

Product Number:	104822
Lot Number:	504300
Expiration:	28-Aug-2025
Platform(s):	HD-X



Data below  
represents  
results  
generated on  
the Simoa<sup>®</sup> HD-  
X Analyzer.

Component	Part Number	Lot Number	Lot Number
Bead Reagent	104800	418003	N/A
Detector Reagent	104802	418307	N/A
SBG Reagent	104804	418308	N/A
Calibrator Diluent	104808	405913	N/A
Control Diluent	104809	405914	N/A
Plasma Sample Diluent	104805	406011	N/A
CSF Sample Diluent	104806	406012	N/A
Calibrator Concentrate	104818	317316	317316A
Control 1 Concentrate	104820	317317	317317A
Control 2 Concentrate	104821	317318	317318A
RGP 2.0 Reagent	104321	N/A <sup>1</sup>	N/A
Activation Buffer Reagent	104324	N/A <sup>1</sup>	N/A

<sup>1</sup> Reagents are not Kit Lot Specific

Review/Approval

Dilish Patel

Name

Documentation QA

Title

[Signature] / 17 SEP 2024

Signature/Date

**Release Materials\***

**NF-Light®**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	317317A	15.7	13.2 - 25.0
<b>Control 2</b>	317318A	779	481 - 1091

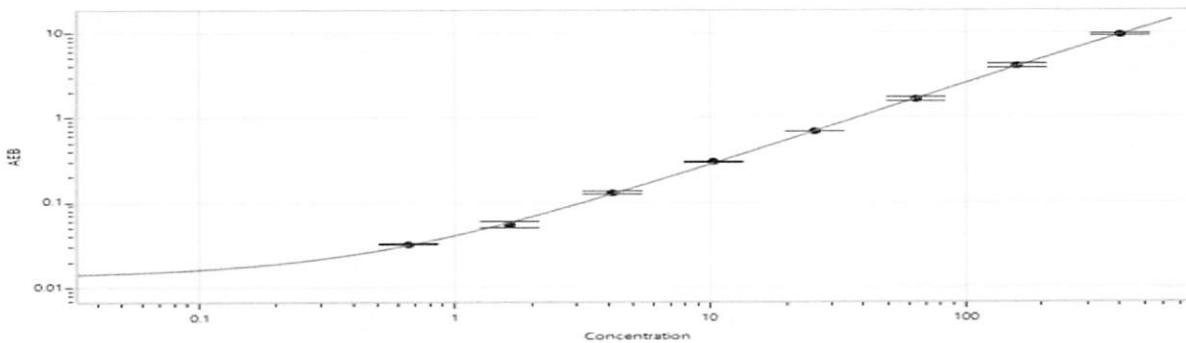
\* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1350

**Calibrator Levels (pg/mL)**

- A 0.000
- B 0.660
- C 1.65
- D 4.13
- E 10.3
- F 25.8
- G 64.4
- H 161
- I 403

**Calibration Curve**



**Release Materials\***

**GFAP®**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	317317A	24.1	17.8 - 34.7
<b>Control 2</b>	317318A	1127	776 - 1442

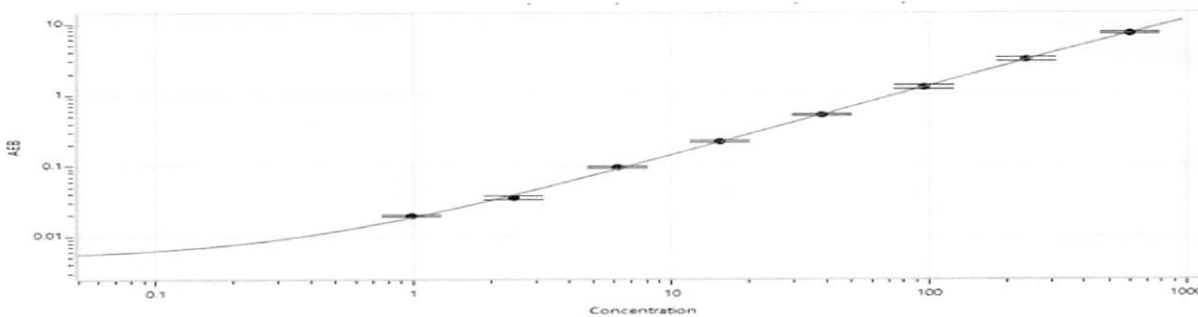
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<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1350

**Calibrator Levels (pg/mL)**

- A 0.000
- B 0.982
- C 2.46
- D 6.14
- E 15.4
- F 38.4
- G 95.9
- H 240
- I 600

**Calibration Curve**



**Release Materials\***

**UCLH-1**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	317317A	160	120 - 222
<b>Control 2</b>	317318A	7034	5026 - 9333

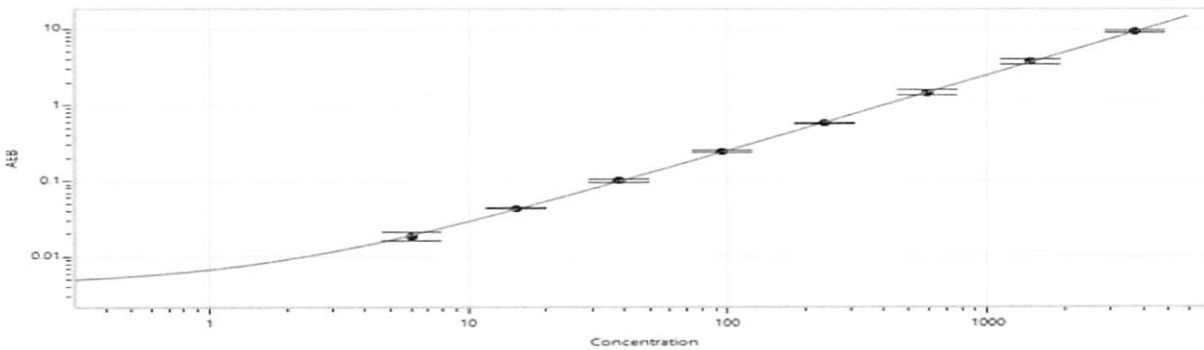
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<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1350

**Calibrator Levels (pg/mL)**

- A 0.000
- B 6.05
- C 15.2
- D 37.9
- E 94.9
- F 237
- G 591
- H 1479
- I 3698

**Calibration Curve**



**Release Materials\***

**BD-Tau**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	317317A	8.09	6.64 - 12.3
<b>Control 2</b>	317318A	381	264 - 491

\* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1350
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1350

**Calibrator Levels (pg/mL)**

- A 0.000
- B 0.293
- C 0.735
- D 1.84
- E 4.59
- F 11.4
- G 28.7
- H 71.7
- I 179

**Calibration Curve**

