EDUCATIONAL COMMENTARY – PREVENTING ERRORS IN THE ANALYTIC PHASE OF THE TESTING PROCESS

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Learning Outcomes
Upon completion of this exercise, participants will be able to:

- delineate common sources of error in the analytic phase of the testing process.
- discuss 6 practices that help prevent analytic errors.
- explain CLIA [Clinical Laboratory Improvement Amendment] regulations that apply to proficiency testing samples.

A widely accepted view of laboratory testing divides the process into 3 phases: (1) the preanalytic phase, which includes all activities that lead up to actual analysis of the specimen; (2) the analytic phase, which includes all activities involved in performing the test; and (3) the postanalytic phase, which includes all activities that occur after the specimen is tested. Studies have consistently shown that, of these 3 phases, the fewest errors occur in the analytic phase.¹,² Even so, the overall rate of errors in the analytic phase ranges from 13% to 32%.¹ Moreover, a study by Nutting and colleagues found substantial differences in analytic error rates depending on the site of testing: the percentage of total errors occurring in the analytic phase at point-of-care testing sites was 40%, which contrasts sharply with 4.4% for tests performed at reference laboratories.³

Sources of Error
In a review of laboratory testing errors, Plebani credits technology improvements, automation, and standardization with improving analytic performance. An exception to this, however, is immunoassay testing, which is subject to interferences from abnormal binding proteins such as heterophilic and anti-animal antibodies. The presence of interfering substances is often unsuspected, which makes it hard to recognize spurious results and can adversely impact patient care.²

Apart from errors caused by interfering substances, most other analytic errors result from either equipment and reagent problems or operator mistakes. Equipment malfunction can result from improper calibration or inadequate maintenance. Likewise, reagents that are improperly reconstituted, improperly stored, or used after their expiration date can cause invalid test results. Mistakes made by the operator include incorrectly identifying or loading samples, incorrectly transcribing results, incorrectly interpreting instrument codes, incorrectly applying quality control rules, and making dilution and calculation errors.

Preventing Analytic Errors
Most analytic errors can be prevented by following 6 basic practices:
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1. Hire staff who are qualified to perform tests at the level of complexity required, and ensure that they receive adequate training.\(^4\) Also, assess competency by observation to ensure compliance and to identify possible sources of error. Studies have long linked inadequate training and insufficient staffing with poor analytic performance in proficiency testing events.\(^5\) \(^8\)

2. Use quality control methods and rules that regulate the instrument within the performance range specified by the manufacturer.\(^4,6\) Do not accept the run if quality control results exceed acceptable limits.

3. Validate the instrument’s analytical measurement range as specified by the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88), or more often if recommended by the manufacturer.\(^4\) CLIA ‘88 regulations require calibration verification at least every 6 months with 3 or more levels of calibration materials that include a low, mid, and high range. CLIA ‘88 regulations also require calibration verification after major maintenance, when reagent lot numbers change, and when quality control data show unusual trends or exceed limits. More frequent calibration may be needed if indicated by the laboratory’s performance.

4. Follow consensus guidelines established by panels of experts.\(^4\) For example, failure to follow antimicrobial susceptibility testing guidelines and interpretive criteria published by the Clinical Laboratory Standards Institute (CLSI) can cause invalid susceptibility test results.

5. Review standard deviation index (SDI) data provided in proficiency test reports.\(^9\) This can help discover systematic errors (shifts) or random errors (increased imprecision) before they are large enough to be detected by quality control results (see Figure below).

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**Figure.** How To Evaluate Proficiency Testing Standard Deviation Index Data.

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6. Evaluate all unacceptable proficiency test results, including results that were not graded due to lack of consensus, even if overall performance on the proficiency testing event is satisfactory. Doing so may detect a problem that is just beginning to develop.

Errors in Proficiency Testing
In addition to these 6 practices, the following 3 considerations apply to preventing errors with proficiency test specimens:

1. After reconstitution, analyze the sample within the time limit specified by the manufacturer. Exceeding the time limit could allow the analyte to deteriorate, thus causing an unacceptable result.

2. Ensure that you are enrolled in the correct proficiency test program for the instrument or method that you use. Different analyzers or methods require different types of proficiency samples, and using the wrong sample type can cause unacceptable results.

3. Do not send proficiency test samples to another laboratory for analysis, even if the other laboratory is part of your facility. The purpose of proficiency testing is to assess whether a laboratory can reliably perform those tests it offers on site, and sending a sample elsewhere for analysis defeats that purpose. Sending proficiency test samples to another laboratory to verify your results is a serious violation of CLIA ’88 regulations. Doing so could result in sanctions ranging from fines to revocation of your laboratory’s CLIA certificate.

Conclusion
Technological improvements, automation, and standardization have reduced but not eliminated errors in the analytical phase of the testing process. Following basic good laboratory practices can minimize operator error or instrument malfunction, and evaluating proficiency test data can reveal potential problems before they adversely impact patient results. Always investigate the cause of an unacceptable proficiency test result, even if overall performance is satisfactory, and examine the SDI data for evidence of systematic or random error.

References


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