Poster 36

Enhancing Error Detection Capabilities in Point-of-Care Analyzer

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Since primary users of point-of-care (POC) devices are health professionals from a non-laboratory background, POC clinical analyzers should be designed as simple as possible for the operator and, at the same time, as well-controlled internally as possible. A key requirement in developing such a system is having a total quality assurance (QA) program with capability to detect errors during each stage of the testing process, that is, pre-analytical, analytical and post analytical. The Intelligent Quality Management (iQM) in the GEM analyzers for measurement of blood gases, electrolytes, metabolites and CO-Oximetry is an example of such comprehensive QA program. The primary method of error detection in iQM is based on monitoring sensor baseline drift by process control solutions and using drift limit as control parameter for detecting errors caused by patient blood samples. The source of error, such as interfering substances and blood clots, is detected through identifying specific known patterns in the sensor baseline drift.

In this paper, we describe application of a new sensor response pattern check during sample measurement for enhancing and expediting error detection capabilities of iQM. The methodology is based on fitting a multitude of sensor response readings to a logarithmic polynomial function for determining the fit coefficients. The magnitude of the fit coefficients is being used as an indicator of the sample response shape and detecting analyte errors by identifying abnormality in the response pattern.

MATERIALS AND METHODS

Sensor outputs during sample exposure in the GEM® Premier 4000 analyzer (Instrumentation Laboratory, Bedford, MA) were collected at one second intervals and the response from 15 to 30 seconds was fit to a second degree logarithmic polynomial. A linear logarithmic fit was used for the electrolytes. For calculating the fit coefficients, outliers in the sensor response data were identified by studentized residual technique and removed.

RESULTS

Response patterns for blood gases, electrolytes and metabolites from about 1,500 samples obtained from multitude of cartridges in a test version of the GEM Premier 4000 analyzer covering the reportable range of the analytes were used in establishing the mean and standard deviations (SD) of the fit coefficients. Normal sample response patterns were set based on the fit coefficients being within normal distribution around its mean. Analyte results with fit coefficient lie several SD's (4-6) outside of the normal range were found to be deviating from their target values, mostly exceeding the recommended total allowable error ("Estimation of total analytical error for clinical laboratory methods", CLSI EP21-A 2003). Although occurrence frequency of these detected outliers was very low (around 0.1%), the response pattern check was selective enough to identify them without generating excessive false flags. The sample pattern check was very effective in detecting random transient errors like air bubble hang-ups on sensors that normally do not get detected by iQM process control solution drift checks.

CONCLUSION

This study demonstrated the effectiveness of the sample response pattern check in complementing and enhancing existing iQM error detection in the GEM system. The new checks could expedite detection of certain transient errors to the time of measuring and before reporting sample result.