

Product Number:	104465
Lot Number:	504676
Expiration:	23-Jan-2027
Platform(s):	HD-X and SR-X

Component	Part Number	Lot Number
Bead Reagent	104448	522002
Detector Reagent	104450	522507
SBG Reagent	104452	522508
Calibrator Diluent Reagent	104453	520409
Plasma Sample Diluent Reagent	104647	520410
CSF Sample Diluent Reagent	104648	520512
Control Diluent Reagent	104649	520408
Calibrator Concentrate	104466	317331
Control 1 Concentrate	104468	317355
Control 2 Concentrate	104469	317356
RGP 2.0 Reagent	104321	N/A ¹
Activation Buffer Reagent	104324	N/A ¹

¹ Reagents are not Kit Lot Specific



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

Review/Approval

Dhruvi Patel QA Specialist II, QA SR 15 Sep 2025

Name

Title

Signature/Date

Release Materials*

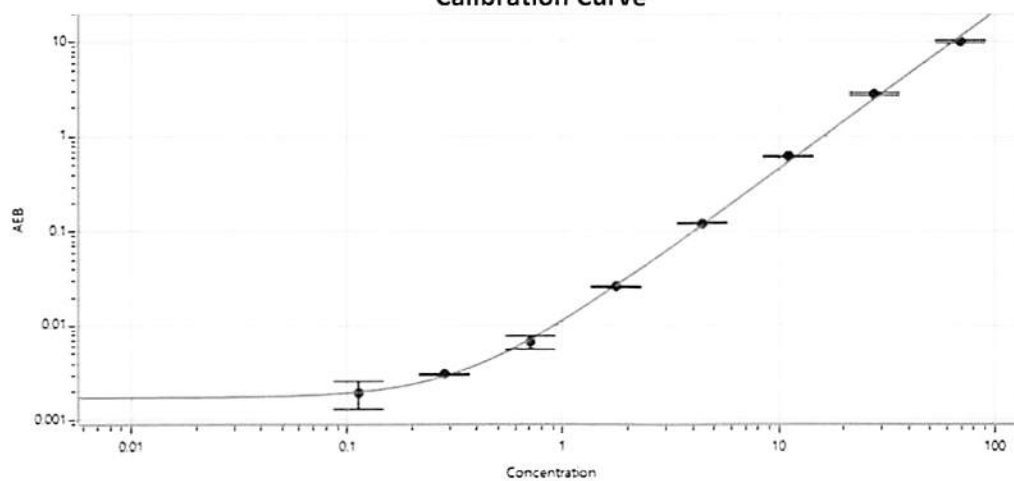
Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	317355	5.18	3.24 - 6.80
Control 2	317356	78.4	52.2 - 97.0

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

Calibrator Concentrate Reconstitution Volume (uL)	972
Control 1 Concentrate Reconstitution Volume (uL)	972
Control 2 Concentrate Reconstitution Volume (uL)	972

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.113
C	0.284
D	0.708
E	1.77
F	4.42
G	11.1
H	27.6
I	69.1

Release Materials*

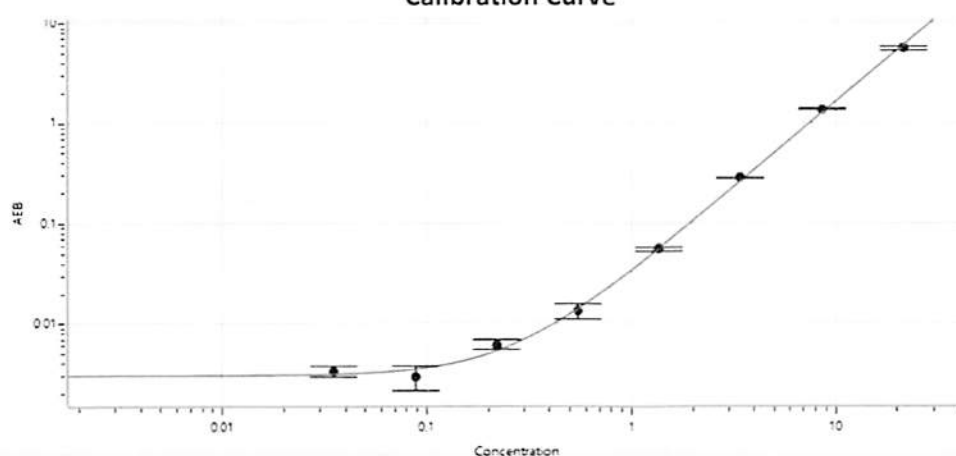
Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	317355	2.28	1.63 - 3.79
Control 2	317356	33.7	26.4 - 49.0

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Calibrator Concentrate Reconstitution Volume (uL)	972
Control 1 Concentrate Reconstitution Volume (uL)	972
Control 2 Concentrate Reconstitution Volume (uL)	972

Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.035
C	0.088
D	0.219
E	0.548
F	1.37
G	3.43
H	8.60
I	21.4

Release Materials*

GFAP

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	317355	140	107 - 204
Control 2	317356	1779	1189 - 2633

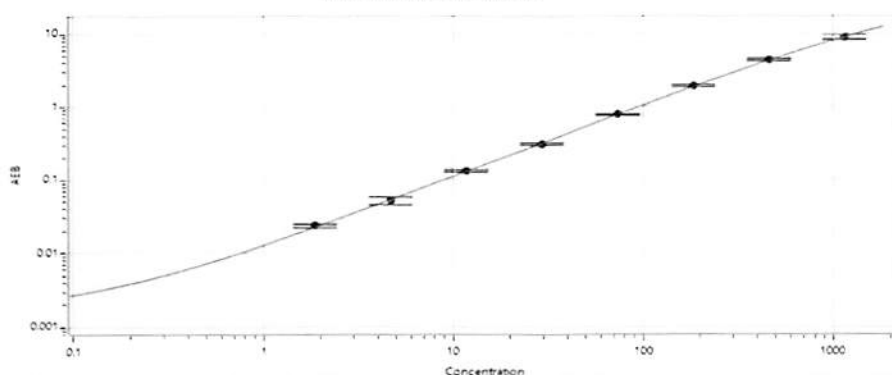
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL)	972
Control 1 Concentrate Reconstitution Volume (uL)	972
Control 2 Concentrate Reconstitution Volume (uL)	972

**Calibrator Levels
(pg/mL)**

A	0.000
B	1.88
C	4.70
D	11.7
E	29.4
F	73.6
G	183
H	459
I	1149

Calibration Curve



Release Materials*

NF-Light

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	317355	94.0	71.6 - 147
Control 2	317356	1280	862 - 1798

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

Calibrator Concentrate Reconstitution Volume (uL)	972
Control 1 Concentrate Reconstitution Volume (uL)	972
Control 2 Concentrate Reconstitution Volume (uL)	972

**Calibrator Levels
(pg/mL)**

A	0.000
B	1.11
C	2.76
D	6.91
E	17.2
F	43.2
G	108
H	270
I	675

Calibration Curve

