

Product Number:	103670
Lot Number:	504270
Expiration:	6-Jan-2025
Platform(s):	HD-X

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



Component	Part Number	Lot Number	Control Lot Number
Bead Reagent	103653	323402	N/A
Detector Reagent	103655	323610	N/A
SBG Reagent	103657	323409	N/A
Plasma Sample Diluent	103659	318704	318704A
CSF Sample Diluent	103727	323502	N/A
Calibrators	103667	324402	N/A
Control 1	103668	324403	N/A
Control 2	103669	324403	N/A
RGP Reagent	103159	N/A ¹	N/A ¹

¹ Reagents are not Kit Lot Specific

Review/Approval

ROBERT SOMOGYI
Name

QC MANAGER
Title

[Signature]
21 MAY 2024
Signature/Date

Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	19.1	15.6 - 23.4
Control 2	324403	116	86.9 - 134
Panel 1	226304	25.6	20.8 - 31.2
Panel 2	225507	56.6	44.5 - 66.8
Panel 3	226908	259	183 - 312

Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	8.47	6.79 - 10.2
Control 2	324403	40.1	31.2 - 46.8
Panel 1	226304	2.36	1.65 - 2.97
Panel 2	225507	20.9	16.5 - 24.7
Panel 3	226908	58.7	41.2 - 61.9

GFAP®

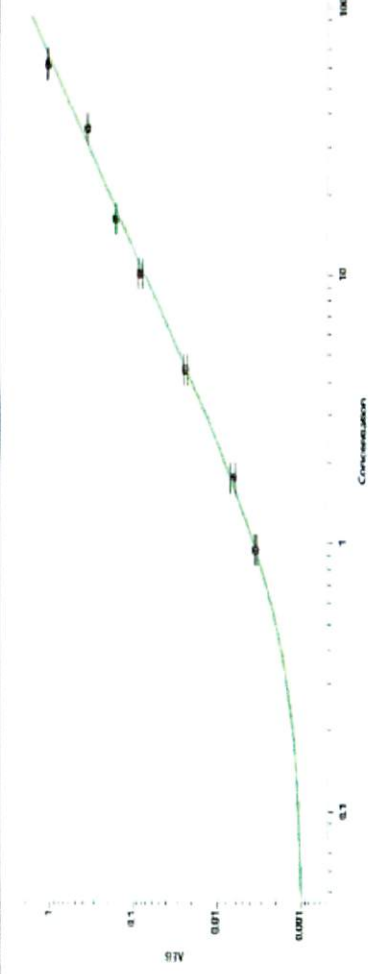
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	186	150 - 225
Control 2	324403	3971	2980 - 4470
Panel 1	226304	40.3	28.1 - 58.2
Panel 2	225507	291	248 - 372
Panel 3	226908	2599	2078 - 3165

NF-Light®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	23.6	19.5 - 29.2
Control 2	324403	563	429 - 643
Panel 1	226304	2.63	1.38 - 4.84
Panel 2	225507	95.5	85.7 - 128
Panel 3	226908	535	367 - 698

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

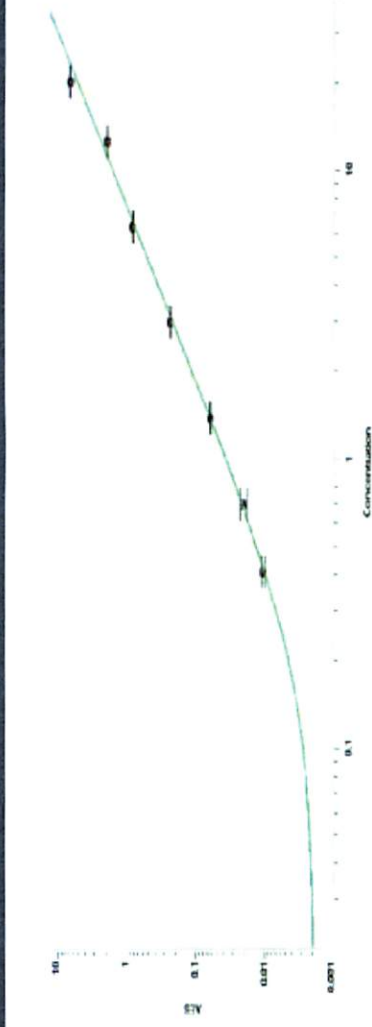
Abeta 40 Calibrator Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.947
C	1.75
D	4.46
E	10.1
F	16.2
G	35.2
H	61.4

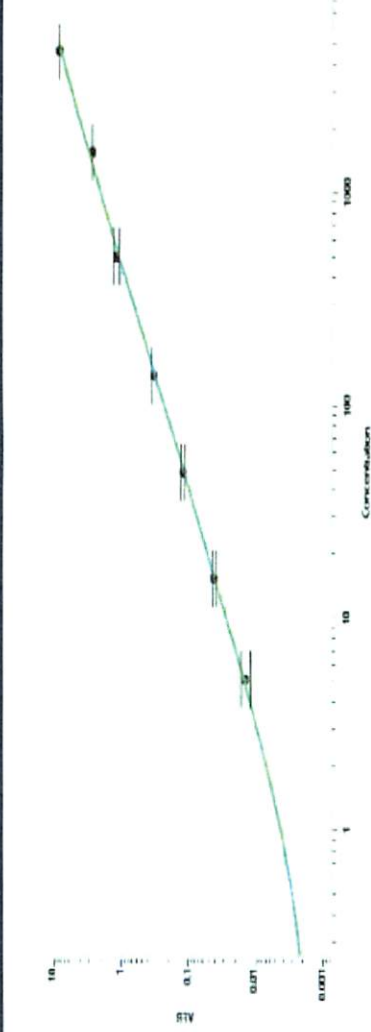
Abeta 42 Calibrator Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.405
C	0.692
D	1.39
E	2.97
F	6.31
G	12.4
H	20.1

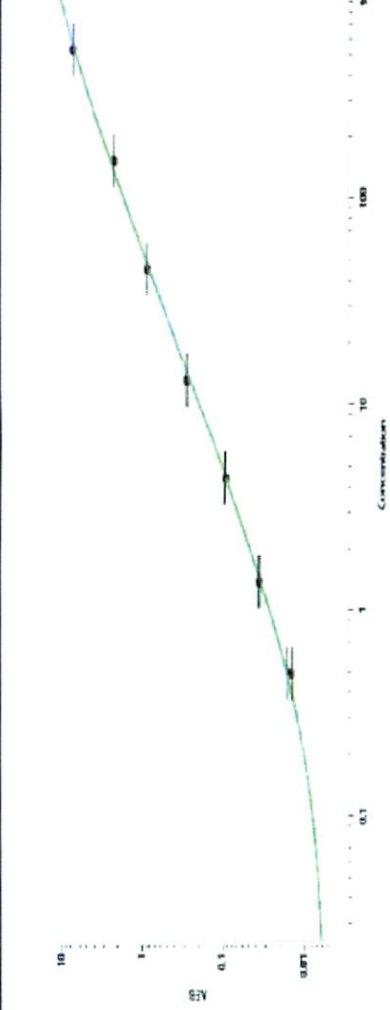
GFAP® Calibrator Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	5.13
C	15.2
D	48.3
E	138
F	501
G	1529
H	4577

NF-Light® Calibrator Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.489
C	1.38
D	4.38
E	13.0
F	45.5
G	152
H	525