

Product Number:	103670
Lot Number:	504019
Expiration:	20-Jan-2025
Platform(s):	HD-X

Component	Part Number	Lot Number
Bead Reagent	103653	334203
Detector Reagent	103655	334204
SBG Reagent	103657	334504
Plasma Sample Diluent	103659	334506
CSF Sample Diluent	103727	334505
Calibrators	103667	329705
Control 1	103668	329706
Control 2	103669	329706
RGP Reagent	103159	N/A ¹

¹ Reagents are not Kit Lot Specific



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

Review/Approval

Cody Carlson

QC Manager

Name

Title

Cody Carlson 17 JAN 2024
Signature/Date

Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	17.8	14.8 - 22.2
Control 2	329706	119	100 - 150
Panel 1	226304	26.8	20.8 - 31.2
Panel 2	332403	54.0	44.6 - 67.0
Panel 3	333807	131	101 - 151

Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	7.63	6.08 - 9.30
Control 2	329706	36.7	30.6 - 45.9
Panel 1	226304	1.98	1.65 - 2.97
Panel 2	332403	9.96	7.83 - 11.7
Panel 3	333807	50.4	40.9 - 61.4

GFAP®

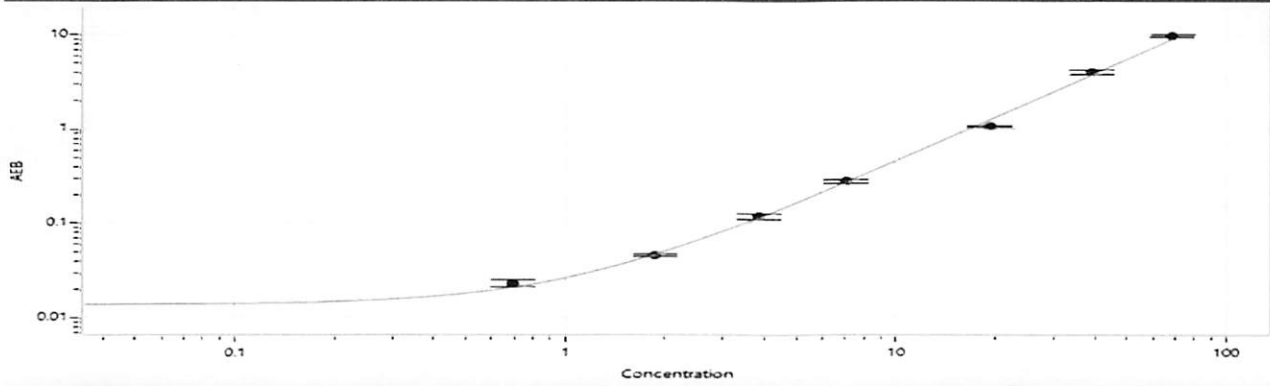
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	200	166 - 248
Control 2	329706	4212	3507 - 5260
Panel 1	226304	34.9	28.1 - 58.0
Panel 2	332403	227	166 - 272
Panel 3	333807	1027	747 - 1120

NF-Light®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	24.8	19.7 - 29.5
Control 2	329706	554	474 - 711
Panel 1	226304	2.35	1.38 - 4.84
Panel 2	332403	76.1	59.8 - 89.7
Panel 3	333807	543	371 - 665

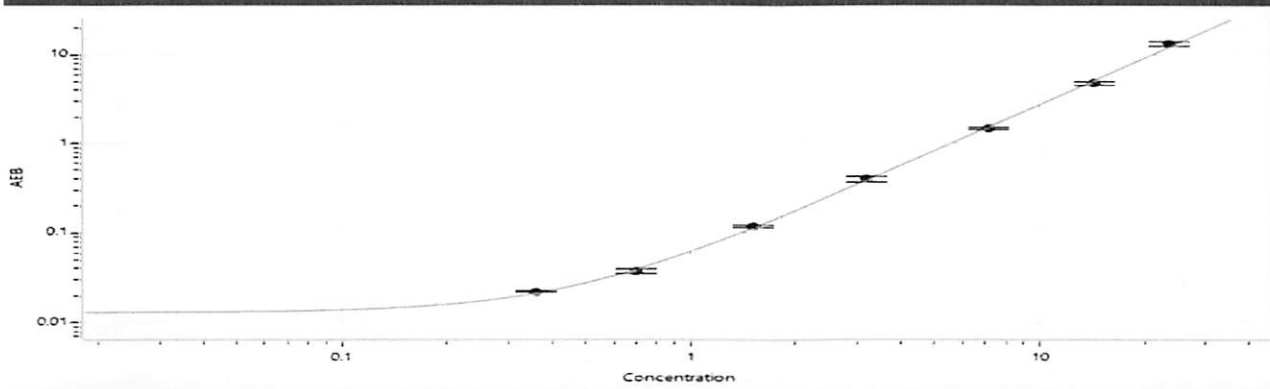
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Abeta 40 Calibrator Curve



