

Product Number:	103670
Lot Number:	504153
Expiration:	5-Jan-2025
Platform(s):	HD-X



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

Component	Part Number	Lot Number	Control Number
Bead Reagent	103653	318614	318614A
Detector Reagent	103655	318707	318707A
SBG Reagent	103657	318710	318710A
Plasma Sample Diluent	103659	318714	318714A
CSF Sample Diluent	103727	318713	318713A
Calibrators	103667	321303	N/A
Control 1	103668	321305	N/A
Control 2	103669	321305	N/A
RGP Reagent	103159	N/A ¹	N/A ¹

¹ Reagents are not Kit Lot Specific

Review/Approval

Cody Carlson
Name

QC Manager
Title

Cody Carlson 16 FEB 2024
Signature/Date

Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	20.5	14.8 - 22.2
Control 2	321305	111	86.8 - 130
Panel 1	226304	28.6	20.8 - 31.2
Panel 2	225507	53.0	44.5 - 66.8
Panel 3	226908	229	183 - 312

Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	8.84	6.58 - 9.87
Control 2	321305	42.4	32.3 - 48.4
Panel 1	226304	2.49	1.65 - 2.97
Panel 2	225507	19.7	16.5 - 24.7
Panel 3	226908	56.4	41.2 - 61.9

GFAP®

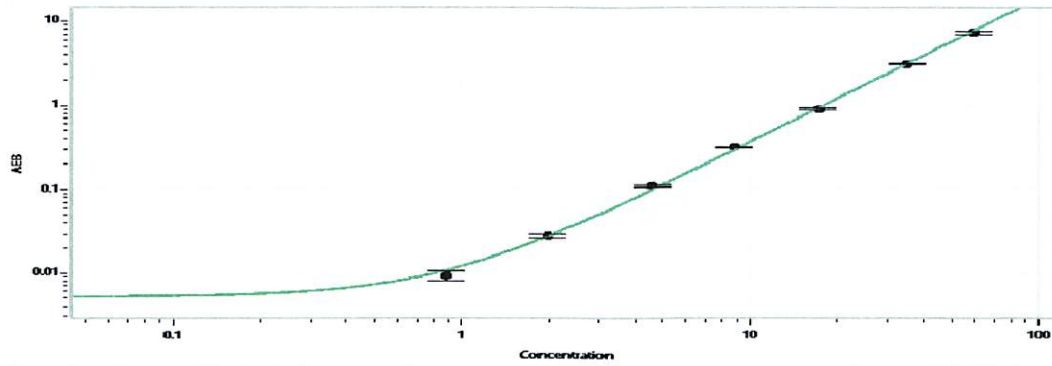
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	182	134 - 201
Control 2	321305	3653	2719 - 4078
Panel 1	226304	48.9	28.1 - 58.0
Panel 2	225507	318	248 - 372
Panel 3	226908	2851	2078 - 3165

NF-Light®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	23.3	19.0 - 28.5
Control 2	321305	536	403 - 604
Panel 1	226304	3.08	1.38 - 4.84
Panel 2	225507	102	85.7 - 128
Panel 3	226908	591	367 - 698

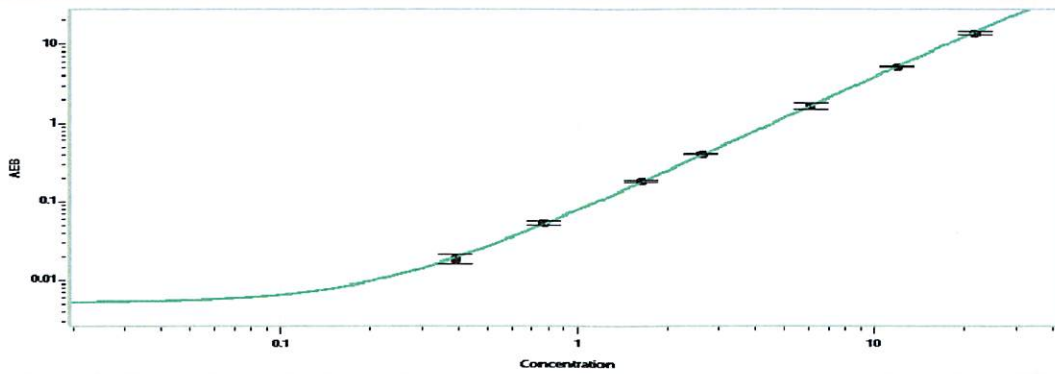
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Abeta 40 Calibrator Curve



