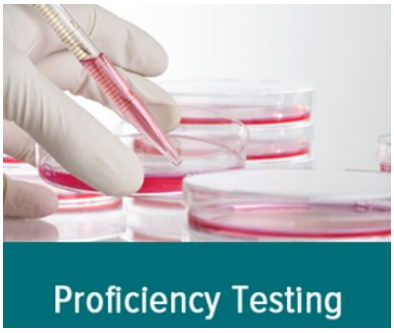
IOWA | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa — Fourth Quarter 2024

In This Issue…



Proficiency testing is the testing of unknown samples sent to a laboratory by a Health and Human Services (HHS) approved PT program. PT programs send samples to the laboratory on a regular basis, which is usually 2-3 times a year. The PT program grades results submitted by the laboratory according to CLIA defined grading criteria (found in Subpart I of the CLIA Regulations) and sends scores back to the laboratory. While CMS and accreditation organizations routinely monitor PT performance for laboratories under their jurisdiction, it is up to the laboratory to take and document corrective action when necessary.

When is Corrective Action Necessary?

The laboratory is responsible for taking and documenting corrective action for the following:

Unsatisfactory PT scores

A laboratory receives unsatisfactory PT scores when it fails to achieve a minimum satisfactory score for an analyte, test, specialty, or subspecialty within a testing event. ***NOTE: Anytime the laboratory receives a score of less than 100%, comprehensive corrective action must be taken and documented, even if the laboratory receives an overall passing score.***

Ungraded PT scores

A laboratory may receive ungraded PT scores when the PT program fails to evaluate the laboratory's results due to:

- Less than 10 participants in a particular peer group
- Less than 80% consensus among the peer group participants

A review of the PT summary may indicate that the PT program gave the laboratory an artificial score of 100% for a particular analyte when in actuality, the results were not evaluated by the program. When this occurs, the laboratory is required to perform a self-evaluation of its results by comparing them to the peer group data and expected results provided in the PT program's summary; the laboratory is responsible for determining whether or not its results are acceptable. If, during the self-evaluation, the laboratory determines it received an unsatisfactory score, then the laboratory is required to take and document corrective action.

Failure to submit results on time

Laboratories will receive a score of zero for failing to participate in a survey or failing to submit the survey results to the PT program by the program's submission deadline. Consideration may be given to laboratories that fail to participate in PT if:

- The laboratory suspended patient testing during the time frame allotted for testing and reporting PT results;
- The laboratory notifies the inspecting agency and the PT program (within the time frame for submitting PT results) of the suspension of patient testing and the associated circumstances; and
- The laboratory participated in the previous two PT events.

***NOTE: When the laboratory receives a score of zero due to either failing to submit results or failing to submit results on time, comprehensive corrective action must be taken and documented*.** The corrective action must include performing a self-evaluation of the laboratory's PT results compared to the PT program's expected results. If the laboratory would have received unsatisfactory PT score(s), the laboratory must take and document corrective action for those analytes, specialties, and subspecialties. In addition, the laboratory must also document how it plans to ensure results are submitted on time for future PT events.

What is Included in Corrective Action?

As stated previously, ***anytime the laboratory receives a score of less than 100%, comprehensive corrective action must be taken and documented, even if the laboratory receives an overall passing score.*** The following steps must be completed to ensure acceptable and effective corrective action:

Investigate

The first step is investigating the source of the unsatisfactory score(s). This may include, but is not limited to, review of the following:

- PT specimen receipt/condition, storage, and handling;
- Whether PT sample instructions were followed in a timely and accurate manner;
- Result transcription from the instrument printout to worksheets and electronic submission, if applicable, including units of measure and method codes;
- Quality control, calibrations, maintenance records, and test system troubleshooting; and
- Personnel competency and technique.

The laboratory must document the steps it took and records it reviewed during the investigation process.

NOTE: Rerunning PT samples may be performed as part of the investigation process, but MUST NOT be the only investigation. A conclusion of random error because the results of rerun PT samples fell within the PT program's expected ranges is **not acceptable** without further investigation.

If you would like your name added to our CLIA Corner google group, send an email to:

Kristine-Rotzoll@uiowa.edu or Melinda-Bochmann@uiowa.edu

Identify

After the laboratory investigates the source of the unsatisfactory score(s), it must identify the problem. Was the problem due to incorrect specimen handling, clerical errors, test system malfunction, poor technique, or a combination of multiple sources?

The laboratory must also review patient test records from the same time frame as the failed PT results and determine whether or not patient testing was also affected. If the review identifies that patients were affected, or potentially affected, the laboratory must address the patient results and document what corrective actions were taken to notify responsible parties (e.g., physicians and other healthcare providers). As part of the investigative process, the laboratory must document the steps that were taken to determine if patient testing was affected.

If the laboratory cannot determine the cause of the problem, it must, at a minimum, document the investigative steps taken to try to identify the problem.

Resolve

After investigating and identifying the problem, the laboratory must take and document steps to resolve the problem and prevent its recurrence. This may include:

- Personnel training and education
- Technical assistance (e.g., contacting the manufacturer for additional maintenance or function checks)
- Development and/or revision of procedures and policies

Rerunning PT samples and determining that random error is the problem without further investigation is not a resolution to the problem.

Monitor

The final step in the process is monitoring the corrective action plan to ensure that the action(s) taken have been effective in preventing recurrence of the original problem. If the laboratory were to receive an additional unsatisfactory result, whether it is the same or a different analyte, and it is determined to be the same problem (e.g., clerical error), the laboratory's corrective action was not effective and a new corrective action plan would need to be developed and monitored for its effectiveness.

Proficiency testing is an important quality assurance tool used to monitor the laboratory's overall performance. Unfortunately, all laboratories receive unsatisfactory PT scores periodically. By conducting a thorough investigation, developing an effective corrective action plan, and monitoring the entire process, the laboratory will ensure that it is reporting the highest quality patient test results.

Visit our new website:

Iowa CLIA Laboratory Certification Program

The State Hygienic Laboratory recently went live with an all-new website and we have a new home! Visit our new site to find answers to frequently asked questions related to CLIA and archived issues of the CLIA Corner. Unfortunately, not all previous issues have been migrated to the new site, but we will be working to update and release the older issues in the future.