

<b>Product Number:</b>	104465
<b>Lot Number:</b>	504399
<b>Expiration:</b>	23-Mar-2026
<b>Platform(s):</b>	HD-X

Component	Part Number	Lot Number
Bead Reagent	104448	426708
Detector Reagent	104450	426901
SBG Reagent	104452	426902
Calibrator Diluent Reagent	104453	426812
Plasma Sample Diluent Reagent	104647	426810
CSF Sample Diluent Reagent	104648	426809
Control Diluent Reagent	104649	426811
Calibrator Concentrate	104466	402940
Control 1 Concentrate	104468	402941
Control 2 Concentrate	104469	402942
RGP 2.0 Reagent	104321	N/A <sup>1</sup>
Activation Buffer Reagent	104324	N/A <sup>1</sup>

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



*Data below represents results generated on the Simoa® HD-X Analyzer.*

Review/Approval

*Dhvami Patel*  
Name

*Doc Control I, QA*  
Title

*DP 15 Nov 2024*  
Signature/Date

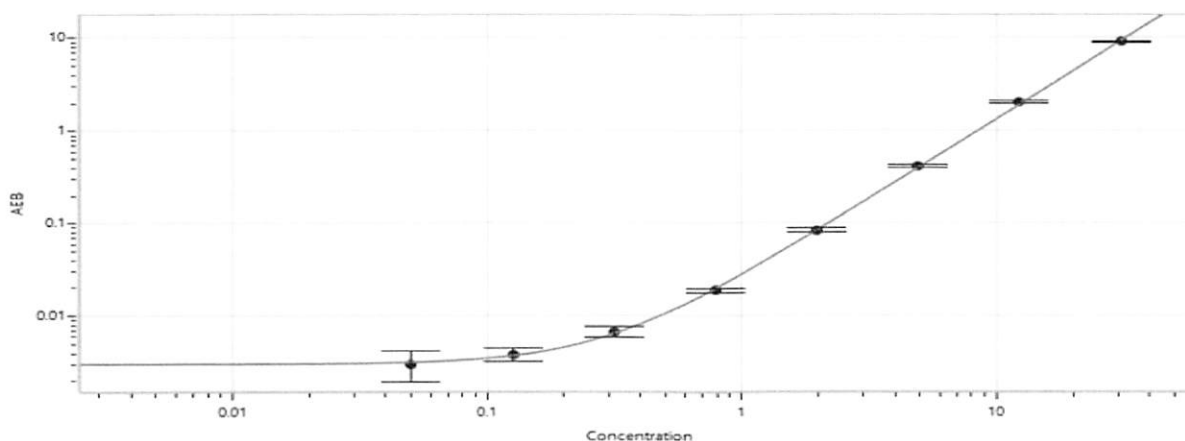
**Release Materials\***

**Abeta 40**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	402941	4.58	2.84 - 5.28
<b>Control 2</b>	402942	62.6	44.7 - 83.1

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1144

**Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.050
C	0.127
D	0.316
E	0.790
F	1.98
G	4.94
H	12.3
I	30.9

**Release Materials\***

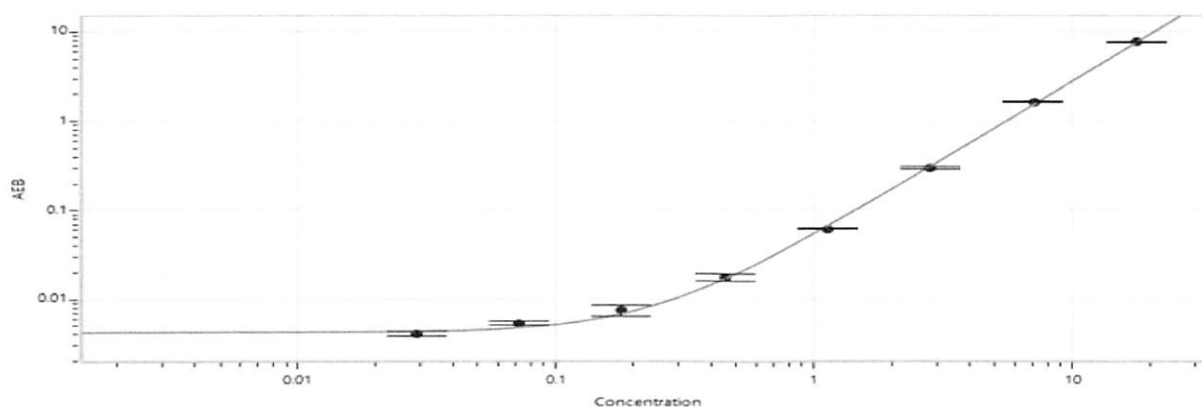
**Abeta 42**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	402941	2.19	1.56 - 2.90
<b>Control 2</b>	402942	30.9	22.6 - 42.1

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

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1144

**Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.029
C	0.072
D	0.180
E	0.451
F	1.12
G	2.82
H	7.05
I	17.6

**Release Materials\***

**GFAP®**

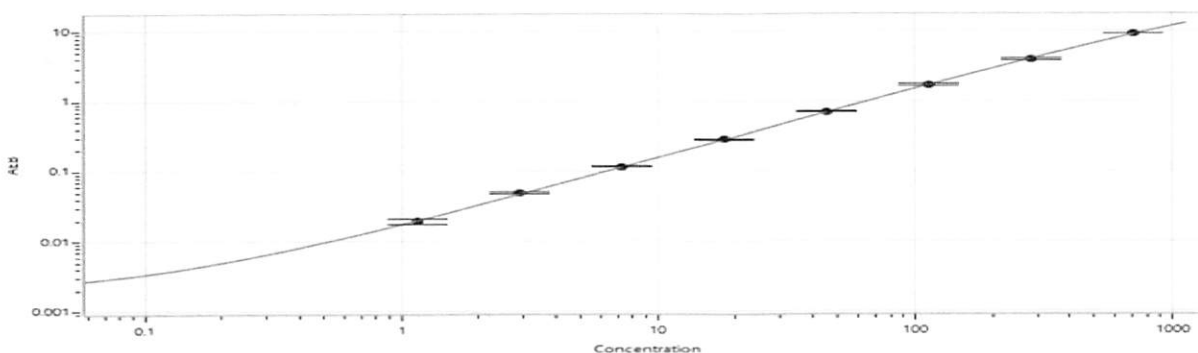
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	402941	103	70.0 - 130
<b>Control 2</b>	402942	1339	917 - 1704

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1144

**Calibrator Levels  
(pg/mL)**

<b>A</b>	0.000
<b>B</b>	1.16
<b>C</b>	2.90
<b>D</b>	7.25
<b>E</b>	18.2
<b>F</b>	45.3
<b>G</b>	113
<b>H</b>	283
<b>I</b>	708

**Calibration Curve**



**Release Materials\***

**NF-Light®**

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
<b>Control 1</b>	402941	83.2	58.4 - 108
<b>Control 2</b>	402942	1014	760 - 1412

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

<b>Calibrator Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 1 Concentrate Reconstitution Volume (uL)</b>	1144
<b>Control 2 Concentrate Reconstitution Volume (uL)</b>	1144

**Calibrator Levels  
(pg/mL)**

<b>A</b>	0.000
<b>B</b>	0.866
<b>C</b>	2.17
<b>D</b>	5.41
<b>E</b>	13.5
<b>F</b>	33.8
<b>G</b>	84.6
<b>H</b>	211
<b>I</b>	529

**Calibration Curve**

