

Note: If the laboratory director (LD) is the only individual testing and reporting test results, they must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting.

Who is responsible for performing the competency assessment?

The Technical Consultant for moderate complexity testing (42 CFR §493.1413(b)(8)) is responsible for performing and documenting competency assessments. The competency assessments may also be performed by other personnel who meet the regulatory qualification requirements for TC for moderate complexity testing.

The Technical Supervisor for high complexity testing (42 CFR 493.1451(b)(8)) is responsible for performing and documenting competency assessments. This responsibility can be delegated, in writing, to a General Supervisor as long as the GS meets the regulatory qualifications as a GS for high complexity testing.

Peer testing personnel who do not meet the regulatory qualifications of a TC, TS, or GS cannot be designated to perform competency assessments.

Ultimately, the LD is responsible to ensure that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results.

How often should competency assessment be performed?

Evaluating and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual tests patient specimens. Thereafter, competency assessment must be performed at least annually. **Competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.**

Note: If test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

FREQUENTLY ASKED QUESTIONS

I am the laboratory director of a large laboratory that performs some moderate complexity testing in a clinical setting point of care testing (POCT). I have a number of TP that perform POCT who are overseen by a nurse manager. Is it acceptable under CLIA for the nurse manager to perform competency assessment of the POCT personnel?

It is acceptable for the nurse manager to perform the competency assessment of these individuals if the nurse manager meets the regulatory requirements to qualify as a TC and you have delegated this responsibility in writing.

Do I need to assess all six (6) procedures of competency?

Yes, all six procedures must be addressed for personnel performing testing for all tests performed; however, the competency assessment can be done throughout the entire year by coordinating it with routine practices and procedures to minimize impact on workload.

If my laboratory only performs waived testing, do I need written policies for assessing personnel competency?

CLIA does not require policies for assessing personnel competency for waived testing. Even though CLIA has no specific requirements for personnel performing waived testing, you need to ensure that patient testing results are correct to assist in making an accurate patient diagnosis. You will need to ensure that testing personnel are following all manufacturers' instructions. Testing personnel who are properly trained and performing the test correctly will aid the physician/provider in making an accurate patient diagnosis. If your laboratory is accredited, you may need to consult your accrediting organization's standards.

I am a sole practitioner and perform all of my own laboratory testing; does CLIA require that I have written policies for assessing my own competency?

You will need to ensure that you maintain the required competency for reliable testing and reporting. You must also establish a minimal level of proficiency in order to demonstrate your competency. This could be accomplished via testing of proficiency testing samples or another entity reviewing your work to determine your competency. You will also be evaluated during the survey to ensure that you are meeting your regulatory responsibilities.

My laboratory performs only provider-performed microscopy (PPM) and a mid-level practitioner performs the testing; do I need to perform a competency assessment on this person?

Yes, if the individual is performing this type of non-waived testing, a competency assessment of that person must be performed. All testing personnel, including mid-level practitioners, in PPM laboratories are required to undergo competency assessment.

What must I include in the personnel assessment for this mid-level practitioner?

The competency assessment for mid-level practitioners must include the six procedures. Some things to consider for the competency assessment for all tests performed by that individual can:

- Is the test actually 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?
- Does the mid-level practitioner perform the test and report results according to the laboratory's procedure?

If I am the laboratory director and act as my own clinical consultant (CC) but employ another individual as technical consultant (TC), technical supervisor (TS) or general supervisor (GS) for testing performed in my laboratory, do I need to assess that individual's competency?

Yes, you must perform a competency assessment of the individual serving as the TC, TS, and/or GS based on their regulatory responsibilities.

Note: Clinical consultants, technical consultants, technical supervisors, and general supervisors who are performing testing on patient specimens are also required to have a competency assessment including the six procedures.

What should I include in the competency assessment for the TC (moderate complexity) and TS (high complexity testing)?

In order to decide what to include in the competency assessment for the technical consultant and technical supervisor, you must first consider which, if any, of the dual responsibilities for director and TC or TS have been delegated to this individual. (See CMS CLIA brochure on laboratory director responsibilities on CLIA website.) All laboratory director responsibilities which are delegated to the TC and TS must be in writing.

The following is a list of items you may consider when assessing the competency of the TC and TS, assuming that all dual responsibilities have been delegated.

- Is the TC/TS available to provide consultation to the laboratory?
- Does the TC/TS select test methods that are appropriate for the laboratory's patient population?
- Does the TC/TS assure that performance specifications are established or verified for necessary tests?
- Does the TC/TS ensure that the laboratory is enrolled and participating in an approved HHS approved proficiency testing program for each test requiring PT? How well does the laboratory perform PT? Are the appropriate staff reviews conducted when PT results are received from the provider?
- Does the TC/TS ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory's testing performance?
- Does the TC/TS resolve technical problems and insure remedial actions are taken whenever there is a test system failure?

