EDUCATIONAL COMMENTARY – PROFICIENCY TESTING AS A QUALITY IMPROVEMENT TOOL

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Learning Outcomes

Upon completion of this exercise the participant will be able to:

- Describe a graphical means to trend proficiency testing (PT) results.
- Identify 4 ways to use proficiency testing as a quality improvement tool.
- Describe 4 actions to take when receiving an unacceptable PT result.

Proficiency testing is a laboratory testing program in which samples are periodically sent to members of a group of laboratories for analysis and/or identification, following which, each laboratory’s results are compared to those of other laboratories and/or to an assigned value, and subsequently reported to the participating laboratory and regulatory agencies. In addition to evaluating results for each analyte tested to ensure compliance with Clinical Laboratory Improvement Amendments (CLIA) performance requirements and to quickly correct any problems, PT results—both acceptable and unacceptable—can be used in a proactive approach to quality improvement. This commentary provides readers with ideas for using PT information to improve their laboratories. Because a detailed discussion of all the tools described below is beyond the scope of this publication; readers are encouraged to refer to CLSI Guideline GP27-A2, Using Proficiency Testing to Improve the Clinical Laboratory.¹

One way to affect laboratory improvement is to monitor PT performance across time. This activity helps detect an overall trend of systematic error or imprecision that may not be noticeable when evaluating day-to-day performance, thus allowing preventive action to be taken before a PT failure occurs. The easiest way to monitor PT results is to plot a standardized score (such as standard deviation interval or % error) on the vertical axis against its respective testing event, placed on the horizontal axis (Figure 1). Scores that are consistently above or below the PT target value could indicate a systematic error or calibration error. A significant change in values could reflect reagent lot differences, recalibration, or system failure.

As shown in Figure 1, event 06-1 demonstrates an apparent positive bias, with one result near the limit of acceptability (SDI=3). The laboratory corrected this bias in event 06-2, but there remains evidence of a wide spread of results and one result (SDI > -2.5) near the lower acceptance limit. This could be due to small biases at different concentrations or to other factors, such as interferences. The precision improved in event 06-3, as evidenced with a tighter cluster of SDIs. Event 07-1 suggests that the bias has returned, although all results are within acceptable limits. This bias should be monitored, and corrected if it persists.
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Figure 1. Monitoring proficiency testing (PT) results using standard deviation intervals (SDI). The progression of SDIs for every test item in 4 consecutive PT events, each containing 5 samples, is shown.

The PT event summary statistics (Participant Data Summary) provide a second insight into method performance. Summaries of means or medians from different methods usually show consistent relative biases between methods, which can be used to compare instruments within a laboratory or compare with the same instrument in another laboratory. However, PT samples may behave differently on different devices or with different measurement procedures, and any differences could reflect matrix effects (i.e., the effects of the nonanalyte materials used to contain the analyte in question) rather than bias in a measurement procedure.

Differences in the results between laboratories using the same instrument system or reagents provide a third way to use PT information. Such differences reflect the reproducibility of the method—that is, performance under different conditions such as operator and equipment differences, among others. Therefore, if the comparison is based on a sufficient number of laboratories, the relative standard
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deviations (or %CV, coefficient of variation) can indicate the consistency of the method. The smaller the standard deviation (SD) or CV, the more precise or consistent is the method.

For the 3 tools described above, results that are plotted on line graphs or control charts provide laboratories with the opportunity to recognize any unfavorable trends and take preventive action before PT failures occur. When laboratories receive reports of unacceptable PT results, they should systematically evaluate every aspect of the testing process to detect problems and take action to understand and correct any problems identified. Appropriate actions include an assessment of the impact of the problem on patient test results, an investigation into the root cause of the problem, a determination of corrective action (with elimination of the root cause where appropriate), and subsequent evaluation to verify that the corrective action implemented was effective.

A final quality improvement tool is to use PT events as educational exercises. Three ways to do so are described:

1. Discussion and action on postevent commentaries: These commentaries discuss the results of the event and their relevance to laboratory performance. A discussion of less desirable and incorrect responses is usually included to alert participants to faulty logic and processes. The laboratory can use this postevent information as the basis of a continuing education program on the subject or as a means to modify and improve work processes.

2. Circulation of postevent commentary information to affected parties: PT providers often include additional information in their postevent materials. This information is sometimes, but not always, related to the event topic itself. Some of this information could be used as subject matter for laboratory continuing education programs or staff discussions. Whether the postevent material is provided by the PT provider in paper or electronic format, posting it for staff—as printed reading material or distributing as individual e-mails—is another means to inform and educate.

3. Discussion about educational or ungraded samples: Educational PT samples are sometimes provided to gather and share information throughout the laboratory community. After the diffusion of the information (e.g., change in nomenclature of a microbiological organism, or specificity of a RBC alloantibody), a sample about that subject may be sent for assessment. In contrast, occasionally the reference laboratory responses for a particular PT sample lack consensus or are so variable as to render the sample ungradable due to some unanticipated cause; this may represent an opportunity for the PT provider to improve the PT program itself. Postevent critiques in either situation usually include information relevant to the specific sample and to related clinical scenarios.
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Like all properly conducted measurement and monitoring schemes, participation in PT programs answers performance questions—in this case, about the laboratory’s test methods. Performance results should always be used to identify opportunities for work process improvements, both to correct any performance failures and, more importantly, to anticipate unfavorable future performance and prevent any PT failures.

Reference


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