



## Audit™ MicroCV™ D-Dimer Linearity Set (Low)

Cat. No. **K717M-5**  
Contents 5 x 1mL

Lot No. 06017A, 06017B, 06017C,  
06017D, 06017E

Expires 05/16/07

For In Vitro Diagnostic Use Only.

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### INTENDED USE

Audit™ MicroCV™ D-Dimer Linearity Set (Low) is unassayed calibration verification material consisting of human plasma based solutions. It is intended to simulate human patient plasma samples for the purpose of verifying and validating the analytical measurement range (AMR) for moderately complex D-Dimer 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 components<sup>1</sup>. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit™ MicroCV™ D-Dimer Linearity Set (Low) may be used as one would use human plasma to verify and validate the AMR.

### REAGENTS

Audit™ MicroCV™ D-Dimer Linearity Set (Low) is an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human plasma matrix.

### WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each plasma, 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.

Audit™ MicroCV™ D-Dimer Linearity Set (Low) 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™ D-Dimer Linearity Set (Low) 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.

When used for the purpose of verifying and validating the AMR for non-waived D-Dimer testing methods, it is recommended that Audit™ MicroCV™ D-Dimer Linearity Set (Low) be used within 48 hours after reconstitution, 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 run<sup>1</sup>:

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™ D-Dimer Linearity Set (Low), 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 while keeping the contents at 2-8°C. Do not shake. Do not mix mechanically.
2. Continue to mix the vial contents by gentle swirling and inversion for an additional 10 minutes, allowing the contents to be completely dissolved, while keeping the contents at 2-8°C.
3. Refer to instrument or assay instruction manual for analyzing control material.
4. 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™ D-Dimer Linearity Set (Low) is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation<sup>2</sup> 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](http://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

Audit™ MicroCV™ D-Dimer Linearity Set (Low) 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.

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

<sup>2</sup>Dilution 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.

**ORDERING INFORMATION**

| Product Number | Product Description                         | Product Packaging |
|----------------|---|-------------------|
| K717M-5        | Audit™ MicroCV® D-Dimer Linearity Set (Low) | 5 x 1mL           |

**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.

Analytes include:

|         | A        | B          | C          | D          | E          |
|---------|----------|------------|------------|------------|------------|
| D-Dimer | 70 ng/mL | 1321 ng/mL | 2417 ng/mL | 3728 ng/mL | 5256 ng/mL |