

Neuro 4-Plex E Kit	
Product Number:	103670
Lot Number:	502957
Expiration:	26-May-2022
Neuro 4-Plex E Bulk Kit	
Product Number:	103971
Lot Number:	502958
Platform(s) :	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	120701
Detector Reagent	103655	120604
SBG Reagent	103657	114812
Plasma Sample Diluent	103659	114813
CSF Sample Diluent ¹	103727	114610
Calibrators	103667	116204
Control 1	103668	116205
Control 2	103669	116205
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	116205	15.2	11.9 - 17.9
Control 2	116205	108	90.2 - 135
Panel 1	027301	24.3	23.3 - 34.9
Panel 2	018109	47.6	42.3 - 64.6
Panel 3	018109	109	108 - 162
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	116205	5.51	4.22 - 6.34
Control 2	116205	31.8	24.2 - 36.4
Panel 1	027301	2.03	2.00 - 3.00
Panel 2	018109	20.2	16.6 - 24.8
Panel 3	018109	44.0	36.0 - 54.0
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	116205	190	146 - 219
Control 2	116205	4278	3090 - 4634
Panel 1	027301	44.8	37.5 - 56.2
Panel 2	018109	534	446 - 668
Panel 3	018109	2400	1916 - 2948
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	116205	20.0	16.7 - 25.2
Control 2	116205	474	328 - 632
Panel 1	027301	8.5	7.10 - 12.6
Panel 2	018109	74.3	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

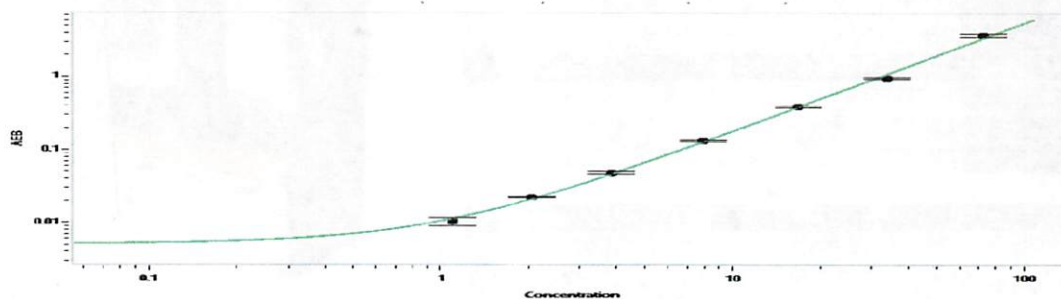
Junpil Park
Name

QC Supervisor
Title

Signature/Date

[Signature] 03 Aug 2021

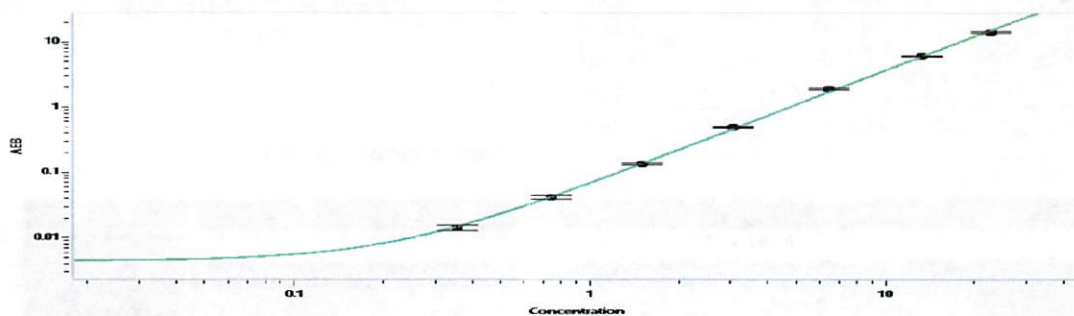
Abeta 40 Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	1.09
C	2.04
D	3.83
E	7.95
F	16.7
G	33.6
H	72.3

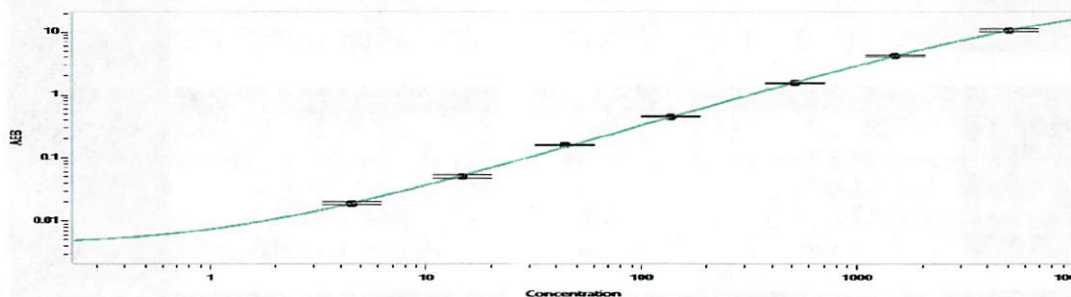
Abeta 42 Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.356
C	0.739
D	1.50
E	3.07
F	6.45
G	13.2
H	22.7

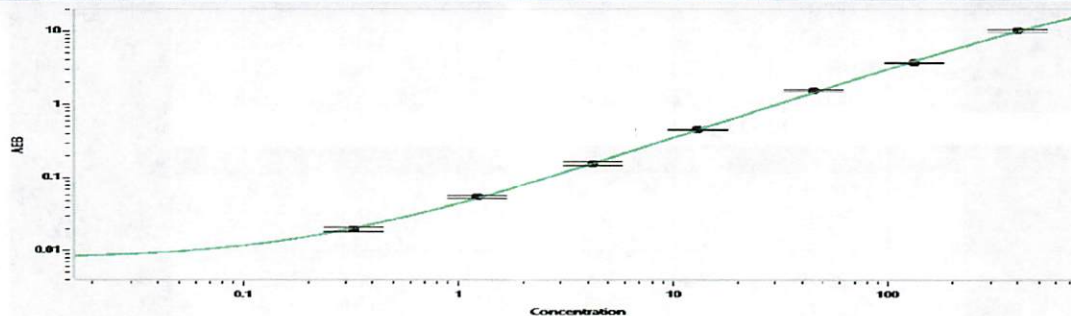
GFAP® Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	4.54
C	14.6
D	44.2
E	136
F	514
G	1503
H	5038

NF-light® Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.323
C	1.22
D	4.25
E	13.1
F	45.0
G	133
H	397