

Product Number:	104465
Lot Number:	504350
Expiration:	12-Feb-2026
Platform(s):	HD-X



Component	Part Number	Lot Number
Bead Reagent	104448	422702
Detector Reagent	104450	422715
SBG Reagent	104452	422716
Calibrator Diluent Reagent	104453	422627
Plasma Sample Diluent Reagent	104647	422523
CSF Sample Diluent Reagent	104648	422522
Control Diluent Reagent	104649	422626
Calibrator Concentrate	104466	402917
Control 1 Concentrate	104468	402918
Control 2 Concentrate	104469	402919
RGP 2.0 Reagent	104321	N/A ¹
Activation Buffer Reagent	104324	N/A ¹

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

¹ Reagents are not Kit Lot Specific

Review/Approval

Dipesh Patel Documental-IT QA

[Signature] / 27 Sep 2024

Name

Title

Signature/Date

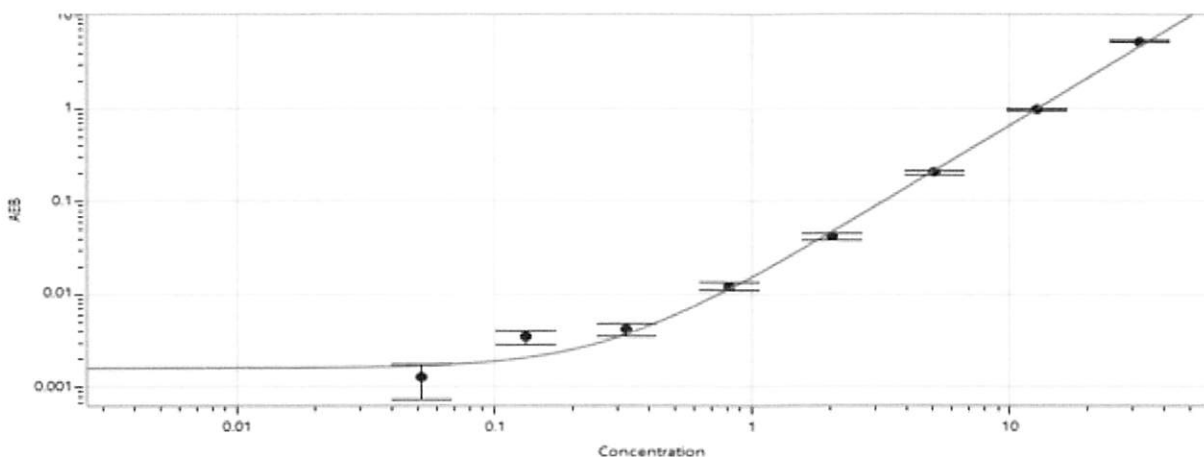
Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402918	4.22	2.76 - 5.12
Control 2	402919	56.4	38.0 - 71.2

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	0.052
C	0.131
D	0.326
E	0.815
F	2.04
G	5.10
H	12.7
I	31.9

Release Materials*

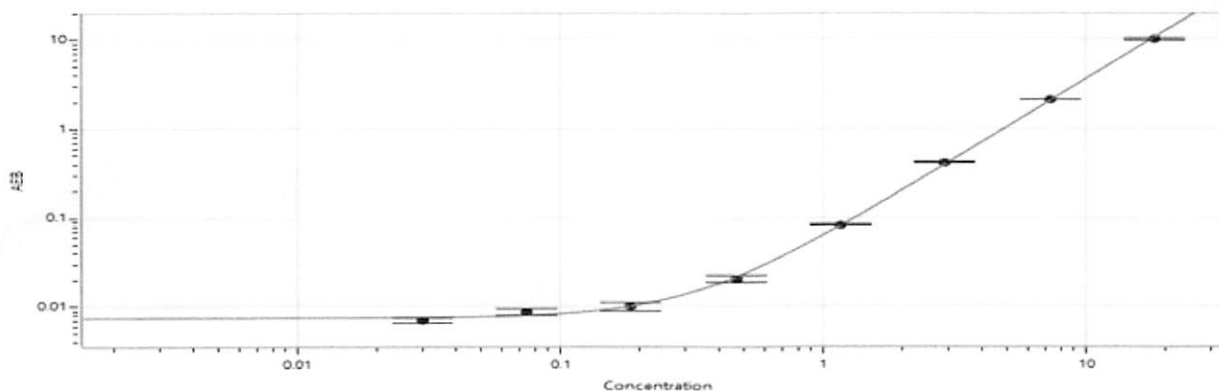
Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402918	2.02	1.45 - 2.69
Control 2	402919	31.5	20.4 - 37.9

* 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	0.030
C	0.074
D	0.186
E	0.465
F	1.16
G	2.91
H	7.27
I	18.1

Release Materials*

GFAP®

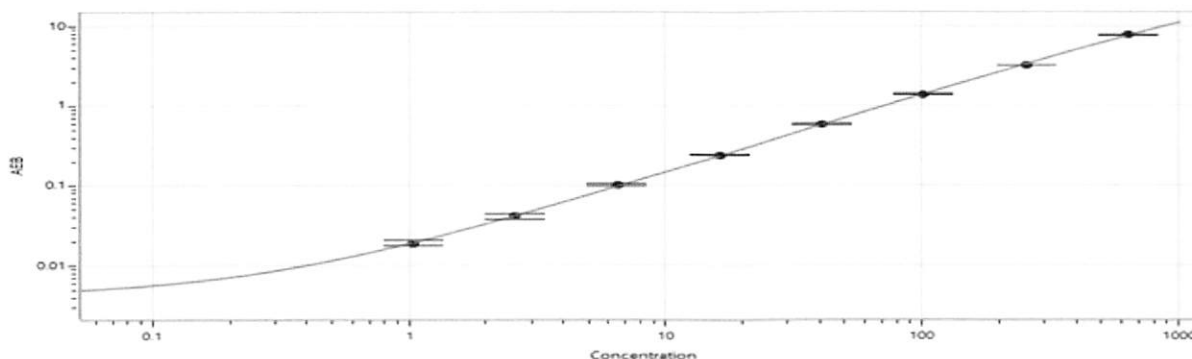
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402918	96.0	63.1 - 117
Control 2	402919	1167	744 - 1382

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

**Calibrator Levels
(pg/mL)**

A	0.000
B	1.04
C	2.60
D	6.49
E	16.3
F	40.5
G	101
H	254
I	634

Calibration Curve



Release Materials*

NF-Light®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	402918	98.0	65.9 - 122
Control 2	402919	1277	801 - 1487

* 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

**Calibrator Levels
(pg/mL)**

A	0.000
B	0.944
C	2.36
D	5.90
E	14.7
F	36.8
G	92.2
H	230
I	577

Calibration Curve

