



Audit™ MicroCV™ Tumor Markers Linearity Set

Cat. No. **K719M-5**
Contents 5 x 1mL

Lot No. 06068A, 06068B, 06068C,
06068D, 06068E

Expires 8/23/09

For In Vitro Diagnostic Use Only.

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INTENDED USE

Audit™ MicroCV™ Tumor Markers Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA 125, CA 15-3, Free prostatic acid phosphatase (PSA), Total prostatic acid phosphatase (PSA). 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 analytical measurement range (AMR) at least every six months as well as following changes in lots of analytically critical reagents or major system components⁴. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit™ MicroCV™ Tumor Markers Linearity Set may be used as one would use human serum to verify and validate the AMR.

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™ Tumor Markers 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™ Tumor Markers 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 reconstituted immediately and used according to the instrument manufacturer's instructions.

When used for the purpose of verifying and validating the AMR for non-waived tumor marker testing methods, it is recommended that Audit™ MicroCV™ Tumor Markers Linearity Set be used within seven days after reconstitution when stored tightly capped at 2-8°C. Leaving the vial uncapped, or prolonging its time at room temperature, will void this reconstituted stability claim. Make sure the contents of the vial are well mixed before use.

PROCEDURE

Follow the manufacturer's instructions provided for quality control and 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. CLIA directed 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™ Tumor Markers Linearity Set, 5 x 1mL

INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with 1ml of deionized water, and gently swirl occasionally for 10 minutes. Do not shake. Do not mix mechanically.
2. Refer to instrument or assay instruction manual for verifying and validating the AMR.
3. After sampling, replace stopper and return to original package at 2-8°C to obtain the maximum seven-day reconstituted stability.

CALCULATIONS OF RESULTS

Each set of Audit™ MicroCV™ Tumor Markers 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.

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.

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) (i).

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.

ORDERING INFORMATION

Product Number	Product Description	Product Packaging
K719M-5	AUDIT MicroCV Tumor Markers Linearity Set	5 x 1mL

	UNITS	A	B	C	D	E
AFP	ng/mL	2.5	83	163	243	323
CEA	ng/mL	1.6	316	630	944	1258
CA 125	U/mL	6.8	289	572	854	1137
CA 15-3	U/mL	12	192	372	552	732
Free PSA	ng/mL	0	5.1	10.2	15.3	20.4
Total PSA	ng/mL	0.03	10	20	30	40