Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP, UCH-L1)

REF **K846M-10**

10 x 1 mL

LOT 07099

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2025-10-19

ENGLISH

INTENDED USE

The Audit® MicroControls™ Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) is intended to simulate human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for the following analytes: GFAP, UCH-L1. This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit® MicroControls™ Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP, UCH-L1) should not be used for calibration or standardization of the GFAP, UCH-L1 assays. The Audit® MicroControls™ Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP, UCH-L1) is for In Vitro Diagnostic use only.

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[2]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) may be used as one would use human blood 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.

Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP, UCH-L1) 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.

Warning: H317
May cause an allergic skin reaction

Contains 2-methyl-2H-isothiazol-3-one and N,N′-Dimethylthiourea. Avoid breathing dust/fume/gas/mist/vapors/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Harmful to aquatic life with long lasting effects. Dispose of contents/container to an approved waste disposal plant. Safety Data Sheet (SDS) available for professional users at *www.auditmicro.com*

Instability or degradation should be suspected if, after reconstitution, there are visible precipitates, or if the material will not reconstitute. If this occurs, the product should not be used.

MATERIALS PROVIDED

The Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) is an IVD device consisting of 10 levels (2 sets of 5 levels) of freeze dried material and additives in human serum, bovine serum albumin.

Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI Set 1 (GFAP), 5 x 1 mL

Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI Set 2 (UCH-L1), 5 x 1 mL

STORAGE AND STABILITY

Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) is stored at 2-8C and will remain stable in the unopened bottle until the expiration date. Do not store in a frost-free freezer. After reconstituting, the contents should be used according to the instrument manufacturer's instructions and stored at 2-8C for 48 hours.

PROCEDURE

Follow the manufacturer's instructions provided for quality control and for verifying and validating the AMR. Verify that the lot number on each bottle matches the package insert. To avoid evaporation, do not leave the bottle 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 run[3]:

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.

INSTRUCTIONS FOR USE

1. Remove a vial from the package.
2. Using a pipette, reconstitute the product with 1 mL of deionized water.
3. Allow the vial to sit at room temperature for 5 minutes.
4. Occasionally swirl for 15 minutes, or until all visible material is dissolved. Do not shake. Do not mix mechanically. Avoid getting any undissolved material on the sides of the vial or the stopper.
5. When all visible solid material is dissolved, invert several times to dissolve any material on the stopper.
6. Swirl occasionally for at least 5 minutes.
7. Use within 10 minutes or store at the appropriate temperature.

CALCULATIONS OF RESULTS

Each set of Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the CLSI recommendation[1] for preparing linearity sets.

Once each bottle 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

This product is intended for use with quantitative assays on the indicated analyzer provided in this package insert.

The Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1) should not be used for calibration or standardization of GFAP, UCH-L1 assays.

Target values and ranges are intended only as guidelines. Laboratories should determine ranges based on their own test system and tolerance limit.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

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. 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
K846M-10	Linearity FD GFAP, UCH-L1 for bioMérieux VIDAS® TBI (GFAP. UCH-L1)	10 x 1 mL

Distributed by AUDIT® MicroControls™, Inc. - please call (866) 252-8348 or visit www.auditmicro.com

[1] Dilution schemes are based on guidelines provided by The Clinical and Laboratory Standard Institute (CLSI) in approved guideline EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline", April 2003.

[2] Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; p.3690.

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

Set 1							
	Instrument	Units	A	B	C	D	E
GFAP	bioMerieux, VIDAS 3	pg/mL	16.2	80.1	144	212	288

Set 2							
	Instrument	Units	A	B	C	D	E
UCHL1	bioMerieux, VIDAS 3	pg/mL	85.9	604	1118	1687	2219

REF Catalog Number

IVD For In Vitro Diagnostic Use

Use By (YYYY-MM-DD)

LOT Lot Number

Caution

www.auditmicro.com/inserts

2 – 8°C Temperature Limit

Manufactured By

INS288 REV: 001
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