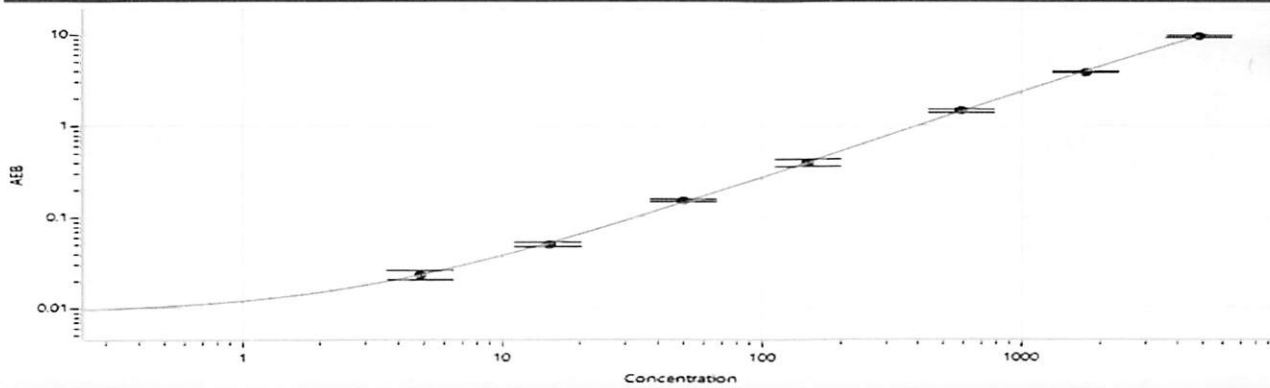
Calibrator Levels (pg/mL)	
A	0.000
B	0.693
C	1.87
D	3.83
E	7.07
F	19.2
G	39.4
H	68.3

Abeta 42 Calibrator Curve



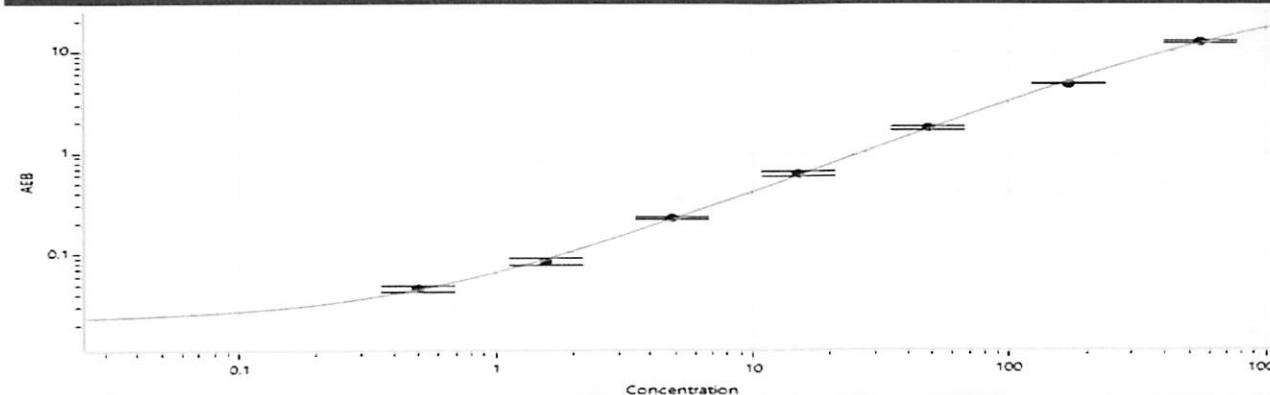
Calibrator Levels (pg/mL)	
A	0.000
B	0.360
C	0.700
D	1.50
E	3.20
F	7.11
G	14.3
H	23.5

GFAP® Calibrator Curve



Calibrator Levels (pg/mL)	
A	0.000
B	4.88
C	15.2
D	49.8
E	151
F	591
G	1757
H	4803

NF-Light® Calibrator Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.498
C	1.56
D	4.82
E	15.0
F	48.3
G	170
H	558