

Product Number:	104465
Lot Number:	504578
Expiration:	22-Jul-2026
Platform(s):	HD-X and SR-X



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

Component	Part Number	Lot Number	Control Lot Number
Bead Reagent	104448	502905	502905A
Detector Reagent	104450	510501	N/A
SBG Reagent	104452	510502	N/A
Calibrator Diluent Reagent	104453	502221	N/A
Plasma Sample Diluent Reagent	104647	509913	N/A
CSF Sample Diluent Reagent	104648	509814	N/A
Control Diluent Reagent	104649	502220	N/A
Calibrator Concentrate	104466	317333	N/A
Control 1 Concentrate	104468	402941	N/A
Control 2 Concentrate	104469	402942	N/A
RGP 2.0 Reagent	104321	N/A ¹	N/A ¹
Activation Buffer Reagent	104324	N/A ¹	N/A ¹

¹ Reagents are not Kit Lot Specific

Review/Approval

Dipesh Patel Sr. Doc. Control QA DM 26 Jun 2025

Name

Title

Signature/Date

Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402941	4.00	2.63 - 5.13
Control 2	402942	65.4	46.5 - 86.4

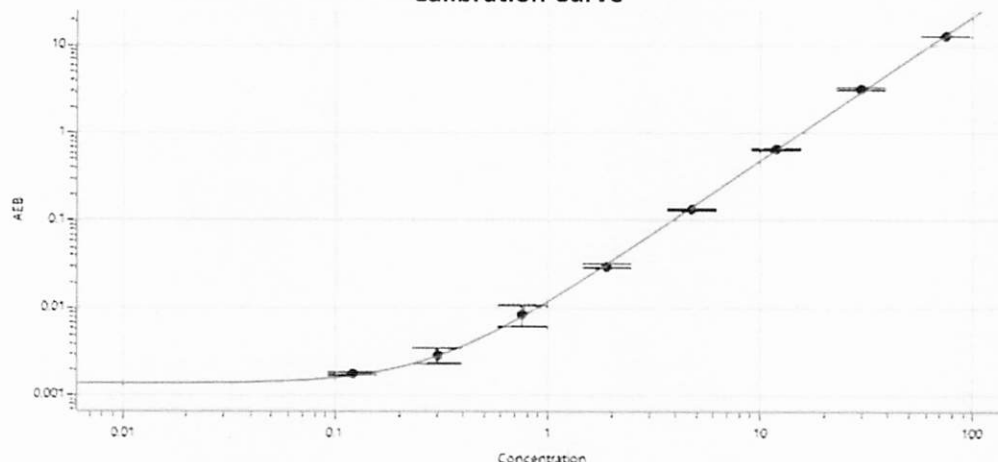
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL) 1144

Control 1 Concentrate Reconstitution Volume (uL) 1144

Control 2 Concentrate Reconstitution Volume (uL) 1144

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.121
C	0.302
D	0.756
E	1.88
F	4.72
G	11.8
H	29.5
I	73.8

Release Materials*

Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402941	2.12	1.39 - 3.12
Control 2	402942	31.4	21.4 - 39.8

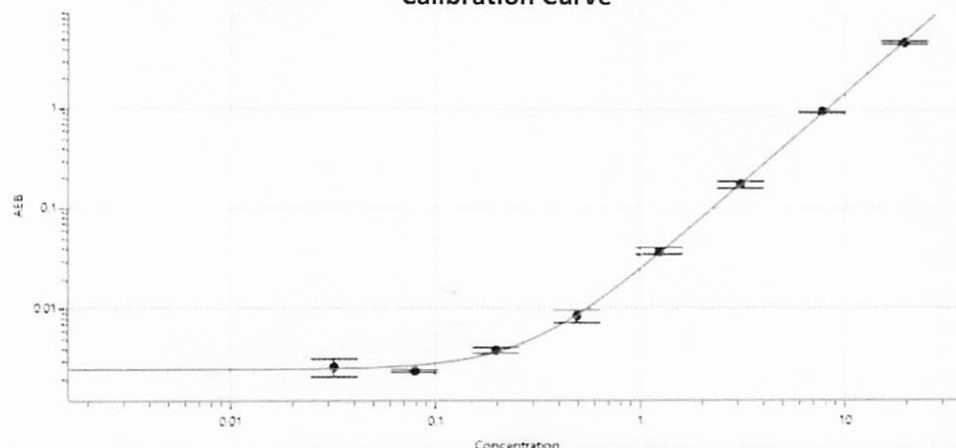
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL) 1144

Control 1 Concentrate Reconstitution Volume (uL) 1144

Control 2 Concentrate Reconstitution Volume (uL) 1144

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.032
C	0.079
D	0.198
E	0.494
F	1.24
G	3.09
H	7.69
I	19.3

Release Materials*

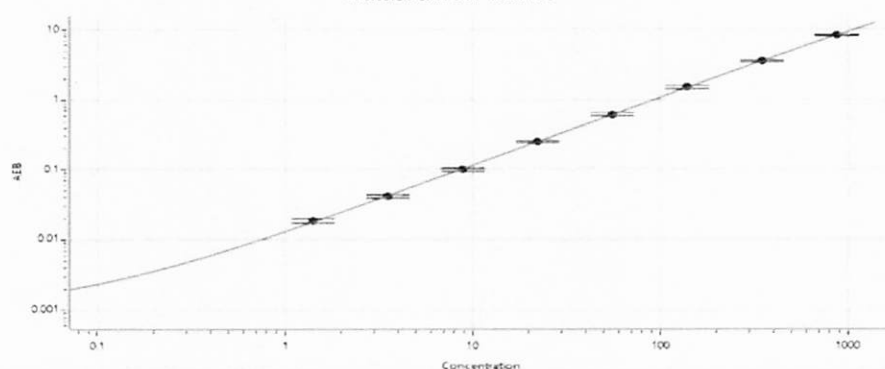
GFAP

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402941	84.1	61.9 - 115
Control 2	402942	1200	755 - 1403

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Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	1.42
C	3.56
D	8.88
E	22.2
F	55.7
G	140
H	348
I	870

Release Materials*

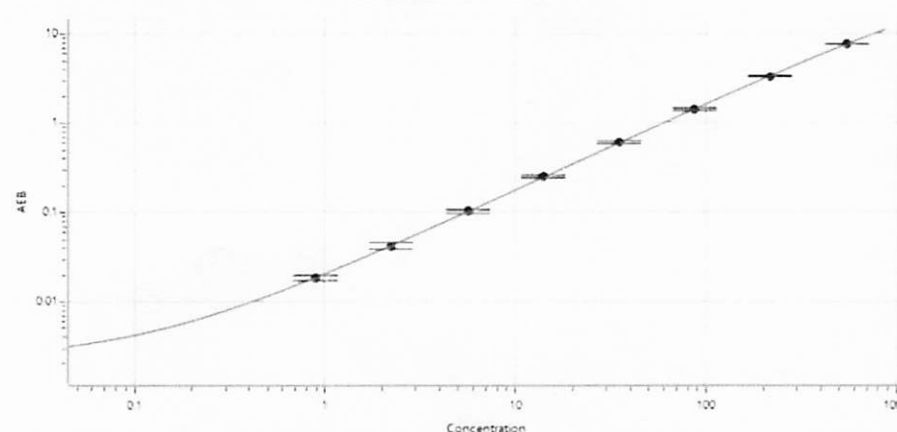
NF-Light

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402941	77.0	61.6 - 114
Control 2	402942	1138	749 - 1390

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Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.894
C	2.23
D	5.59
E	14.0
F	35.0
G	87.3
H	218
I	546