PRODUCT QUALITY ASSURANCE REPORT

Linearity FD GFAP, UCH-L1 for bioMerieux VIDAS TBI (GFAP, UCH-L1) Set 2 Level A

Lot Number: 240700AA-1	**Date: 11/13/24**
Aalto Part Number:	**21433**
Audit Part Number:	**K846M-10**
Audit Lot Number:	**07099AA**
Date of Manufacture:	**08/19/24**
Expiration Date:	**2025-10-19**
FILL SIZE	**1 mL**
UCH-L1 **By BioMerieux, VIDAS 3**	**85.9 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:** 11-13-24

Reviewed by: Stefan Thiessen **Date:** 11/14/24
Rev: (New)

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING

PRODUCT QUALITY ASSURANCE REPORT

Linearity FD GFAP, UCH-L1 for bioMerieux VIDAS TBI (GFAP, UCH-L1) Set 2 Level B

Lot Number: 240700AA-2	**Date: 11/13/24**
Aalto Part Number:	**21434**
Audit Part Number:2	**K846M-10**
Audit Lot Number:	**07099BB**
Date of Manufacture:	**08/19/24**
Expiration Date:	**2025-10-19**
FILL SIZE	**1 mL**
UCH-L1 **By BioMerieux, VIDAS 3**	**603.8 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**

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Compiled by: _____ **Date:** 11-13-24

Reviewed by: Stefan Thiessen **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 2 Level C

Lot Number: 240700AA-3	**Date: 11/13/24**
Aalto Part Number:	**21435**
Audit Part Number:	**K846M-10**
Audit Lot Number:	**07099CC**
Date of Manufacture:	**08/19/24**
Expiration Date:	**2025-10-19**
FILL SIZE	**1 mL**
UCH-L1 **By BioMerieux, VIDAS 3**	**1118.2 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**

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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: _____ **Date:** 11-13-24

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Rev: (New)

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PRODUCT QUALITY ASSURANCE REPORT

Linearity FD GFAP, UCH-L1 for bioMerieux VIDAS TBI (GFAP, UCH-L1) Set 2 Level D

Lot Number: 240700AA-4 **Date: 11/13/24**

Aalto Part Number:	**21436**
Audit Part Number:	**K846M-10**
Audit Lot Number:	**07099DD**
Date of Manufacture:	**08/19/24**
Expiration Date:	**2025-10-19**
FILL SIZE	**1 mL**
UCH-L1 **By BioMerieux, VIDAS 3**	**1687.0 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:** 11-13-24

Reviewed by: Stephen Thiessen **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 2 Level E

Lot Number: 240700AA-5 **Date: 11/13/24**

Aalto Part Number:	**21437**
Audit Part Number:	**K846M-10**
Audit Lot Number:	**07099EE**
Date of Manufacture:	**08/19/24**
Expiration Date:	**2025-10-19**
FILL SIZE	**1 mL**
UCH-L1 **By BioMerieux, VIDAS 3**	**2219.3 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:** 11-13-24

Reviewed by: Stefan Niessen **Date:** 11/14/24
Rev: (New)

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