

Product Number:	103670
Lot Number:	502877
Expiration:	14-Apr-2022
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	110406
Detector Reagent	103655	110407
SBG Reagent	103657	110514
Plasma Sample Diluent	103659	110707
CSF Sample Diluent	103727	110520
Calibrators	103667	112506
Control 1	103668	112507
Control 2	103669	112507
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	112507	14.0	11.2-16.8
Control 2	112507	91.0	83.3-128
Panel 1	027301	31.0	23.3-34.9
Panel 2	018109	55.1	42.3-64.6
Panel 3	018109	127	108-162
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	4.59	3.70-5.54
Control 2	107704	26.0	17.0-32.2
Panel 1	027301	2.80	2.00-3.00
Panel 2	018109	22.7	16.6-24.8
Panel 3	018109	39.8	36.0-54.0
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	199	151-227
Control 2	107704	3715	3076-4614
Panel 1	027301	54.2	37.5-56.2
Panel 2	018109	573	446-668
Panel 3	018109	2065	1916-2948
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	29.3	20.1-30.1
Control 2	107704	555	386-695
Panel 1	027301	10.0	7.10-12.6
Panel 2	018109	83.6	59.5-89.3
Panel 3	018109	351	310-474

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

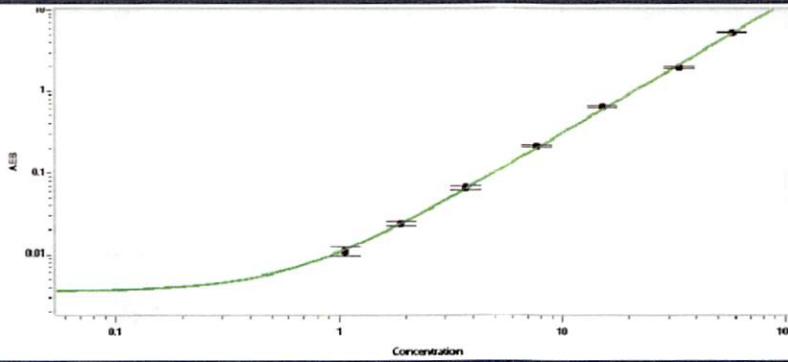
Review/Approval

Junpil Park
Name

QC Supervisor
Title

 25 May 2021
Signature/Date

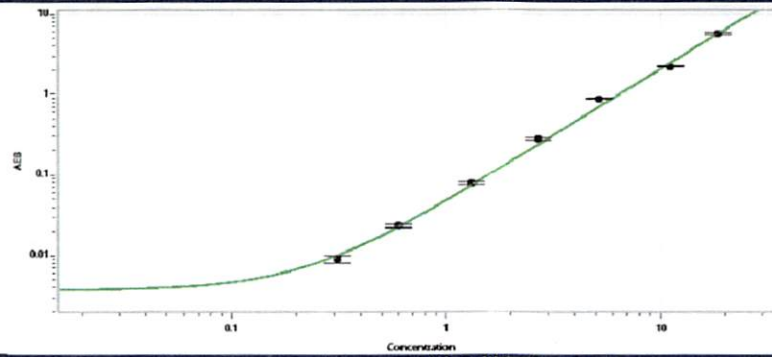
Abeta 40 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	1.07
C	1.90
D	3.71
E	7.65
F	15.2
G	33.5
H	57.6

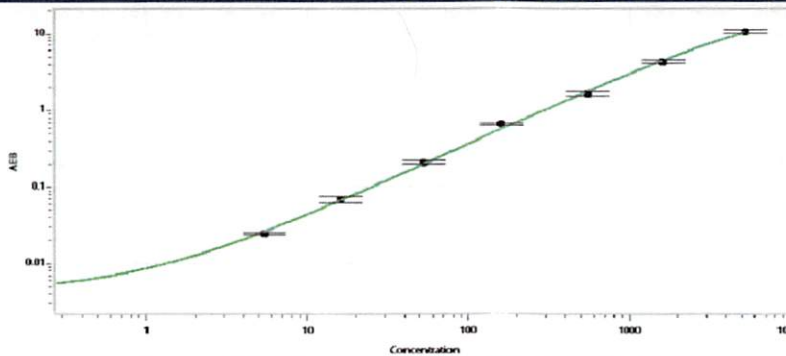
Abeta 42 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.311
C	0.600
D	1.32
E	2.70
F	5.20
G	11.1
H	18.6

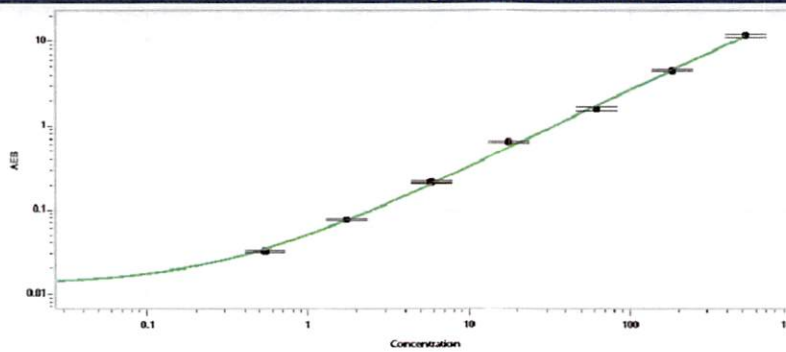
GFAP® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	5.37
C	16.0
D	52.8
E	158
F	550
G	1600
H	5210

NF-light® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.535
C	1.73
D	5.82
E	17.5
F	61.2
G	183
H	518