



CONFIDENTIAL
FORM 192
CERTIFICATE OF ANALYSIS (SOPQ-0091)

Form No: **192**
Rev No: **002**
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PRODUCT QUALITY ASSURANCE REPORT

Control FD-GFAP, UCH-L1 for bioMerieux VIDAS TBI (GFAP, UCH-L1) Set 1 Level 1

Lot Number: 240737AA

Date: 11/27/24

Aalto Part Number:

21369

Audit Part Number:

K089M-8

Audit Lot Number:

07055A-1

Date of Manufacture:

08/20/24

Expiration Date:

2025-10-20

FILL SIZE

2 mL

GFAP

14.2 pg/mL

By BioMerieux, VIDAS

Microbial Growth

< 100 CFU/mL

48 hours @ 37 °C

Reconstituted Stability

< 10 % loss

4 hours after reconstitution @ 20 °C

Reconstituted Stability

< 10 % loss

48 hours after reconstitution @ 2-8 °C

Reconstituted Stability

< 10 % loss

1 months after reconstitution @ -20 °C

Freeze/Thaw Stability

< 10 % loss

5 freeze-thaw cycles @ -20 °C

RECOMMENDED STORAGE:

2 - 8 °C

Aalto Scientific, Ltd. certifies that the bovine serum albumin used to manufacture this lot was obtained from cattle that have received ante and post mortem health inspections from US Veterinary Service Inspectors within facilities inspected by the US Department of Agriculture.

Aalto Scientific, Ltd. Certifies that all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to be nonreactive for HbsAg, HIV-1, HIV-2, and HCV.

Compiled by:

Date: 11/27/24

Reviewed by:

Date: 11/27/24

Rev: (New)

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING



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PRODUCT QUALITY ASSURANCE REPORT

Control FD GFAP, UCH-L1 for bioMerieux VIDAS TBI (GFAP, UCH-L1) Set 1 Level 2

Lot Number: 240738AA

Date: 11/27/24

Aalto Part Number: 21370

Audit Part Number: K089M-8

Audit Lot Number: 07055A-2

Date of Manufacture: 08/20/24

Expiration Date: 2025-10-20

FILL SIZE 2 mL

GFAP 140.4 pg/mL

By BioMerieux, VIDAS

Microbial Growth < 100 CFU/mL
48 hours @ 37 °C

Reconstituted Stability < 10 % loss
4 hours after reconstitution @ 20 °C

Reconstituted Stability < 10 % loss
48 hours after reconstitution @ 2-8 °C

Reconstituted Stability < 10 % loss
1 months after reconstitution @ -20 °C

Freeze/Thaw Stability < 10 % loss
5 freeze-thaw cycles @ -20 °C

RECOMMENDED STORAGE: 2 - 8 °C

Aalto Scientific, Ltd. certifies that the bovine serum albumin used to manufacture this lot was obtained from cattle that have received ante and post mortem health inspections from US Veterinary Service Inspectors within facilities inspected by the US Department of Agriculture.

Aalto Scientific, Ltd. Certifies that all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to be nonreactive for HbsAg, HIV-1, HIV-2, and HCV.

Compiled by:

Rachel Holton

Date: 11/27/24

Reviewed by:

[Signature]

Date: 11/27/24

Rev: (New)

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING