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Proficiency Testing: A Guide to Maintaining Successful Performance

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Abstract

To participate successfully in proficiency testing, laboratories should follow basic good laboratory practices, pay attention to proficiency testing details, and investigate unsatisfactory results thoroughly and methodically. Good laboratory practices include maintaining staff proficiency, using appropriate quality control rules, accurately validating the instrument's performance range, and following consensus guidelines. Proficiency testing details include confirming shipping dates and peer groups, avoiding clerical and specimen handling errors, and reviewing SDIs (standard deviation indexes). A thorough investigation of an unsatisfactory result includes consideration of clerical, specimen handling, and operator errors; quality control failures; and instrument instability.

After reading this article, readers should be able to (1) discuss 4 good laboratory practices that can help maintain successful proficiency test performance; (2) discuss 5 proficiency testing practices that can help avoid proficiency test failures; and (3) list 5 steps to follow when investigating an unsatisfactory proficiency test result.

Compliance exam 110701 questions and corresponding answer form is located after the CE Update section on p. 187.

The first proficiency test event occurred in 1946, when the Committee on Laboratories of the Medical Society of the State of Pennsylvania sent samples to 59 laboratories that had agreed to participate in a survey to assess the accuracy of common laboratory tests.[1] Two decades later, the Clinical Laboratory Improvement Act of 1967 mandated proficiency testing for all laboratories that participated in interstate commerce, but thousands of small laboratories in physicians offices and clinics were exempt. This changed with the enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), which requires all laboratories performing moderate- and high-complexity testing on patient samples to participate in a proficiency testing program.

Besides requiring laboratories to participate in a proficiency testing program, CLIA '88 also specifies performance standards laboratories must achieve. The regulations define satisfactory performance as a score of 80% of results within acceptable limits (4 acceptable results out of 5 samples) in a single proficiency testing event for most analytes.[2] For ABO/Rh blood groups and compatibility samples, however, 100% of results must be within acceptable limits.[2] Unsatisfactory performance occurs when a laboratory scores less than 80% (or less than 100% for ABO/Rh and compatibility samples) in a single proficiency testing event.

Unsuccessful proficiency test performance occurs when a laboratory fails to achieve a satisfactory score on 2 consecutive proficiency test events, or 2 out of 3 consecutive proficiency test events.[2] Laboratories designated as unsuccessful in proficiency testing must resolve the problem and successfully complete 2 proficiency testing events before continuing to test patient samples or else face possible sanctions ranging from fines to revocation of their CLIA certificate.

Clearly, proficiency testing failures are best avoided altogether or else resolved before unsatisfactory performance in a single event evolves into unsuccessful performance in subsequent events. In the following discussion, we present a strategy for doing this. First, we offer suggestions for avoiding unsatisfactory proficiency testing performance. Next, we present a step-by-step plan for troubleshooting proficiency testing failures when they occur.

Preventing Proficiency Testing Failures

Beginning with the first proficiency testing event in 1946, investigators have asked why some laboratories perform poorly, and their studies have uncovered many reasons for proficiency test failures. Equally important, the results of these studies suggest steps laboratory managers and supervisors can take to prevent unsatisfactory results and unsuccessful performance. These steps encompass basic good laboratory practices essential for good patient care and specific practices related to proficiency testing.

Good Laboratory Practices

Good laboratory practices are policies and procedures that experts deem essential in all laboratories to ensure high quality performance. In particular, the following 4 good laboratory practices can help achieve successful performance on proficiency testing events:

1. *Ensure the staff are adequately trained*. Studies examining the reasons for proficiency testing failures consistently cite inadequate training as a significant factor in poor proficiency test performance. In fact, inadequate training and insufficient staffing were blamed for many laboratories' poor performances in the first proficiency testing event in 1946.[1] Recent studies continue to implicate inadequately trained personnel as an important cause of proficiency test failure. For example, a study analyzing the reasons for proficiency testing failures in toxicology identified operator mistakes such as dilution errors and incorrect interpretation of instrument codes as a major cause.[3] Two studies that analyzed performance in physicians office laboratories noted better performance in proficiency testing and better compliance with minimum quality standards (including proficiency testing) in laboratories that employed trained laboratory personnel.[4,5]

