

Product Number:	103670
Lot Number:	502592
Expiration:	23-Oct-2021
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	035611
Detector Reagent	103655	035612
SBG Reagent	103657	029708
Plasma Sample Diluent	103659	030403
CSF Sample Diluent	103727	029705
Calibrators	103667	030705
Control 1	103668	030706
Control 2	103669	030706
RGP Reagent	103159	N/A ¹

¹ RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	030706	13.7	11.3-16.9
Control 2	030706	104	83.3-125
Panel 1	027301	29.0	23.3-35.0
Panel 2	018109	48.0	42.3-64.6
Panel 3	018109	129	108-162
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	030706	5.56	4.40-6.59
Control 2	030706	29.8	23.9-35.9
Panel 1	027301	2.53	2.02-3.02
Panel 2	018109	19.0	16.6-24.8
Panel 3	018109	44.1	36.0-54.0
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	030706	188	117-256
Control 2	030706	4042	2457-5511
Panel 1	027301	46.9	37.8-56.6
Panel 2	018109	556	446-668
Panel 3	018109	2512	1916-2948
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	030706	27.7	16.5-36.8
Control 2	030706	598	374-745
Panel 1	027301	8.94	7.84-12.5
Panel 2	018109	73.5	59.5-89.3
Panel 3	018109	404	310-474

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

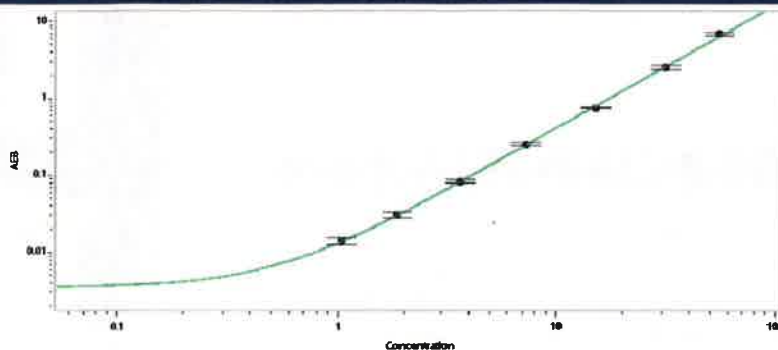
Review/Approval

Junpil Park
Name

QC Supervisor
Title

 05 Jan 2021
Signature/Date

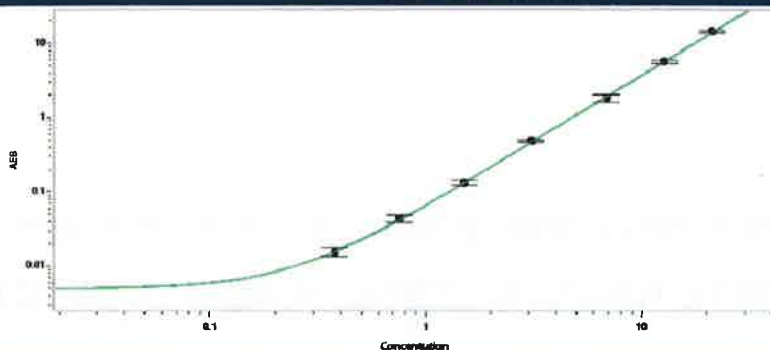
Abeta 40 Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	1.04
C	1.87
D	3.63
E	7.28
F	15.0
G	31.3
H	55.0

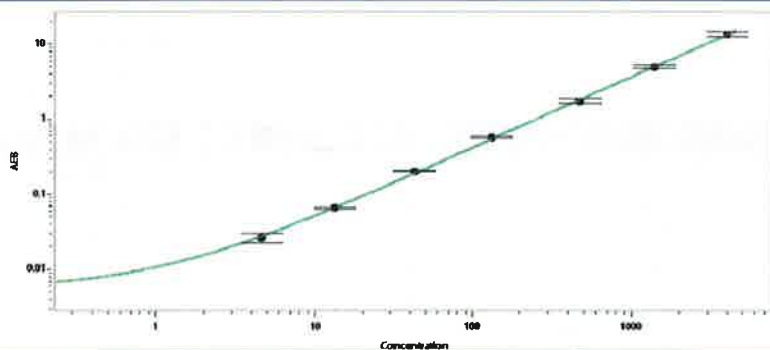
Abeta 42 Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.376
C	0.749
D	1.51
E	3.07
F	6.82
G	12.6
H	20.8

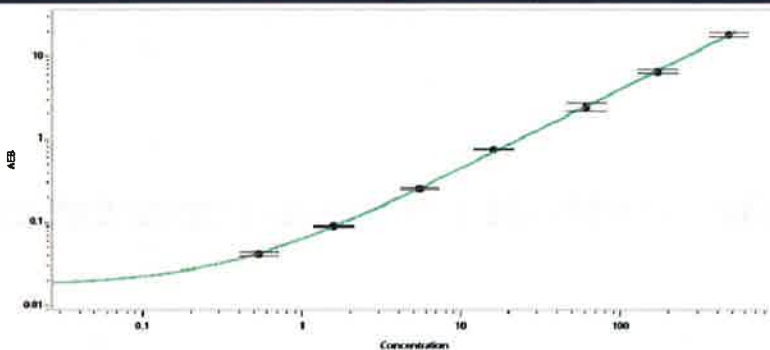
GFAP® Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	4.59
C	13.2
D	42.7
E	131
F	473
G	1385
H	3978

NF-light® Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.535
C	1.57
D	5.45
E	16.1
F	60.2
G	168
H	474