Instrument Reproducibility & Accuracy Checks

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Principle

Sound laboratory practice requires full characterization of each test/method/instrument system before its use in patient testing, without regard to when the test was first introduced by a given laboratory. The laboratory must have data on accuracy and precision prior to the test or instrument implementation. There are other circumstances that warrant this type of checking. All automated systems can experience performance issues from time to time and if warranted, will be checked for reproducibility and accuracy. This can be accomplished by running 10 replicates of a sample, with a known concentration, consecutively on the analyzer. The Mean, Standard Deviation and Coefficient of Variation will then be calculated and recorded.

Reproducibility

Within Run

To verify that the reproducibility is within acceptable limits, the obtained CV must be within a designated acceptable limit. Whenever applicable, this limit is taken from the manufacturer's specifications for the system and analyte in question. If this is unavailable, the limit will be set to the average CV of CAP proficiency testing respondents for that particular analyte on that particular analyzer.
If the CV falls outside the acceptable limits, the data should be reviewed for either typographical errors, or system errors, such as evaporation. If the failure is attributable to one of these, the samples may be reanalyzed. If this is not the cause of the problem, the analyzer should be checked. All appropriate routine maintenance and routine troubleshooting should be performed at this point. The specimens should then be repeated, and a new CV calculated. Finally, if the results still do not meet the specified guidelines, Field Service for the analyzer may be required.

Between Runs

This can be accomplished by the monthly evaluation of QC data points and the resulting CV, which is observed. This CV will be compared to peer data, when available. If the results of the data are outside our peer or acceptable range, the issue will be investigated.

Accuracy

The mean of the data points that were run are then compared to the absolute concentration for the analyte. The mean must be within the range either established internally or suggested by the manufacturer of the material. If this is not the case, appropriate troubleshooting mechanisms as listed above, should be followed.

Since it is not practical, precision and accuracy for all analytes is only determined during implementation of a new assay, or in the case of instrument failure with suspected issues related to precision. This can be accomplished by analyzing 10 replicates of QC material of a known concentration consecutively on each pipetting system (AU 480/680/5812 analyzers, Siemens XP, Beckman Access, and Diasorin instruments). The Tosoh does not require specific dilutions to be made therefore this policy does not apply to this instrument.
If results fall outside of manufacturer's recommendation, testing should be suspended, and appropriate troubleshooting and maintenance should be performed, and reproducibility repeated until results are acceptable.