



CONFIDENTIAL
FORM 192
CERTIFICATE OF ANALYSIS (SOP Q-0091)

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

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 1

Lot Number: 240860AA-1

Date: 11/22/24

Aalto Part Number:

21456

Audit Lot Number:

07101-1

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

13.9 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

Reviewed by:
Rev: (New)

[Signature]

Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 2

Lot Number: 240860AA-2

Date: 11/22/24

Aalto Part Number:

21457

Audit Lot Number:

07101-2

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

26.9 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

Reviewed by:
Rev: (New)

Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 3

Lot Number: 240860AA-3

Date: 11/22/24

Aalto Part Number:

21458

Audit Lot Number:

07101-3

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP
by Biomerieux, VIDAS

42.3 pg/mL

Microbial Growth
48 hours @ 37°C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

Reviewed by:
Rev: (New)



Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 4

Lot Number: 240860AA-4

Date: 11/22/24

Aalto Part Number:

21459

Audit Lot Number:

07101-4

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP

by Biomerieux, VIDAS

46.6 pg/mL

Microbial Growth
48 hours @ 37 °C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

Reviewed by:
Rev: (New)



Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 5

Lot Number: 240860AA-5

Date: 11/22/24

Aalto Part Number:

21460

Audit Lot Number:

07101-5

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP
by Biomerieux, VIDAS

60.1 pg/mL

Microbial Growth
48 hours @ 37 °C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

Reviewed by:
Rev: (New)



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 6

Lot Number: 240860AA-6

Date: 11/22/24

Aalto Part Number:

21461

Audit Lot Number:

07101-6

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

70.1 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 7

Lot Number: 240860AA-7

Date: 11/22/24

Aalto Part Number:

21462

Audit Lot Number:

07101-7

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

84.5 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

**Reviewed by:
Rev: (New)**

Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 8

Lot Number: 240860AA-8

Date: 11/22/24

Aalto Part Number:

21463

Audit Lot Number:

07101-8

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

99.5 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8 °C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 - 8 °C

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: 11/22/24

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Rev: (New)**



Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 9

Lot Number: 240860AA-9

Date: 11/22/24

Aalto Part Number:

21464

Audit Lot Number:

07101-9

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP
by Biomerieux, VIDAS

108.6 pg/mL

Microbial Growth
48 hours @ 37°C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

R. Hobson

Date: 11/22/24

Reviewed by:
Rev: (New)

[Signature]

Date: 11/26/24
11/26/24
KHA 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 10

Lot Number: 240860AA-10

Date: 11/22/24

Aalto Part Number:

21465

Audit Lot Number:

07101-10

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

114.1 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

**Reviewed by:
Rev: (New)**

Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 11

Lot Number: 240860AA-11

Date: 11/22/24

Aalto Part Number:

21466

Audit Lot Number:

07101-11

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP
by Biomerieux, VIDAS

141.3 pg/mL

Microbial Growth
48 hours @ 37°C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

Reviewed by:



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 12

Lot Number: 240860AA-12

Date: 11/22/24

Aalto Part Number:

21467

Audit Lot Number:

07101-12

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

148.3 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

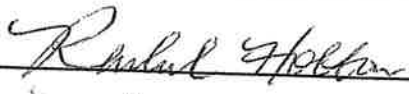
≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

**Reviewed by:
Rev: (New)**



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 13

Lot Number: 240860AA-13

Date: 11/22/24

Aalto Part Number:

21468

Audit Lot Number:

07101-13

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

159.8 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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: 11/22/24

Reviewed by:
Rev: (New)



Date: 11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 14

Lot Number: 240860AA-14

Date: 11/22/24

Aalto Part Number:

21469

Audit Lot Number:

07101-14

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

173.1 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8 °C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 - 8 °C

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:

11/22/24

Reviewed by:

Rev: (New)



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 15

Lot Number: 240860AA-15

Date: 11/22/24

Aalto Part Number:

21470

Audit Lot Number:

07101-15

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

183.9 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

**Reviewed by:
Rev: (New)**



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 16

Lot Number: 240860AA-16

Date: 11/22/24

Aalto Part Number:

21471

Audit Lot Number:

07101-16

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

211.7 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

Reviewed by:
Rev: (New)



Date:

11/26/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 17

Lot Number: 240860AA-17

Date: 11/27/24

Aalto Part Number:

21472

Audit Lot Number:

07101-17

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

219.2 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:
Rev: (New)



Date: 11/27/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 18

Lot Number: 240860AA-18

Date: 11/27/24

Aalto Part Number:

21473

Audit Lot Number:

07101-18

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

GFAP

by Biomerieux, VIDAS

228.1 pg/mL

Microbial Growth
48 hours @ 37 °C

<100 CFU/mL

Reconstituted Stability
48 hours @ 2-8°C

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

HA

Date: 11/27/24

Rev: (New)

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 19

Lot Number: 240860AA-19

Date: 11/22/24

Aalto Part Number:

21474

Audit Lot Number:

07101-19

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

241.5 pg/mL

**Microbial Growth
48 hours @ 37°C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 - 8 °C

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:

R. Michael Holton

Date:

11/22/24

Reviewed by:
Rev: (New)

[Signature]

Date:

11/26/24

CAUTION: FOR MANUFACTURING, PROCESSING, OR REPACKING

PRODUCT QUALITY ASSURANCE REPORT

Method Val FD GFAP bioMerieux VIDAS TBI (GFAP) Level 20

Lot Number: 240860AA-20

Date: 11/22/24

Aalto Part Number:

21475

Audit Lot Number:

07101-20

Audit Part Number:

K853M-20

Date of Manufacture:

10/21/24

Expiration Date:

2025-12-21

RECONSTITUTION with deionized water:

0.5 mL

**GFAP
by Biomerieux, VIDAS**

265.4 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

**Reconstituted Stability
48 hours @ 2-8°C**

≤ 15 % loss

RECOMMENDED STORAGE:

2 – 8 °C

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:

11/22/24

**Reviewed by:
Rev: (New)**



Date:

11/26/24

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