

Product Number:	103670
Lot Number:	503085
Expiration:	26-May-2022
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	121404
Detector Reagent	103655	121405
SBG Reagent	103657	121408
Plasma Sample Diluent	103659	121409
CSF Sample Diluent	103727	114612
Calibrators	103667	122806
Control 1	103668	122807
Control 2	103669	122807
RGP Reagent	103159	N/A

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

Release Materials			
<b>Abeta 40</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	122807	16.9	13.0 - 19.5
Control 2	122807	119	93.1 - 140
Panel 1	027301	24.6	23.3 - 34.9
Panel 2	018109	48.4	42.3 - 64.6
Panel 3	018109	107	100 - 163
<b>Abeta 42</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	122807	5.35	4.23 - 6.34
Control 2	122807	31.4	24.5 - 36.7
Panel 1	027301	2.05	2.00 - 3.00
Panel 2	018109	21.6	16.6 - 24.8
Panel 3	018109	46.2	36.0 - 54.0
<b>GFAP®</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	122807	189	141 - 211
Control 2	122807	4004	2947 - 4421
Panel 1	027301	44.2	37.5 - 56.2
Panel 2	018109	529	446 - 668
Panel 3	018109	2350	1916 - 2948
<b>NF-light®</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	122807	20.0	15.4 - 23.0
Control 2	122807	426	318 - 477
Panel 1	027301	10.8	7.10 - 12.6
Panel 2	018109	80.1	59.5 - 89.3
Panel 3	018109	414	310 - 474

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

Review/Approval

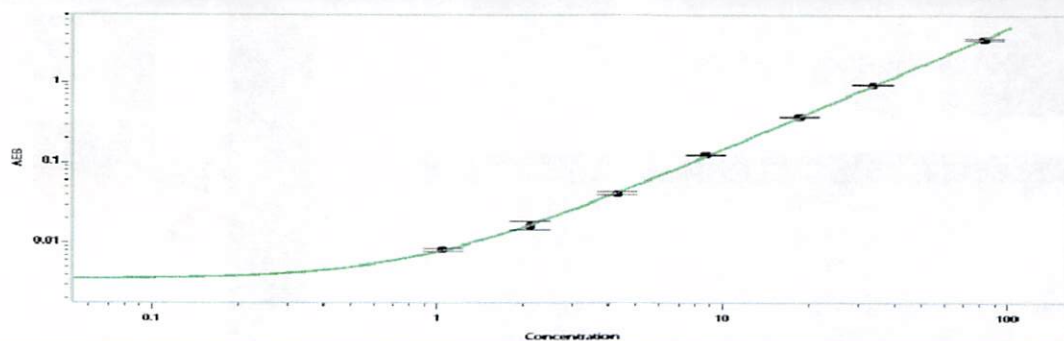
Junpil Park

QC Supervisor

*[Signature]* 27 Aug 2021



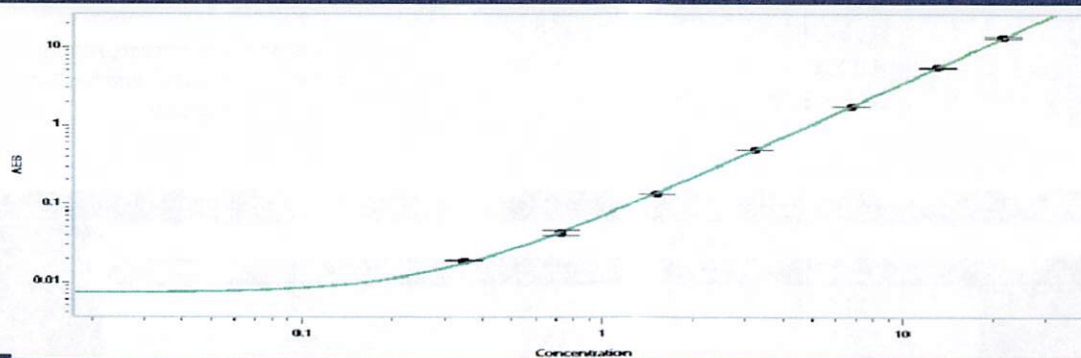
**Abeta 40 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	1.05
C	2.11
D	4.29
E	8.75
F	18.6
G	33.6
H	83.3

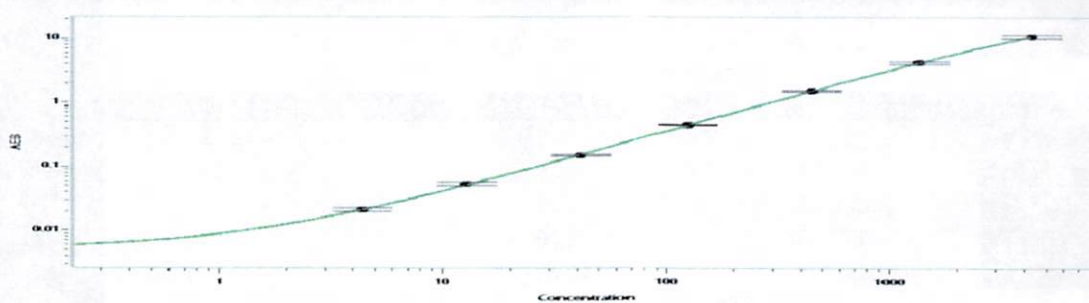
**Abeta 42 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	0.346
C	0.727
D	1.52
E	3.21
F	6.76
G	13.0
H	21.5

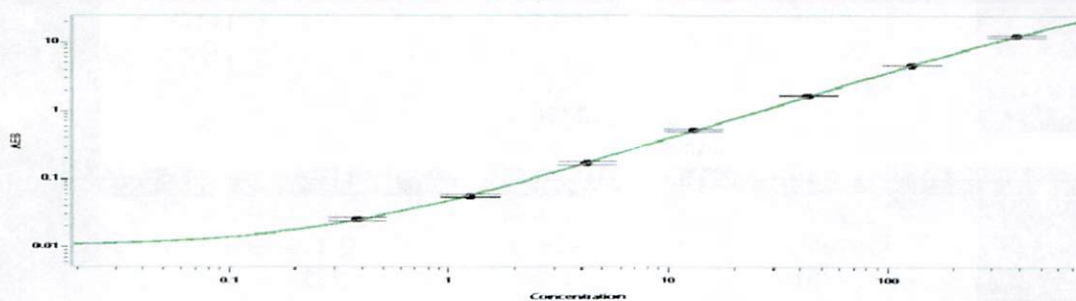
**GFAP® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	4.41
C	12.7
D	41.4
E	125
F	451
G	1344
H	4326

**NF-light® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	0.380
C	1.25
D	4.25
E	13.0
F	43.5
G	128
H	387