



# Management Bulletin

North Carolina State Laboratory of Public Health | Laboratory Improvement Unit

## Proficiency Testing versus Competency Assessment

Nothing strikes fear in the hearts of lab personnel like the words, “The Proficiency Testing (PT) samples have arrived!” PT is usually sent out three times per year, and one must enroll in a Centers for Medicare and Medicaid Services (CMS) approved PT program. Another top pulse-increasing yearly activity is the mention of Competency Assessment (CA). This assessment should be done on testing personnel every six months during the first year of employment and annually thereafter. Although both PT and CA are performed annually, the two are separate because they focus on different aspects of a good Quality Management System.

### Proficiency Testing

PT involves testing unknown samples from a CMS approved PT program to verify the accuracy of a lab’s testing. The PT samples are usually sent three times per year, and the results are recorded on a paper form sent by the PT provider or entered electronically on the PT provider’s website. Always pay close attention to the due date of the results because failure to submit on time will result in a failure of the PT event. The PT samples must be treated the same way as a patient sample and should be rotated around the different testing personnel that normally perform the test. The PT samples provide an external validation of the quality of a laboratory’s results and can be used as a self-monitoring tool by looking for trends in PT results compared with those of cohort labs. Each laboratory should have policies and procedures for handling the processing and testing of PT samples. There should also be a procedure in place for responding to all unacceptable PT results.

So, what action should you take if you don’t get a passing score on a PT event? First, review your answers; many times it is a clerical error that occurred in the entering or reporting of your results. The unacceptable PT results must be investigated to try and determine the cause. Labs should use PT results, both acceptable and unacceptable, as part of a continuous quality improvement plan. Monitoring results for trends that could indicate a problem can lead to preventative action. If you find errors, then you must take action to correct the errors and document how you corrected the errors. You must keep a copy of PT testing including the steps that were done in testing, a copy of the results form, and a copy of the evaluation showing your lab’s performance. All records pertaining to PT must be kept for a minimum of two years from the date of the PT event. Never discuss your PT results with another lab before the event due date or you may lose your certificate from your accrediting organization. Never send PT samples out of your lab for any reason, even if you routinely send out patient specimens for additional or confirmatory testing.

### Competency Assessment

Competency is defined as “the application of knowledge, skills, and behaviors in performance.” Competency must be assessed on anyone performing non-waived testing. Personnel who only perform waived testing or only do pre or post analytical processes are not required to do CA under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), but some accrediting organizations may require it.

Competency of the individual must be checked semi-annually during the first year of employment and annually thereafter. CLIA states six elements of competency that must be addressed. The six elements do not have to be done all at once; they can be documented throughout the year.

**Six areas of competency that must be done for each person, test, and year:**

- Direct observations of routine patient testing to include patient preparation (if applicable), specimen handling, processing, and testing
- Monitoring the recording and reporting of test results
- Review of intermediate test results or worksheets, QC records, PT results, and preventive maintenance records
- Direct observations of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously analyzed specimens, internal blind samples, or external PT samples
- Assessment of problem solving skills

Labs are often confused as to who can oversee or grade the assessments under the regulations. In a moderately complex lab, the person performing the CA must be qualified as a technical consultant. To qualify as a technical consultant, a person must have a bachelor's degree and two years of lab training or experience with non-waived testing. A technical consultant may delegate to a technical supervisor or a general supervisor the ability to perform assessments, but this must be done in writing. Provider-Performed Microscopy (PPM) is a type of non-waived testing certificate, and CA of the person doing the testing is required even if that person is a mid-level practitioner. Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform patient testing are also required to have CA.

A CA plan should be integrated into the normal daily workflow of the lab and should assess performance of testing, reviewing results, and checking instrument maintenance. If test methodology or instrumentation changes, then the personnel performing testing need to be reevaluated on this new method or instrument prior to reporting patient test results. PT performance may be used as a **part** of CA, but it is not sufficient to just do PT every year because it does not include all six required elements of CA. Training and personnel evaluations should not be included in the assessment of competency.

CA and PT are often discussed together, but they focus on two different aspects of laboratory functions. CA samples are known (previously tested) samples and PT samples are unknowns. CA focuses on the individual performing patient testing and shows whether or not the person possesses the skill and knowledge to report accurate results. PT focuses on the laboratory's ability to report accurate test results and compares the lab's results to peer labs, reference standards, or reference labs. When you combine CA and PT, they work together as part of a good Quality Assessment Plan.

## Quick Reference Guide

	<b>Competency Assessment</b>	<b>Proficiency Testing</b>
<b>Must be done in non-waived labs</b>	Yes	Yes
<b>Part of a Quality Assessment Plan</b>	Yes	Yes
<b>Frequency</b>	Every 6 months first year of employment – yearly thereafter	Usually 3 events per year
<b>Focus</b>	The individual	The laboratory
<b>Required of all testing personnel?</b>	Yes	Yes, but rotate throughout staff
<b>Run like normal patient</b>	Yes	Yes
<b>Limitations</b>	Availability of samples	Only addresses analytical process

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