

CLIA Corner

State Hygienic Laboratory at The University of Iowa



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In This Issue of the CLIA Corner we address:

- **Initial and Non-Initial Proficiency Testing (PT) Failures (Updated 6/18)**
- **Centers for Disease Control (CDC) Educational Tools**

INITIAL AND NON-INITIAL PT FAILURES

Unsatisfactory PT scores result from the failure to attain a minimum satisfactory score for an analyte, subspecialty or specialty for a testing event. In most cases, receiving less than 80 percent is considered unsatisfactory, with the exception of the analytes: ABO grouping, Rho typing, and compatibility testing. For these analytes, anything less than 100 percent are considered unsatisfactory scores. ***Anytime the laboratory receives a score of less than 100 percent, corrective action must be taken and documented.***

INITIAL UNSUCCESSFUL PT

Unsuccessful PT performance is defined as receiving unsatisfactory PT scores in two consecutive or two out of three PT events for a specialty, subspecialty, or analyte. The first time a laboratory fails PT for two consecutive events or two out of three events, it is considered initial unsuccessful PT. The State Agency (SA), working with the Regional Office (RO), will determine if the laboratory: 1) has a good history of compliance; 2) has no immediate jeopardy, no PT referral, and no current significant quality problems; and 3) has agreed to correct the problem causing the unsuccessful PT. If the laboratory is in good standing, the laboratory will be asked to undertake training and/or technical assistance. During this time:

- The laboratory may continue testing;
- The laboratory must document completion of training and/or technical assistance; and
- The laboratory must document correction of the problem(s) that caused the unsuccessful PT performance.

Example 1: The laboratory receives PT scores of 60 percent in 2017 event 3 and 40 percent in 2018 event 1 for the analyte, hemoglobin. This is considered initial unsuccessful PT, because the laboratory received unsuccessful PT scores in two consecutive events.

Example 2: The laboratory receives PT scores of 20 percent in 2017 event 2, 100 percent in 2017 testing event 3, and 40 percent in 2018 testing event 1 for the subspecialty, bacteriology. This is considered initial unsuccessful PT, because the laboratory received unsuccessful PT scores in two out of three events.

NON-INITIAL UNSUCCESSFUL PT

CMS monitors PT scores on a rolling time frame, which is currently a three-year period. *If during the three-year, rolling time frame the laboratory were to fail the same analyte, specialty, or subspecialty: three consecutive events; three out of four events; or an additional two consecutive or two out of three events, then more stringent sanctions are imposed.* These sanctions could include a limitation of the laboratory's certificate in the area of failure and cancellation of Medicare and/or Medicaid payments immediately for **no less than six months**. The laboratory will need to document correction of the problem(s) that caused the unsuccessful PT performance AND obtain satisfactory PT scores for two consecutive PT events. The laboratory may contact their PT company and request an additional (re-instatement) event. Most PT companies have an extra set of PT samples that can be purchased for the purpose of PT failure reinstatement.

The laboratory may voluntarily withdraw from testing for the failed analyte, specialty or subspecialty prior to the Regional Office sending a letter imposing sanctions or limitation of the laboratory's certificate. This is accomplished by sending the State Agency written notification of the failed analyte, specialty or subspecialty and the effective date of withdrawal. If the laboratory voluntarily withdraws from testing, it must still obtain satisfactory PT scores for two consecutive events and document correction of the problems(s) that caused the unsuccessful PT performance. As soon as this is accomplished, the laboratory can be put back in compliance (which may be completed in less than six months). Therefore, it can be advantageous for the laboratory to voluntarily withdraw from testing when non-initial unsuccessful PT occurs.

Example 1: The laboratory receives PT scores of zero for 2017 testing event 2, 20 percent for 2017 testing event 3, and 40 percent for 2018 testing event 1 for the analyte, sodium. This is considered non-initial unsuccessful PT because the laboratory received unsuccessful PT scores for three consecutive testing events.

Example 2: The laboratory received PT scores of 60 percent for 2016 testing event 1, 40 percent for 2016 testing event 2, 100 percent for 2016 testing event 3, 100 percent for 2017 testing event 1, 40 percent for 2017 testing event 2 and 40 percent for 2017 testing event 3 for the analyte, potassium. This is considered non-initial unsuccessful PT because the laboratory received unsuccessful PT scores for two consecutive testing events, twice during the three-year rolling time frame.

Whenever the laboratory has questions about unsuccessful PT performance, it should contact its State Agency for guidance. Here is a link to the State Agency contact list:

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>

CDC EDUCATIONAL TOOLS

Are you looking to obtain continuing education credits? Do you need a competency tool for waived testing? What about information on microbiology or biosafety preparedness? The CDC has some great educational tools on their website.

WAIVED TESTING

This training will help ensure that testing personnel have the basic training necessary to safely and accurately perform patient testing waived under the Clinical Laboratory Improvement Amendments of 1988. After viewing this training module, participants will understand that waived testing can produce inaccurate results and that these results could adversely impact patients. There are many things they can do, however, to minimize the risk of inaccurate testing. The learning objectives itemize several specific things that the participant will be able to do as a result of this training.

<https://www.cdc.gov/labtraining/training-courses/ready-set-test.html>

BASIC MICROBIOLOGY

The Basic Microbiology eLearning Curriculum provides online training for public health laboratory professionals in the area of basic microbiology laboratory skills and procedures necessary to identify microorganisms from clinical specimens. The basic microbiology curriculum includes six eLearning courses. Each course is comprised of interactive, concise content allowing for completion during open periods throughout the day. Job aids and laboratory exercises are included so participants may work with a supervisor/mentor to comprehend and perform proper microbiology techniques.

<https://www.cdc.gov/labtraining/training-courses/basic-microbiology/index.html>

FUNDAMENTALS OF CENTRIFUGE SAFETY

Centrifuges are instruments used to separate mixtures, based on particle size and density, by spinning the mixtures at high speeds. These instruments are essential tools in all types of laboratories. Serious injuries or potential exposures can occur if centrifuges are improperly used or maintained.

This basic-level e-Learning course provides information on the safe use of centrifuges. Topics covered include major parts of a centrifuge, types of centrifuges, potential hazards, how to work safely with a centrifuge, and what to do if there is an emergency.

<https://www.cdc.gov/labtraining/training-courses/fundamentals-centrifuge-safety.html>

BIOTHREAT PREPAREDNESS FOR SENTINEL LABORATORIES

Each of these intermediate-level, interactive online courses review a component of the Laboratory Response Network (LRN) protocols for bioterrorism agent identification. The courses include case studies, real-life laboratory scenarios and links to resource information. Course materials may be used as part of a laboratory's competency assessment program for terrorism preparedness. The five courses are listed on the left side of the web page. <https://www.cdc.gov/labtraining/training-courses/biothreat-preparedness-sentinel/index.html>

These are just a few examples of the courses offered by the CDC. For a complete list, go to:

<https://www.cdc.gov/labtraining/index.html>.

