Verifying Performance Specifications

Posted on: August 1, 2008

Vol. 17 •Issue 8 • Page 10
POL Profit Connection

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By Nancy J. Grove, BS, MT(ASCP)

Whenever planning to replace an analyzer or add a new kit test method to a current test menu, the laboratory needs to determine how it will meet the CLIA regulations for verifying the manufacturer's performance specifications. The regulations apply to each non-waived test or test system introduced into the laboratory for the first time. For example, if the laboratory installs a new chemistry analyzer or adds a new chemistry test to an existing instrument, the laboratory must ensure that the new instrument or test performs within the specifications established by the manufacturer. The validation of the new test system must be completed prior to reporting patient test results.

The verification process is required whether the test system produces quantitative or qualitative results. If the laboratory is introducing a test system or method that is non-FDA approved or cleared, modified or developed in house, the laboratory must establish and verify its own performance specifications for which there are additional CLIA regulations. The CLIA regulations for verifying the performance specifications do not apply to test systems categorized as "waived," but may be required by one of the accrediting

agencies.

Meeting the Standards

The laboratory must verify accuracy, precision, reportable range and reference intervals (normal values). In addition, the lab must meet several general requirements to be in compliance.

Accuracy. Depending on the test system, the laboratory may choose either a comparison or reference method to verify test accuracy.

With the comparison method, the laboratory assesses the accuracy using split samples. For example, the laboratory obtains 20 patient samples with test results covering the reportable range of the test system. The samples are split and tested on the new test system and by a comparative method either in house or by sending them to another facility with the same test system. The laboratory compares the results from the two methods or instruments to determine if significant differences exist. Accuracy is considered met if the laboratory's percent bias is not greater than the manufacturer's claim. (Refer to CLSI document EP15-A2 for percent bias calculation.)

With the reference method, the laboratory assesses accuracy using reference materials with known values that cover the entire reportable range of the test system. Using the assayed reference material, for example, the laboratory compares the results obtained from the new test method to the expected reference value. Accuracy is considered met if the results are within the assayed methods.

Precision. The laboratory is responsible for verifying that it can repeatedly test the same samples on the same day—as well as on different days—and get the same or comparable results. This may be accomplished by repeat testing of known patient samples over time, testing quality control material in duplicate and over time or repeat testing of calibration material over time.

Reportable Range. This is defined as the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response. To determine how high and low test values can be and still be accurate, the laboratory needs to choose samples with known values at the highest and lowest levels of which the manufacturer claims accurate results can be produced by the test system. The laboratory may only report patient test results that fall within the verified levels. The reportable range can be expanded if the results are verified. Additionally, the laboratory must decide how to report results

that are greater than the highest verified level or less than the lowest level.

Reference Range. This is defined as the range of test values expected for a designated population of individuals (e.g., 95 percent of individuals presumed to be healthy/normal). The laboratory may use the manufacturer's suggested ranges or may use other published ranges from a textbook or journal. Reference ranges can vary based on the type of patient (e.g., pediatric, male, female, etc.). The laboratory may need to adjust the reference range to better fit the patient population it routinely tests.

Final Steps

The number of specimens needed for each part of the verification study may vary depending on the test system and the laboratory's testing volume. The sample size must be adequate to ensure the accuracy and precision of the test method. When planning the verification process, the laboratory may use the same samples to verify accuracy, precision and reportable range.

Once the verification studies have been completed, the laboratory director must review and approve the results prior to reporting patient test results. If the study indicates the test system is not accurate or results cannot be consistently reproduced, the test system manufacturer should be consulted regarding steps to resolve the problem.

Nancy J. Grove is senior laboratory consultant, Iowa CLIA Laboratory Program, University of Iowa Hygienic Laboratory.