



CONFIDENTIAL
FORM 192
CERTIFICATE OF ANALYSIS (SOPQ-0091)

Form No: **192**

Rev No: **002**

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PRODUCT QUALITY ASSURANCE REPORT

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

Lot Number: 240699AA-1

Date: 11/12/24

Aalto Part Number:

21428

Audit Part Number:

K846M-10

Audit Lot Number:

07099A

Date of Manufacture:

08/19/24

Expiration Date:

2025-10-19

FILL SIZE

1 mL

GFAP

16.2 pg/mL

By BioMerieux, VIDAS 3

Microbial Growth

< 100 CFU/mL

48 hours @ 37 °C

Reconstituted Stability

48 hours after reconstitution @ 2-8 °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:

Date: 11-12-24

Reviewed by:

Date: 11/14/24

Rev: (New)

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING



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PRODUCT QUALITY ASSURANCE REPORT

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

Lot Number: 240699AA-2

Date: 11/12/24

Aalto Part Number:

21429

Audit Part Number:

K846M-10

Audit Lot Number:

07099B

Date of Manufacture:

08/19/24

Expiration Date:

2025-10-19

FILL SIZE

1 mL

GFAP

80.1 pg/mL

By BioMerieux, VIDAS 3

Microbial Growth

< 100 CFU/mL

48 hours @ 37 °C

Reconstituted Stability

48 hours after reconstitution @ 2-8 °C

< 10 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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Compiled by:

Date: 11-12-24

Reviewed by:

Date: 11/14/24

Rev: (New)

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PRODUCT QUALITY ASSURANCE REPORT

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

Lot Number: 240699AA-3

Date: 11/12/24

Aalto Part Number:

21430

Audit Part Number:

K846M-10

Audit Lot Number:

07099C

Date of Manufacture:

08/19/24

Expiration Date:

2025-10-19

FILL SIZE

1 mL

GFAP

By BioMerieux, VIDAS 3

143.9 pg/mL

Microbial Growth

48 hours @ 37 °C

< 100 CFU/mL

Reconstituted Stability

48 hours after reconstitution @ 2-8 °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.

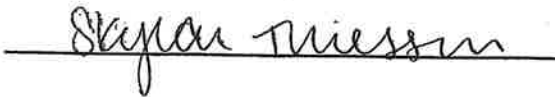
Aalto Scientific, Ltd. Certifies that all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to be nonreactive for HbsAg, HIV-1, HIV-2, and HCV.

Compiled by:



Date: 11-12-24

Reviewed by:



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PRODUCT QUALITY ASSURANCE REPORT

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

Lot Number: 240699AA-4

Date: 11/12/24

Aalto Part Number:

21431

Audit Part Number:

K846M-10

Audit Lot Number:

07099D

Date of Manufacture:

08/19/24

Expiration Date:

2025-10-19

FILL SIZE

1 mL

GFAP

By BioMerieux, VIDAS 3

211.8 pg/mL

Microbial Growth

48 hours @ 37°C

< 100 CFU/mL

Reconstituted Stability

48 hours after reconstitution @ 2-8 °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.

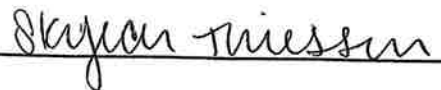
Aalto Scientific, Ltd. Certifies that all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to be nonreactive for HbsAg, HIV-1, HIV-2, and HCV.

Compiled by:



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PRODUCT QUALITY ASSURANCE REPORT

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

Lot Number: 240699AA-5

Date: 11/12/24

Aalto Part Number: 21432

Audit Part Number: K846M-10

Audit Lot Number: 07099E

Date of Manufacture: 08/19/24

Expiration Date: 2025-10-19

FILL SIZE 1 mL

GFAP 287.6 pg/mL

By BioMerieux, VIDAS 3

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

Reconstituted Stability < 10 % loss
48 hours after reconstitution @ 2-8 °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: [Signature] Date: 11-12-24

Reviewed by: [Signature] Date: 11/14/24
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