

Product Number:	103670
Lot Number:	504018
Expiration:	5-Oct-2024
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	327812
Detector Reagent	103655	327904
SBG Reagent	103657	327814
Plasma Sample Diluent	103659	327906
CSF Sample Diluent	103727	328211
Calibrators	103667	329705
Control 1	103668	329706
Control 2	103669	329706
RGP Reagent	103159	N/A <sup>1</sup>

<sup>1</sup> RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	17.5	15.0 - 22.5
Control 2	329706	121	102 - 153
Panel 1	226304	27.2	20.8 - 31.2
Panel 2	225507	55.3	44.5 - 66.8
Panel 3	226908	257	183 - 312
Abeta 42			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	7.92	5.85 - 9.57
Control 2	329706	36.8	31.0 - 46.5
Panel 1	226304	2.40	1.65 - 2.97
Panel 2	225507	21.0	16.5 - 24.7
Panel 3	226908	53.9	41.2 - 61.9
GFAP®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	202	168 - 251
Control 2	329706	4377	3552 - 5328
Panel 1	226304	38.2	28.1 - 58.0
Panel 2	225507	313	248 - 372
Panel 3	226908	2844	2078 - 3165
NF-light®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	329706	26.3	19.3 - 29.8
Control 2	329706	557	485 - 727
Panel 1	226304	3.01	1.38 - 4.84
Panel 2	225507	85.8	85.7 - 128
Panel 3	226908	447	367 - 698

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

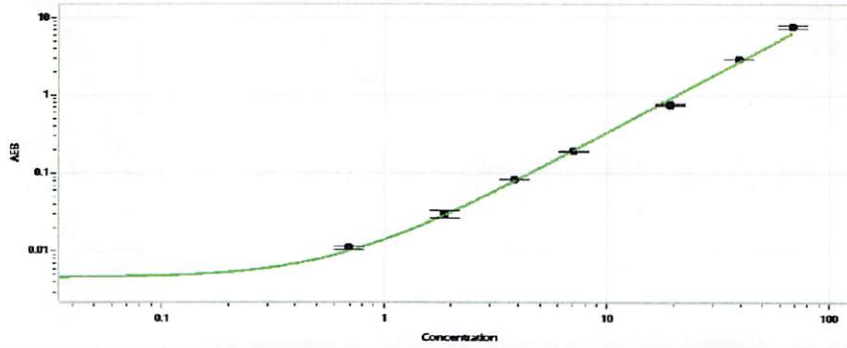
Review/Approval

*Sonia Khillan*  
Name

*Senior QC Analyst*  
Title

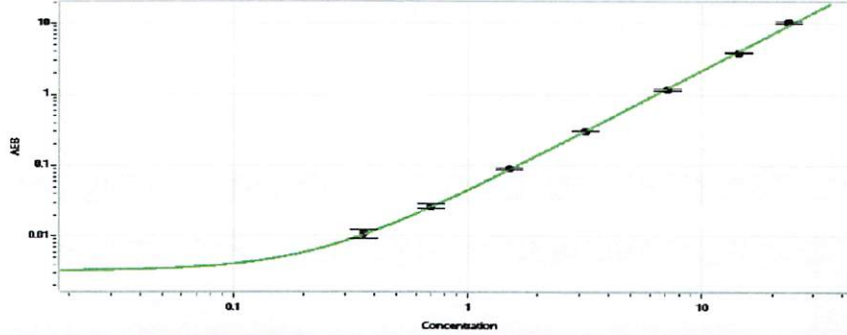
*Sonia Khillan 07 DEC 2023*  
Signature/Date

**Abeta 40 Calibration Curve**



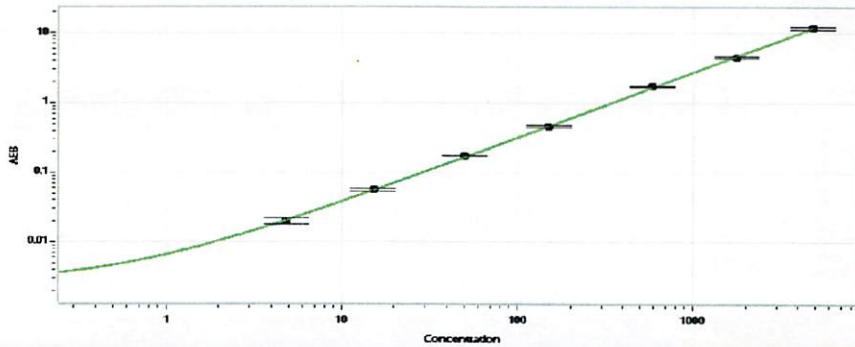
Calibrator Levels (pg/mL)	
A	0.000
B	0.693
C	1.87
D	3.83
E	7.07
F	19.2
G	39.4
H	68.3

**Abeta 42 Calibration Curve**



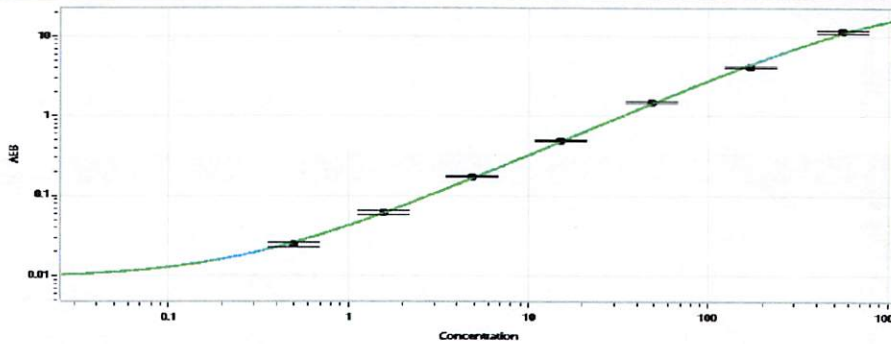
Calibrator Levels (pg/mL)	
A	0.000
B	0.360
C	0.700
D	1.50
E	3.20
F	7.11
G	14.3
H	23.5

**GFAP® Calibration 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® Calibration 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