



Audit® MicroCV™ Ammonia/Ethanol Linearity Set

Cat. No. **K712M-5**
Contents 5 x 2 mL

Lot No. 06093A, 06093B, 06093C,
06093D, 06093E

Expires 3/19/10

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit® MicroCV™ Ammonia/Ethanol Linearity Set consists of five levels of a liquid protein (bovine) based solution. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments¹.

This product may also be used as unassayed quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. In addition, it may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification² for these same analytes in accordance with current CLIA-88 guidelines and regulations³.

SUMMARY AND PRINCIPLE

As defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC), each laboratory must revalidate each test method's AMR at least every six months as well as following changes in lots of analytically critical reagents or major system components¹. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit® MicroCV™ Ammonia/Ethanol Linearity Set may be used as one would use human serum to verify and validate the AMR.

WARNINGS AND PRECAUTIONS

This product contains 0.3% thimerosal. Heavy metals will interfere with the assay's reaction in certain ammonia reagent test kits by inhibiting GLDH (glutamate dehydrogenase).

Audit® MicroCV™ Ammonia/Ethanol Linearity Set is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

STORAGE AND STABILITY

Audit® MicroCV™ Ammonia/Ethanol Linearity Set is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be used according to the instrument manufacturer's instructions.

It is recommended that Audit® MicroCV™ Ammonia/Ethanol Linearity Set be used within two days after puncturing the septum and stored at 2-8°C. Leaving the vial for a prolonged period of time at room temperature will void this stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for verifying and validating the AMR. Verify that the lot number on each vial matches the package insert. To avoid evaporation, do not leave the vial uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Calibration verification linearity material should be run⁴:

1. every six (6) months.
2. when a complete change of reagents for a procedure is introduced.
3. when there is major preventive maintenance or replacement of critical parts that may influence test performance.
4. when control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits.
5. when the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

Materials provided

- Audit® MicroCV™ Ammonia/Ethanol Linearity Set, 5 x 2 mL

INSTRUCTIONS FOR USE

1. Remove a vial from the package. Do not shake. Do not mix mechanically.
2. Insert the needle of a syringe into the septum of the vial for sample transfer.
3. Refer to instrument or assay instruction manual for verifying and validating the AMR.
4. After sampling, return to original package at 2-8°C to obtain the maximum open vial stability.

CALCULATIONS OF RESULTS

Each set of Audit® MicroCV™ Ammonia/Ethanol Linearity Set is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation² for preparing linearity sets.

Once each vial of the total set is tested, raw data may be entered via the AUDITOR™ QC Program at www.auditmicro.com. An on-line graph showing actual values versus predicted values for each analyte is then available to print, along with slope and intercept data. Call (866) 25-AUDIT for more information.

LIMITATIONS OF THE PROCEDURE

Make sure that each vial is brought to room temperature before testing. If the contents of any of the vials become frozen, discard all vials and request a replacement set, as the results will not be valid. If the diluent becomes cloudy, do not use as bacterial contamination may be suspected.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. The analyte concentrations in this insert were derived from multiple replicate analyses. Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte. The material and information presented here in no manner constitutes an overruling of any federal, state or other regulatory body's regulations and/or guidelines.

¹Dilution schemes are based on guidelines provided by The National Committee for Clinical Laboratory Standards (NCCLS) in approved guideline EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", April 2003.

²Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; p.3691.

³Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.2.

⁴Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1255, (b) (1) (ii).

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K712M-5	Audit [®] MicroCV [™] Ammonia/Ethanol Linearity Set	5 x 2 mL

Analytes Include:

	Units	A	B	C	D	E
Ammonia	umol/L	30	172	301	436	571
Ethanol	mg/dL	2	139	275	413	542