Control FD Traumatic Brain Injury (TBI)

REF K083M-8

8 x 2 mL

LOT 07112

Aalto Scientific Ltd
230 Technology Pkwy
Eatonton, GA 31024
USA

IVD

2027-10-03

INTENDED USE

The Audit® MicroControls™ Control FD Traumatic Brain Injury (TBI) is assayed quality control material intended to simulate human patient samples for the purpose of monitoring the precision of immunoassays for the following analyte(s): GFAP, UCH-L1. This product is intended for use with quantitative assays on the indicated analyzer provided in the labeling. The Audit® MicroControls™ Control FD Traumatic Brain Injury (TBI) should not be used for calibration or standardization of the GFAP, UCH-L1 assays. The Audit® MicroControls™ Control FD Traumatic Brain Injury (TBI) is for In Vitro Diagnostic use only.

SUMMARY AND PRINCIPLE

Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Control FD Traumatic Brain Injury (TBI) may be used as one would use human serum to obtain the stated GFAP, UCH-L1 values. This control will assist in the evaluation of proper performance of GFAP, UCH-L1 assays.

REAGENTS

Control FD Traumatic Brain Injury (TBI) is prepared using human serum, bovine serum albumin with purified GFAP, UCH-L1 added to achieve the desired concentration levels. Control FD Traumatic Brain Injury (TBI) is manufactured according to standard quality control procedures. The manufacturer guarantees stability and consistency of this product.

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.

Control FD Traumatic Brain Injury (TBI) 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.

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

Control FD Traumatic Brain Injury (TBI) Set 1 (GFAP), 4 x 2 mL

Control FD Traumatic Brain Injury (TBI) Set 2 (UCH-L1), 4 x 2 mL

STORAGE AND STABILITY

Control FD Traumatic Brain Injury (TBI) is stored at 2-8°C 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 in one of the following ways: at 20°C for up to 4 hours; at 2-8°C for up to 48 hours; or at -20°C or colder for up to 1 month.

PROCEDURE

Follow the manufacturer's instructions provided for GFAP, UCH-L1 procedures. Verify that the lot number on the vial matches the assay sheet. To avoid evaporation, do not leave the vial uncapped. Controls should be run periodically according to the local rules or based on risk management approach. When based on the risk management approach, the frequency must be at minimum compliant with the applicable local regulations or practices.

INSTRUCTIONS FOR USE

For laboratory professional use only.

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

EXPECTED VALUES

The performance range for each level, based on data by combining estimates of assay variance as determined by participating laboratories using approved FDA instruments and reagents, is provided below. Average values obtained in the laboratory should fall within the performance range although the recovery may not be identical with the mean value listed. Variation between labs will be greater than the precision for any one instrument. Accuracy and precision depend on differences in equipment, reagents, supplies and techniques. Therefore, a lab must establish its own acceptable target values and ranges.

LIMITATIONS OF PROCEDURE

The Control FD Traumatic Brain Injury (TBI) should not be used for calibration or standardization of the GFAP, UCH-L1 assays.

REF Catalog Number

IVD For In Vitro Diagnostic Use

Use By (YYYY-MM-DD)

LOT Lot Number

Caution

www.auditmmicro.com/inserts

2 – 8°C Temperature Limit

Manufactured By

2.0 mL DI H_2O Reconstitute With

2025-12-17
INS299 REV: New

ORDERING INFORMATION

PRODUCT NUMBER	PRODUCT DESCRIPTION	PRODUCT PACKAGING
K083M-8	Control FD Traumatic Brain Injury (TBI)	8 x 2 mL

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

Set 1 - GFAP				
Reagent, Instrument	**Level 1, 07112-1**	**Level 1 Range**	**Level 2, 07112-2**	**Level 2 Range**
Abbott, Alinity I	**15.4**	**12.3 - 18.5**	**116**	**93 - 139**

Set 2 - UCHL1				
Reagent, Instrument	**Level 1, 07112-11**	**Level 1 Range**	**Level 2, 07112-22**	**Level 2 Range**
Abbott, Alinity I	**759**	**607 - 911**	**2369**	**1895 - 2843**

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INS299 REV: New