

Calibration Verification/Linearity Summary Report for ABC Laboratory

AUDIT Product No.: K701M-5

Lot No.: 06301

Expiration Date: 08/19/13

Testing Performed: 11/11/11

Calibration verification means testing materials of known concentration in the same manner as patient specimens to assure the test system is accurately measuring samples throughout the reportable range and should be performed every six (6) months (or more frequently if specified in the test system's instructions) and whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers, **unless** the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
- There is major preventive maintenance or replacement of critical parts that may influence the test's performance. This includes when the laboratory sends a test system to the manufacturer for repairs. The laboratory must check the calibration of a repaired test system before resuming patient testing and reporting results.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.
- The laboratory has determined that the test system's reportable range for patient test results should be checked more frequently.

Calibration verification/Linearity – Reportable Range

The slope must fall between 0.95 and 1.05. The mean of x versus y must fall within 10% of one another. The correlation coefficient should be greater than 0.90.

ABC laboratory has performed calibration verification/linearity on their INSERT NAME analyzer on 11/11/11 for all analytes performed in the laboratory. Based on review of all the data and manufacturer's recommendation, the data meets the necessary requirements for successful calibration verification/linearity for all but the following analytes:

(LIST FAILED ANALYTES HERE OR STATE "N/A" OR "NONE")

It is recommended that you take action by repeating calibration verification/linearity or recalibrate any analytes shown to be deficient above.

Reviewed by: _____

Date: _____

Deborah Sumner, Technical Consultant
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