- Does the TC/TS ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly?
- Does the TC/TS identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the tests they are performing?
- Does the TC/TS evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently.
- Does the TC/TS use the following techniques, as well as any additional techniques determined by the laboratory to be appropriate for evaluating the competency of the testing personnel?
    - ◊ Directly observe test performance, including patient preparation, specimen handling, processing and testing.
    - ◊ Monitor the recording and reporting of test results.
    - ◊ Review worksheets, QC records, PT results and preventive maintenance records.
    - ◊ Directly observe performance of instrument maintenance and function checks.
    - ◊ Assess test performance using previously analyzed samples.
    - ◊ Assessment of problem solving skills.
    - ◊ Evaluate and document testing personnel performance at least semiannually for the first year and annually thereafter.

If my laboratory performs high complexity testing and employs a technical supervisor (TS), are there any requirements for competency assessment that differ from those of a technical consultant (TC)?

No, the requirements are the same, but the competency assessment will depend on which, if any, of the responsibilities of the director have been delegated to the TS or TC.

My laboratory performs waived and moderate complexity tests; what do I need to include in assessing the competency of the testing personnel (TP)?

After determining whether the TP has received appropriate training for the tests he/she performs, you will need to assess the competency of the TP performing moderate complexity testing for all of the moderate complexity tests performed and must include all six required procedures. The following items may be used. Does the TP:

- Collect sufficient patient sample and correctly process the specimen used for the testing?
- Complete the test report correctly, using the appropriate test units of measurement?
- Perform the test correctly by adding the proper order and amount of patient specimen and reagent(s)?
- Add the testing solutions in the proper amount and order?
- Collect sufficient patient sample and add it to the testing system correctly?
- Use test solutions and reagents from the same test kit and lot number?
- Maintain records of the patient testing results?
- Treat PT samples in the same manner as patient specimens and maintain records indicating such?
- Adhere to the laboratory's Quality Control (QC) policies and document QC activities?
- Adhere to the laboratory's policies for instrument calibrations and maintenance activities?
- Follow the laboratory's corrective action policies and procedures when a test system fails to meet the laboratory's acceptable level of performance?
- Identify problems that may affect test performance or reporting test results and either correct the problem or notify the TC or director?
- Document all corrective action taken when there is a test system failure?

If my laboratory performs high complexity testing, do the requirements for competency assessment TP differ from those of moderate complexity testing?

No, the six required procedures for assessing TP competency assessment are the same for both moderate and high complexity testing.

May I combine for competency purposes, all tests performed simultaneously on the same testing platform?

As long as there are no unique aspects, problems or procedures associated with any test on the testing platform, all tests performed simultaneously on the same testing platform may be combined. However, any test with unique aspects, problems or procedures within the same testing platform should be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently.

Do all six procedures of competency assessment need to be performed at the same time each year?

No, competency assessment can be done throughout the entire year. The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload.

May I use Proficiency Testing (PT) performance to assess competency?

Yes, PT performance may be used as part of your competency assessment; however use of PT performance alone is not sufficient to meet all six required procedures.

May I use training and personnel evaluations to assess competency?

No, training and personnel evaluation are not the same as competency assessment. While training is important to ensure competency, training is a process to provide and develop the knowledge, skills, and behaviors to meet established requirements. Documentation of training does not satisfy the requirement for documented competency assessment. Personnel evaluations evaluate other behaviors and attributes as they relate to the position or job (such as internal or external customer service). Competency is the application of the knowledge, skills and behaviors for performance. The difference between training and competency is that training happens before someone begins testing and competency assessment confirms that they are doing the testing correctly.

I have personnel in my laboratory that only draw blood and label samples. Does CLIA require that I perform competency assessments on them? What if the phlebotomists perform bleeding times?

No, competency assessment is not required by CLIA for non-testing personnel (e.g., phlebotomists, accessioning personnel, etc). However, this would be considered good laboratory practice and a good quality assurance measure.

Yes, if the phlebotomists or other non testing personnel perform bleeding times, then they will require competency assessment as a bleeding time is a moderate complexity test.

Is competency assessment the same as proficiency testing?

No, Under CLIA, competency assessment is not the same as proficiency testing. Competency assessment is used to confirm that laboratory personnel are adequately performing their laboratory duties. Proficiency testing or PT assesses the laboratory's ability to perform accurate and reliable testing by the testing of unknown samples sent to a laboratory by a CMS approved PT program. (See CLIA Brochure #8, Proficiency Testing).

CLIA website: www.cms.gov/clia

Regulations may be found at:
http://wwwn.cdc.gov/clia/regs/toc.aspx

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992 and are the final authority. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April 24, 2003.

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