Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1)

REF K852M-20

20 x 0.5 mL

LOT 07100

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2026-10-21

ENGLISH

INTENDED USE

The Audit® MicroControls™ Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) is intended for verifying proper installation of the bioMérieux VIDAS® test. The Audit® MicroControls™ Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) may be used as one would use human serum to verify these performance specifications.

WARNINGS AND PRECAUTIONS

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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) consists of 20 levels of freeze dried material and additives in bovine serum albumin.

Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1), 20 x 0.5 mL

STORAGE AND STABILITY

The AUDIT® MicroControls™ Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) 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.

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.
8. 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.

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

INS293 REV: 001
2024-12-10

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 UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1) should not be used for calibration or standardization of 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

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
K852M-20	Method Val FD UCH-L1 for bioMérieux VIDAS® TBI (UCH-L1)	20 x 0.5 mL

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

BIOMÉRIEUX, the BIOMÉRIEUX logo, and VIDAS are used, pending and/or registered trademarks belonging to bioMérieux or one of its subsidiaries.

[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).

UCH-L1			
Level	**Instrument**	**Units**	**Value**
1	Biomérieux, VIDAS	pg/mL	84.9
2	Biomérieux, VIDAS	pg/mL	163
3	Biomérieux, VIDAS	pg/mL	227
4	Biomérieux, VIDAS	pg/mL	315
5	Biomérieux, VIDAS	pg/mL	430
6	Biomérieux, VIDAS	pg/mL	485
7	Biomérieux, VIDAS	pg/mL	602
8	Biomérieux, VIDAS	pg/mL	710
9	Biomérieux, VIDAS	pg/mL	813
10	Biomérieux, VIDAS	pg/mL	903
11	Biomérieux, VIDAS	pg/mL	996
12	Biomérieux, VIDAS	pg/mL	1133
13	Biomérieux, VIDAS	pg/mL	1220
14	Biomérieux, VIDAS	pg/mL	1270
15	Biomérieux, VIDAS	pg/mL	1398
16	Biomérieux, VIDAS	pg/mL	1458
17	Biomérieux, VIDAS	pg/mL	1577
18	Biomérieux, VIDAS	pg/mL	1609
19	Biomérieux, VIDAS	pg/mL	1815
20	Biomérieux, VIDAS	pg/mL	2019