# Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP)

REF K853M-20

20 x 0.5 mL

LOT 07170

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2027-10-06

## ENGLISH

### INTENDED USE

The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is intended for verifying proper installation of the bioMérieux VIDAS® test. The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is intended exclusively for evaluating the bioMérieux VIDAS® test system performance characteristics during initial instrument installation, without examining or interacting with human-derived specimens. The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is not intended to inform any clinical or diagnostic outcome or provide any influence in the medical decision-making process.

The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is only intended to be used during installation and is not intended to be used in routine quality control procedures. The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is not intended to be used for calibration/standardization, calibration verification, and/or determining the linearity of the bioMérieux VIDAS® test system. Control materials intended for the aforementioned uses are provided separately.

### 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 demonstrate that it can obtain performance specifications for an FDA-cleared or approved test system comparable to those established by the manufacturer for accuracy, precision and reportable range of test results for the test system[1]. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) may be used as one would use human serum to verify these performance specifications.

### 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.

Warning: H317
May cause an allergic skin reaction

Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Dispose of contents with local, state, federal and international regulations. Safety Data Sheet (SDS) available for professional users at www.auditmicro.com

Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) is intended solely for the purpose described on the label. AUDIT® MicroControls™, Inc. will not be liable for any unclaimed damages arising from any other usage.

### MATERIALS PROVIDED

The Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) consists of 20 levels of freeze dried material and additives in human serum.

Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP), 20 x 0.5 mL

### STORAGE AND STABILITY

The AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) 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 and immediately returned to 2-8°C.

When used to monitor the precision of laboratory testing procedures for its assays, the AUDIT® MicroControls™ Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) has a reconstituted stability of up to 48 hours under the proper storage conditions. 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 establishing and verifying performance specifications for accuracy, precision and reportable range of test results for the test system. 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. Method Validation material should be run:

1. before the introduction of a new test system into routine use
2. whenever conditions change for which a method has been validated, e.g., an instrument change with different characteristics
3. whenever the method is changed and the change is outside the original scope of the method.

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

0.5 mL DI $H_2O$ Reconstitute With



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**INSTRUCTIONS FOR USE**

1. Remove a vial from the package.
2. Using a pipette, reconstitute the product with 0.5 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.

**THE VIAL SHOULD REMAIN STORED AT 2-8°C AT ALL TIMES. IF ADDITIONAL SAMPLING IS NECESSARY, THE TIME OUTSIDE OF 2-8°C STORAGE SHOULD BE MINIMIZED.CALCULATIONS OF RESULTS**

Refer to the manufacturer's instructions and guidelines for reporting data for the analysis of the test system's method validation studies.

**LIMITATIONS OF THE PROCEDURE**

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

The Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) should not be used for calibration or standardization of GFAP 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**

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 |
|---|---|---|
| K853M-20 | Method Val FD GFAP for bioMérieux VIDAS® TBI (GFAP) | 20 x 0.5 mL |

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[1]Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1253, (b)(1)(i)(A), (b)(1)(i)(B) and (b)(1)(i)(C).

| GFAP | | | |
|---|---|---|---|
| Level | **Instrument** | **Units** | **Value** |
| **1** | bioMerieux, VIDAS 3 | pg/mL | 15.8 |
| **2** | bioMerieux, VIDAS 3 | pg/mL | 28.1 |
| **3** | bioMerieux, VIDAS 3 | pg/mL | 41.9 |
| **4** | bioMerieux, VIDAS 3 | pg/mL | 56.8 |
| **5** | bioMerieux, VIDAS 3 | pg/mL | 70.8 |
| **6** | bioMerieux, VIDAS 3 | pg/mL | 86.3 |
| **7** | bioMerieux, VIDAS 3 | pg/mL | 98.8 |
| **8** | bioMerieux, VIDAS 3 | pg/mL | 106 |
| **9** | bioMerieux, VIDAS 3 | pg/mL | 123 |
| **10** | bioMerieux, VIDAS 3 | pg/mL | 137 |
| **11** | bioMerieux, VIDAS 3 | pg/mL | 155 |
| **12** | bioMerieux, VIDAS 3 | pg/mL | 174 |
| **13** | bioMerieux, VIDAS 3 | pg/mL | 186 |
| **14** | bioMerieux, VIDAS 3 | pg/mL | 199 |
| **15** | bioMerieux, VIDAS 3 | pg/mL | 217 |
| **16** | bioMerieux, VIDAS 3 | pg/mL | 232 |
| **17** | bioMerieux, VIDAS 3 | pg/mL | 250 |
| **18** | bioMerieux, VIDAS 3 | pg/mL | 261 |
| **19** | bioMerieux, VIDAS 3 | pg/mL | 273 |
| **20** | bioMerieux, VIDAS 3 | pg/mL | >320 |



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