EDUCATIONAL COMMENTARY – THE ROLE OF PROFICIENCY TESTING IN PERSONNEL COMPETENCY ASSESSMENT

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Learning Objectives

On completion of this exercise, the participant should be able to:

- understand how clinical laboratory testing is regulated in the United States;
- understand the tenets of proficiency testing;
- understand the tenets of personnel competency assessment;
- understand how proficiency test samples can be used to assess testing personnel; and
- understand some considerations encountered when using proficiency testing to assess competency.

Introduction

It can be said that the goal of any clinical laboratory is to produce accurate testing results to contribute to the high-quality care and safety of patients. The purpose of regulation in the clinical laboratory environment is to ensure laboratories are providing high-quality results for patient care.

Clinical laboratory testing in the United States is regulated by the Department of Health and Human Services (HHS) via the authority of the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC). The Clinical Laboratory Improvement Amendments of 1988 (CLIA) outlined standards to be met for clinical laboratory testing.¹ The Code of Federal Regulations (CFR) Title 42 Part 493 identifies the standards that all laboratories must meet when performing testing and is the guiding force for laboratory regulation in the United States today.²

Two important elements of the federal regulations are participation in a proficiency testing (PT) program, which entails integration of unknown sample materials into the regular laboratory testing workflow, and competency assessment of testing personnel.¹ Laboratories can maximize the value of their obligation to participate in an external PT program by making use of PT samples to help assess the competency of their testing personnel. In the results of a survey by American Public Health Laboratories (APHL), many participants clearly recognized this value.³ It should be noted that CMS makes a clear distinction
between PT and competency assessment, stating that although PT can be a part of competency assessment, it cannot, by itself, completely fulfill the requirements for competency assessment.4

**Essential Tenets of Proficiency Testing**

The CMS has published widely available guidelines on PT, including how to enroll, how to test, and how to report samples.5 By following these guidelines, laboratories can ensure that the PT samples are integrated into their workflow and tested in the same manner as any given patient sample. This is an important challenge to the systems in place at the laboratory, thus incorporating all components of a laboratory test: environment, reagents, test device, sample(s), and testing personnel.

Certain third-party companies are approved through CMS to create and deliver PT programs to clinical laboratories, including the American Proficiency Institute (API), the College of American Pathologists (CAP), and the Wisconsin State Laboratory of Hygiene (WSLH). Each of these companies undertakes to provide external masked samples that can be tested at any given laboratory and will produce comparable results under similar circumstances. The programs administered by these companies are also regulated, with requirements under 42 CFR 493.901.

**Essential Tenets of Competency Assessment**

The CFR outlines key components for assessing clinical competency in laboratory personnel. For nonwaived tests, CLIA lists six elements of competency assessment:4

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing;
(ii) Monitoring the recording and reporting of test results;
(iii) Review of intermediate test results or worksheets, quality control records, PT results, and preventive maintenance records;
(iv) Direct observations of performance of instrument maintenance and function checks;
(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
(vi) Assessment of problem solving skills.

Personnel who are newly trained on a nonwaived testing method or device must be assessed for competency at least twice within the first year of performing that test and annually after that.4 Successful demonstration of the six elements, as outlined by CLIA, is required during each assessment period. Documentation of successful testing of PT samples can be used as part of competency assessment because the analysis of PT samples mirrors that of regular patient samples.
Considerations for Using PT Samples to Evaluate Personnel Competency

To fulfill element five of the CLIA requirements, PT samples can be used to assess the competency of the technologist performing the test. Also, because a PT sample is to be handled the same way as a patient sample, it may be possible to evaluate the testing staff on some of the remaining elements when they are testing a PT sample. The following are considerations when attempting to use PT as competency assessment.

*Rotation of samples among all staff members*

Most PT programs for any particular analyte contain more than one sample to be tested and are sent at least twice (sometimes three times) per year. This program content and shipping schedule can provide many opportunities to perform competency assessment on a group of testing personnel. Because the goal of a PT program is to assess the laboratory testing system, it is generally accepted practice to rotate samples among all staff members in a regular schedule.\(^5\) Doing so will provide an overall view of the testing performed at a particular site and may highlight a particular individual who might be deficient in knowledge or technique. Although not prohibited by any rules, it is not advisable to always assign PT samples to the same testing personnel simply to ensure the samples always pass; doing so may hide serious problems within a testing system.

*Duplicate testing*

Duplicate testing of PT samples before result submission is expressly forbidden.\(^6\) This rule originates in the Public Health Service Act (sec 353(d)(1)(E)) requirement to treat PT samples the same as routine patient samples. However, if sample integrity permits, PT samples may be used to assess competency of another employee after the result due date. In reality, many PT samples are consumed or destroyed in the testing process and thus, duplicate testing may be impractical for some analytes.

*More testing personnel than PT samples in a year*

Having more testing personnel than PT samples in a year is a common situation in large clinical laboratories and also with point-of-care-testing staff members, who may comprise, for example, 100 nurses in an operating room or cardiac catheterization laboratory. To help with this issue, several companies that administer PT programs have now made available extra samples that can be ordered for assessment purposes but that are not reportable as PT (e.g., verification programs offered by API or Quality Cross Check from CAP).\(^7,8\) Using such samples can be particularly helpful for tests in which the sample is used up or nonviable after the initial sample is run (e.g., activated clotting time).
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Summary

Clinical laboratories exist to provide accurate results that contribute to high-quality patient care. There are federal regulations (42 CFR Part 493) in place to ensure that laboratory results are accurate and do not endanger patients. Two important components of these regulations are participation in a PT program and assessment of testing personnel competency. Also, laboratories can use their PT programs to fulfill some of the requirements of personnel competency assessment, with consideration given to following the rules regarding duplicate testing and accommodating more staff members than available PT samples.

References


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