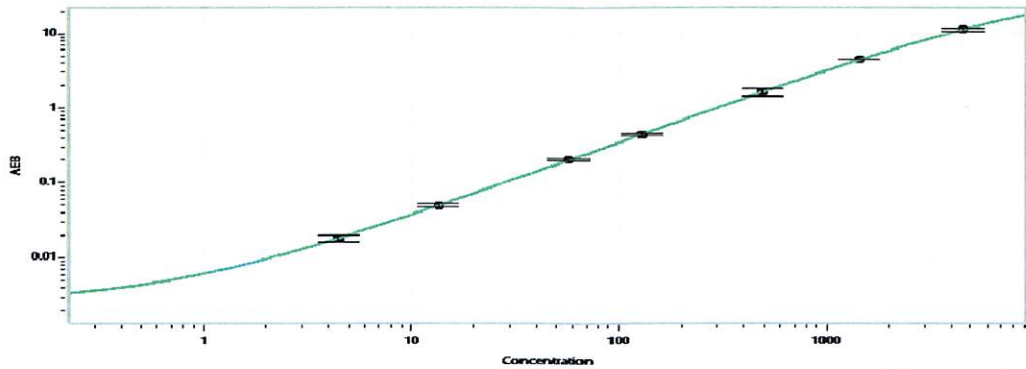
Calibrator Levels (pg/mL)	
A	0.000
B	0.887
C	1.99
D	4.56
E	8.77
F	17.2
G	34.7
H	59.5

Abeta 42 Calibrator Curve



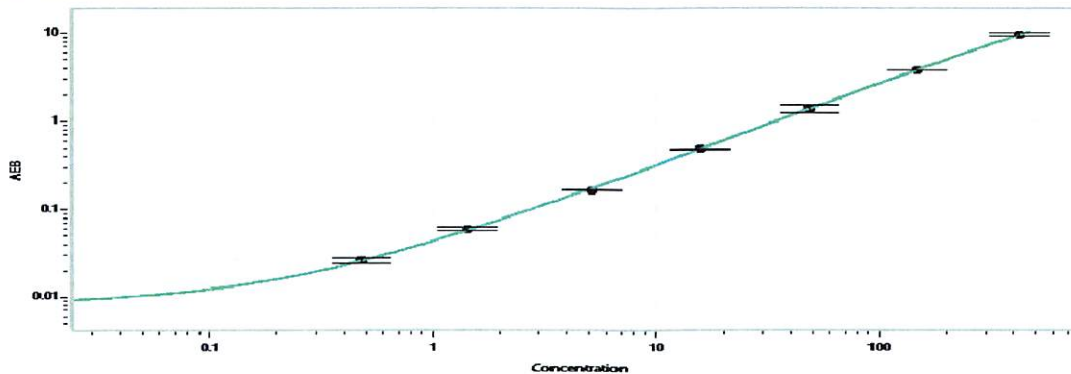
Calibrator Levels (pg/mL)	
A	0.000
B	0.389
C	0.773
D	1.65
E	2.62
F	6.08
G	11.9
H	22.1

GFAP® Calibrator Curve



Calibrator Levels (pg/mL)	
A	0.000
B	4.45
C	13.6
D	57.5
E	130
F	493
G	1432
H	4565

NF-Light® Calibrator Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.482
C	1.42
D	5.17
E	15.9
F	48.3
G	147
H	425