   One way to stay current on issues that directly impact proficiency test performance is to participate in continuing education initiatives offered by proficiency test providers. Proficiency test providers are in a unique position to identify issues that cause problems for many laboratories, and they provide educational commentaries that address these problems.
2. *Use quality control methods that will regulate the instrument within the performance range specified by the manufacturer*. In their study of the reasons for proficiency testing failures in toxicology, Jenny and Jackson-Tarentino found that many laboratories used allowable errors for internal quality control procedures that exceeded manufacturers' recommendations.[3] Quality control criteria should be based on instrument performance specifications provided by the manufacturer.[3,6]
3. *Validate the instrument's analytical measurement range as specified by CLIA '88 regulations, or more often if recommended by the manufacturer.* CLIA '88 regulations require calibration verification at least every 6 months, at every change in reagent lot number, after major preventive maintenance, and when controls show unusual trends or exceed acceptable limits. Calibration verification is important because it can detect calibration drift at the upper and lower limits of the instrument's reportable range before quality control data detect the problem. Accurate calibration verification has been linked to better performance on proficiency testing, as evidenced in a study assessing whether participants in linearity surveys performed better on proficiency testing.[7]
4. *Follow consensus guidelines issued by scientific panels*. Guidelines incorporate the best current practices agreed upon by a panel of experts, and they aim to optimize patient care and use of laboratory resources. However, for reasons that are not clear, laboratories often fail to use current guidelines. Studies have shown, for instance, that laboratories often perform susceptibility studies with inappropriate antibiotics[8,9] or fail to use approved methods for identifying problems and fastidious organisms.[8,10-12] Failure to follow established guidelines can not only adversely impact patient care but also directly cause laboratories to fail proficiency testing. For example, beginning in 2006 the Centers for Medicare and Medicaid Services (CMS) has instructed proficiency test providers to grade as unacceptable responses to antibiotics that have not been approved by the Clinical Laboratory Standards Insitute (CLSI).

Proficiency Testing Tips

In addition to following basic good laboratory practices, the following 5 commonsense proficiency testing practices can also help avoid errors:

First, *confirm your laboratory is assigned to the correct peer group*. Assignment to the wrong peer group can result in unsatisfactory performance because of matrix effects (bias introduced by artificial constituents added to a material). Because matrix effects impact all users of the same instrument/reagent group similarly, peer group grading mitigates this influence.[13]

Second, *mark the shipping dates for proficiency test samples on the calendar*. If the samples fail to arrive within 7 days, immediately notify the proficiency test provider. When the samples arrive, promptly complete the proficiency testing event and submit the results to the provider. Failure to perform a proficiency testing event will result in a score of 0 and unsatisfactory performance on that event.

Third, *avoid specimen handling and clerical errors*. Verify specimens arrive in acceptable condition, and store them according to the proficiency test provider's instructions. If specimens need to be reconstituted, follow the instructions provided, and test them within the allowed time frame. Use the correct instrument, reagent, or kit to perform the test. Record results on the correct form, and check for transcription errors. Verify that results were recorded in the correct units.

Fourth, *submit results by the due date*. CLIA regulations require laboratories that submit late returns receive a score of 0 for that test event.

Fifth, *review standard deviation index (SDI) data on the evaluation supplied by the proficiency test provider*. Doing so can reveal analytic shifts and errors before the instability becomes great enough to cause proficiency test failure. Cembrowski and colleagues have developed an algorithm using quality control rules similar to the multi-rule procedures developed by Westgard to evaluate SDIs.[14] Briefly, the algorithm functions as follows:

1. If no more than 1 of the 5 SDIs exceeds the same (+1 or -1) SDI limit, significant error is unlikely and further scrutiny is not needed.
2. If 2 or more SDIs exceed the same (+1 or -1) SDI limit, calculate the average SDI. If the average SDI is greater than 1.5, a significant systematic error is possible.
3. If the average SDI is less than 1.5, check whether 1 observation exceeds 3 SDI or the difference between the largest and smallest SDI exceeds 4.0. If either of these conditions exists, a significant random error is likely.

