

Neuro 4-Plex E Kit	
Product Number:	103670
Lot Number:	503213
Expiration:	9-Nov-2022
Neuro 4-Plex E Bulk Kit	
Product Number:	103971
Lot Number:	503269
Platform(s) :	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	131311
Detector Reagent	103655	131408
SBG Reagent	103657	131314
Plasma Sample Diluent	103659	131313
CSF Sample Diluent ¹	103727	131315
Calibrators	103667	132007
Control 1	103668	132008
Control 2	103669	132008
RGP Reagent ²	103159	N/A

¹ CSF Sample Diluent is included only in Neuro 4-Plex E kit (Product Number 103670)

² RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	14.9	12.2 - 18.3
Control 2	131403	112	88.0 - 132
Panel 1	027301	24.0	17.4 - 36.4
Panel 2	124507	89.0	69.2 - 104
Panel 3	125905	118	92.1-138
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	5.57	4.49 - 6.74
Control 2	131403	30.5	24.7 - 37.1
Panel 1	027301	2.10	1.87 - 3.00
Panel 2	124507	12.9	10.1 - 15.1
Panel 3	125905	30.8	26.3 - 39.4
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	198	160 - 240
Control 2	131403	3791	3226 - 4839
Panel 1	027301	45.1	32.9 - 57.3
Panel 2	124507	164	110 - 186
Panel 3	125905	2983	2322 - 4127
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	17.6	15.0 - 22.8
Control 2	131403	384	309 - 463
Panel 1	027301	9.82	7.13 - 12.9
Panel 2	124507	34.9	21.8 - 48.2
Panel 3	125905	276	165 - 410

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

Review/Approval

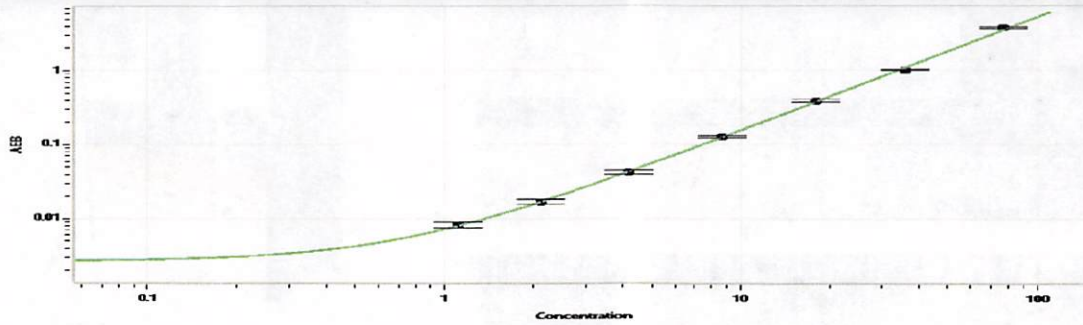
Junpil Park
Name

QC Supervisor
Title


Signature/Date

15 Dec 2021

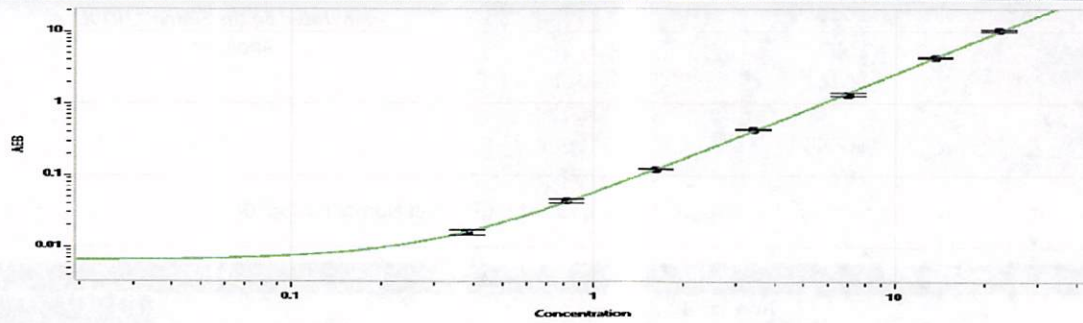
Abeta 40 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	1.12
C	2.11
D	4.19
E	8.67
F	17.9
G	35.8
H	77.3

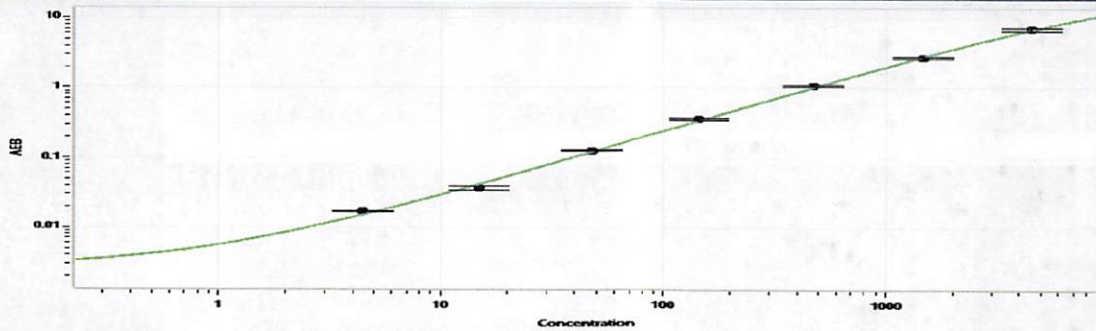
Abeta 42 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.382
C	0.820
D	1.61
E	3.38
F	6.98
G	13.6
H	22.2

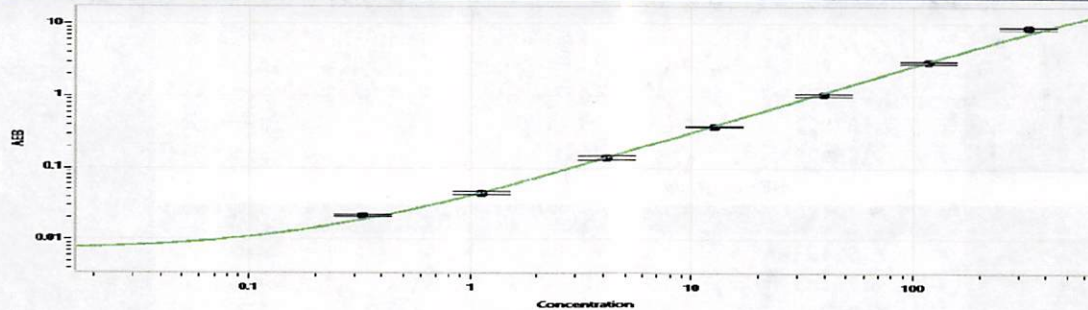
GFAP® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	4.42
C	14.8
D	47.8
E	145
F	472
G	1486
H	4523

NF-light® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.327
C	1.13
D	4.11
E	12.6
F	39.7
G	118
H	331