



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 2 Level 1

Lot Number: 240739AA

Date: 11/27/24

Aalto Part Number:

21371

Audit Part Number:

K089M-8

Audit Lot Number:

07055AA-1

Date of Manufacture:

08/20/24

Expiration Date:

2025-10-20

FILL SIZE--

2 mL

UCH-L1

309.7 pg/mL

By BioMerieux, VIDAS

Microbial Growth

< 100 CFU/mL

48 hours @ 37 °C

Reconstituted Stability

4 hours after reconstitution @ 20 °C

< 10 % loss

Reconstituted Stability

48 hours after reconstitution @ 2-8 °C

< 10 % loss

Reconstituted Stability

1 months after reconstitution @ -20 °C

< 10 % loss

Freeze/Thaw Stability

5 freeze-thaw cycles @ -20 °C

< 10 % loss

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:

Richard Holton

Date:

11/27/24

Reviewed by:

[Signature]

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 2 Level 2

Lot Number: 240740AA

Date: 11/27/24

Aalto Part Number:

21372

Audit Part Number:

K089M-8

Audit Lot Number:

07055AA-2

Date of Manufacture:

08/20/24

Expiration Date:

2025-10-20

FILL SIZE

2 mL

UCH-L1

1014.1 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

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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:

Ronald Holton

Date:

11/27/24

Reviewed by:

[Signature]

Date:

11/27/24

Rev: (New)

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