Troubleshooting Proficiency Test Failures

Good laboratory practices and careful attention to proficiency testing details can improve proficiency test performance, but they cannot always prevent an unsatisfactory result. Each unsatisfactory result should be investigated even if the laboratory's overall performance is successful, because this will help detect and correct problems before they progress to unsuccessful performance in the future. To find the reason for an unacceptable result, you may need to examine the result form or retest the specimen. Therefore, you should always keep a copy of the result form and instrument printouts or result logs and save the proficiency test samples (usually frozen).

Investigate Unsatisfactory Results Thoroughly and Methodically

First, *look for clerical errors*. Check that the results on the evaluation are the same as the results you submitted. If you find a discrepancy, ask the proficiency test provider to correct your evaluation. If the results on the evaluation agree with the results on your copy of the result form, check to be sure that you used the correct form; selected the correct instrument, reagent, or kit; and transcribed the results correctly. Finally, verify that the units in which you reported your results match the units on the form.

Second, *investigate possible specimen handling problems*. Verify that the specimen arrived in acceptable condition, that it was stored according to instructions, that it was reconstituted correctly, and that it was tested within the time allowed for specimen stability. If applicable, examine the specimen for hemolysis. For a microbiology specimen, consider whether the unacceptable result could have been caused by a non-viable culture specimen. Notify the proficiency test provider if you suspect that a problem with specimen handling occurred during manufacture or transit.

Third, *investigate possible operator errors* such as mishandling dilutions, misinterpreting instrument codes, and incorrectly loading or sampling the specimen. Dilution errors were the most common operator error in Jenny and Jackson-Tarentino's study, and they occurred in 4 ways: the operator failed to correct the result for the dilution, the operator failed to communicate to data entry staff that the dilution had been made, the operator used an incorrect dilution factor, or the operator did not know that the instrument automatically corrected for the dilution.[3]

Fourth, *review reagent logs, quality control logs, and calibration records* to look for evidence of instrument or kit malfunction. Confirm that all reagents and media were within their expiration dates and that they were used before their open vial stability was exceeded. Examine refrigerator and room temperature records to confirm that reagents were stored at recommended temperatures. For microbiology samples, review incubator records to confirm that temperatures, gas concentrations, and humidity levels were within acceptable limits. Verify that controls were within acceptable limits and that there were no indications of shifts or trends. Make sure that the instrument had been properly calibrated within the time frame recommended by the manufacturer and that calibration verification had been performed as recommended by the manufacturer. Also check whether the instrument was calibrated during the interval between the proficiency test event and receipt of the evaluation. If so, any problem with calibration may have already been corrected.

Fifth, *review instrument maintenance records*. Look for indications that the instrument may not have been performing optimally on the day samples were tested. Also look for changes that could have impacted performance, such as installation of a new light source. Check for maintenance performed after the proficiency test event which may have corrected a problem that had not been detected on the day samples were tested. If you cannot resolve a suspected problem with the instrument, contact the manufacturer for help.

If only 1 of 5 results was unacceptable and the investigation fails to uncover a reason, random error was the likely cause. In this case, no corrective action is needed. To confirm random error, retest the sample. If the result falls within acceptable limits, the spurious result can be attributed to random error.

Conclusion

Since the first proficiency test event in 1946, proficiency testing has become a critical tool to evaluate performance and judge whether a laboratory is sufficiently proficient to reliably test patient samples. No longer voluntary, successful participation in a proficiency testing program is now required of all laboratories that test patient specimens. The best strategy for maintaining successful performance is to use good laboratory practices to prevent or correct problems early, pay attention to proficiency testing details to avoid clerical and sample handling errors, and investigate unsatisfactory results thoroughly and methodically. LM

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