



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 UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 1

Lot Number: 240861AA-1

Date: 12/02/24

Aalto Part Number:

21477

Audit Lot Number:

07100-1

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

84.9 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:

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

Date:

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 2

Lot Number: 240861AA-2

Date: 12/02/24

Aalto Part Number:

21478

Audit Lot Number:

07100-2

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

163.3 pg/mL

**Microbial Growth
48 hours @ 37 °C**

<100 CFU/mL

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

≤ 15 % loss

RECOMMENDED STORAGE:

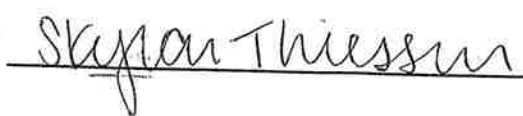
2 – 8 °C

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: 12.02.24

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


Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 3

Lot Number: 240861AA-3

Date: 12/02/24

Aalto Part Number:

21479

Audit Lot Number:

07100-3

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

226.9 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:

[Signature]

Date:

12-02-24

Reviewed by:

Rev: (New)

Slayman Thiessen

Date:

12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 4

Lot Number: 240861AA-4

Date: 12/02/24

Aalto Part Number:

21480

Audit Lot Number:

07100-4

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

314.5 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.

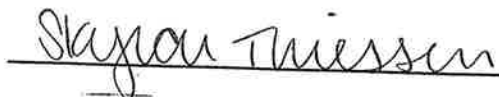
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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 5

Lot Number: 240861AA-5

Date: 12/02/24

Aalto Part Number:

21481

Audit Lot Number:

07100-5

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

429.8 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.

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 6

Lot Number: 240861AA-6

Date: 12/02/24

Aalto Part Number:

21482

Audit Lot Number:

07100-6

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

485.0 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.

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Date: 12-02-24

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Rev: (New)

Stacyon Thiessen

Date: 12/02/24

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 7

Lot Number: 240861AA-7

Date: 12/02/24

Aalto Part Number:

21483

Audit Lot Number:

07100-7

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

602.2 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: 12-02-24

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Date: 12/02/24

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 8

Lot Number: 240861AA-8

Date: 12/02/24

Aalto Part Number:

21484

Audit Lot Number:

07100-8

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

710.2 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.

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 9

Lot Number: 240861AA-9

Date: 12/02/24

Aalto Part Number:

21485

Audit Lot Number:

07100-9

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

813.0 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: 12-02-24

Reviewed by:

Rev: (New)

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 10

Lot Number: 240861AA-10

Date: 12/02/24

Aalto Part Number:

21486

Audit Lot Number:

07100-10

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

902.6 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: 12-02-24

Reviewed by:
Rev: (New)

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 11

Lot Number: 240861AA-11

Date: 12/02/24

Aalto Part Number:

21487

Audit Lot Number:

07100-11

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

996.3 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:

12-02-24

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Date:

12/02/24

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 12

Lot Number: 240861AA-12

Date: 12/02/24

Aalto Part Number:

21488

Audit Lot Number:

07100-12

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

1133.0 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.

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 13

Lot Number: 240861AA-13

Date: 12/02/24

Aalto Part Number:

21489

Audit Lot Number:

07100-13

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

1220.0 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: 12-02-24

Reviewed by:
Rev: (New)

Date: 12/02/24

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Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 14

Lot Number: 240861AA-14

Date: 12/02/24

Aalto Part Number:

21490

Audit Lot Number:

07100-14

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

1270.3 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: 12-02-24

Reviewed by:
Rev: (New)

Skylar Miessen

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 15

Lot Number: 240861AA-15

Date: 12/02/24

Aalto Part Number:

21491

Audit Lot Number:

07100-15

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

1397.7 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.

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Date: 12-02-24

Reviewed by:

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Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 16

Lot Number: 240861AA-16

Date: 12/02/24

Aalto Part Number:

21492

Audit Lot Number:

07100-16

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1
by Biomerieux, VIDAS**

1458.0 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: 12-02-24

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

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 17

Lot Number: 240861AA-17

Date: 12/02/24

Aalto Part Number:

21493

Audit Lot Number:

07100-17

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

1577.1 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: 12-02-24

Reviewed by:

Rev: (New)

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 18

Lot Number: 240861AA-18

Date: 12/02/24

Aalto Part Number:

21494

Audit Lot Number:

07100-18

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

**UCH-L1 — —
by Biomerieux, VIDAS**

1609.0 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: 12-02-24

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

Date: 12/02/24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 19

Lot Number: 240861AA-19

Date: 12/02/24

Aalto Part Number:

21495

Audit Lot Number:

07100-19

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

1814.9 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: 12-02-24

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PRODUCT QUALITY ASSURANCE REPORT

Method Val FD UCH-L1 bioMerieux VIDAS TBI (UCH-L1) Level 20

Lot Number: 240861AA-20

Date: 12/02/24

Aalto Part Number:

21496

Audit Lot Number:

07100-20

Audit Part Number:

K852M-20

Date of Manufacture:

10/21/24

Expiration Date:

2026-10-21

RECONSTITUTION with deionized water:

0.5 mL

UCH-L1

by Biomerieux, VIDAS

2018.8 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: 12-02-24

Reviewed by:

Rev: (New)

Date: 12/02/24

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