

DILUTION PROTOCOL

As is the case with some chemistry and immunoassay analyzers, in order to reach certain levels with the AUDIT® MicroControls™ Calibration Verification/Linearity Sets, it may be necessary to dilute specific levels of one or more of the products. The following protocol describes the steps for making such a dilution to achieve values between specific levels.

Each of the AUDIT® MicroControls™ Calibration Verification/Linearity Sets is manufactured according to GMP standards and follows the Clinical and Laboratory Standards Institute (formerly NCCLS) document EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. Since each level of AUDIT® MicroControls™ Calibration Verification/Linearity Sets is of a known value and equidistant from each other, dilutions can be made of Levels A through E in order to obtain a desired concentration.

For example, if Level A is too low for the analyzer to measure, the end user can simply make a dilution of Level B in order to challenge the lower limit of the analyzer.

Analyzer ABC is capable of reading glucose down to 10 mg/dL.

The concentration for glucose for Level A of the AUDIT® MicroControls™ General Chemistry Calibration Verification/Linearity Set is 5 mg/dL and is too low for the analyzer to read. The concentration for Level B is 20 mg/dL.

The end user could then make a 1:1 dilution (equal parts of Level B reconstituted material and deionized or distilled water) in order to obtain a value at the lower end of the analyzer's reportable range or analytical measurement range (AMR), the theoretical recovery value for the diluted material should be 10 mg/dL.

This Dilution Protocol may be used for most of the AUDIT® MicroControls™ Calibration Verification/Linearity Sets in order to obtain desired values between specific levels of material.

For more information, please contact our technical support team at (866) 252-8348.