

CLIA Corner

State Hygienic Laboratory at the University of Iowa

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In This Issue...

- **When Proficiency Testing (PT) performance is less than perfect**
 - **When corrective action is necessary; and**
 - **The requirements for corrective action.**

Proficiency Testing Less Than Perfect Performance

Unsatisfactory PT scores

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

Failure to submit results on time

The laboratory will receive a score of zero for failing to participate in a survey or failing to submit the survey results on time. Consideration may be given to laboratories failing to participate in PT if:

- Patient testing was suspended 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 circumstances associated with failure to perform tests on PT samples; and
- The laboratory participated in the previous two proficiency testing events.

When the laboratory receives a score of zero due to either failing to submit results or failing to submit the results on time, corrective action must be taken and documented. The corrective action should include, but is not limited to, performing a self-evaluation of the PT results by a comparison of the intended PT results to the laboratory's 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 they plan on ensuring PT results are submitted on time for future PT events.

Ungraded PT scores

Ungraded PT scores occur when the PT program fails to evaluate the laboratory's results due to a problem beyond the control of the participant. In order for the proficiency testing program to evaluate a laboratory's proficiency testing results there must be at least ten participants in a particular peer group and at least 80percent consensus among the participants. Many times looking at the proficiency testing summary it may appear that the laboratory received a score of 100percent for a particular analyte, but in reality the results were not evaluated by the proficiency testing program. When this occurs, it is the ***laboratory's responsibility to perform a self-evaluation*** by comparing the results the laboratory submitted to the PT Company's summary. If during the self-evaluation the laboratory received an unsatisfactory score, then the laboratory is required to take and document corrective action.

Corrective Action

Investigate

The very first step in taking corrective action is to investigate the problem. The laboratory will need to identify the source of the unsatisfactory results. Was the problem due to clerical error, technical problem, personnel competency, or some other reason? The laboratory will need to review a variety of records: check the results entered; review quality control, calibration, and maintenance records; review personnel techniques; review procedure/processes; etc. *Rerunning the PT testing samples can be part of the investigation, but should NOT be the only investigation.* The laboratory must document what investigative steps were performed.

Once the laboratory identifies the cause of the unsatisfactory PT scores they must also determine if patient testing was also affected. The laboratory should review patient testing from the same time period as the failed PT results. If patient test results were found to be affected, the laboratory will need to 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.

Resolution of the Error

The next step in taking corrective action is resolution of the error. The laboratory must document the steps taken to prevent recurrence of the problem. This may include personnel training and education, technical assistance (contacting the manufacturer for additional maintenance), development or revision of procedures and policies, etc. *Random error is not a resolution to the problem.* If a laboratory cannot determine the cause of the problem they must, at a minimum, document the investigative steps that were taken to try and resolve the problem.

Monitor Corrective Action

The final step in taking corrective action 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 analyte 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 will need to be developed and monitored for effectiveness.

Proficiency testing is an important tool in monitoring your laboratory's performance. Unfortunately, from time to time, all laboratories receive unsatisfactory PT score(s). Through investigating, resolving and monitoring corrective action, the laboratory will ensure the reporting of quality patient test results.

Contact Information:

If you want to be added to our e-mailing list, need a change of address, or have a question or topic suggestion for the CLIA Corner you can contact either Kristi Rotzoll at kristine-rotzoll@uiowa.edu or Nancy Grobe at nancy-grobe@uiowa.edu.