



Audit™ MicroCV™ Homocysteine Linearity Set

Cat. No. **K704M-5**
Contents 5 x 1mL

Lot No. 03340A, 03340B, 03340C,
03340D, 03340E

Expires 11/20/05

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit™ MicroCV™ Homocysteine Linearity Set is unassayed calibration verification material consisting of human serum based solutions. It is intended to simulate human patient serum samples for the purpose of verifying and validating the analytical measurement range (AMR) for non-waived Homocysteine testing methods.

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™ Homocysteine Linearity Set may be used as one would use human serum to verify and validate the AMR.

REAGENTS

Audit™ MicroCV™ Homocysteine Linearity Set is an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human serum matrix.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Audit™ MicroCV™ Homocysteine 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™ Homocysteine Linearity Set is stored at 2-8°C and will remain stable in the unopened vial for twenty-four months from the date of manufacture. After opening, the contents should be used according to the instrument manufacturer's instructions.

When used for the purpose of verifying and validating the analytical measurement range (AMR) for moderately complex Homocysteine testing methods, it is recommended that Audit™ MicroCV™ Homocysteine Linearity Set be used within 5 days after opening, storing tightly capped at 2-8°C. Leaving the vial uncapped, or prolonging its time at room temperature, will void this open vial 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 analytical measurement range. Verify that the lot number on each vial matches the assay sheet. To avoid evaporation, do not leave the vial uncapped. Calibration verification linearity material should be run¹:

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™ Homocysteine Linearity Set, 5 x 1mL

INSTRUCTIONS FOR USE

1. Remove a vial from the package and gently swirl. Do not shake. Do not mix mechanically.
2. Refer to instrument or assay instruction manual for verifying and validating the analytical measurement range.
3. After sampling, replace stopper and return to original package for maximum open vial stability at 2-8°C.

CALCULATIONS OF RESULTS

Each set of Audit™ MicroCV™ Homocysteine 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. Using this method of dilution, Levels A and E are prepared. Once done, Levels B, C and D are prepared by combining Level A and E as follows:

Level B is a mixture of three parts of Level A and one part of Level E.
Level C is a mixture of two parts of Level A and two parts of Level E.
Level D is a mixture of one part of Level A and three parts of Level E.

Values can be determined using the recovered values for Levels A and E. Using this method, the following formula applies:

Level B = 0.75 (Level A) + 0.25 (Level E)
Level C = 0.5 (Level A) + 0.5 (Level E)
Level D = 0.25 (Level A) + 0.75 (Level E)

LIMITATIONS OF THE PROCEDURE

Audit™ MicroCV™ Homocysteine Linearity Set is not intended for use as routine quality control material or as calibration material.

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.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. 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.

ORDERING INFORMATION

<u>Product Number</u>	<u>Product Description</u>	<u>Product Packaging</u>
K704M-5	Audit™ MicroCV™ Homocysteine Linearity Set	5 x 1mL

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

²Dilution 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.