

Product Number:	103345
Lot Number:	502652
Expiration:	20-Nov-2021
Platform(s):	HD-1/HD-X & SR-X

Component	Part Number	Lot Number
Bead Reagent	103338	034307
Detector Reagent	103339	034408
SBG Reagent	103340	034412
Sample Diluent	103341	034410
Calibrators	103342	033705
Control 1	103343	034501
Control 2	103344	034501
SBG Diluent (SR-X)†	103158	N/A ¹
RGP Reagent	103159	N/A ¹

¹ RGP is not Kit Lot Specific

† Specific for use on the SR-X platform - refer to the Simoa™ Neuro 4-Plex B SR-X Kit Instructions (KI-0123).



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

Release Materials


Tau			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	034501	1.75	1.46-2.27
Control 2	034501	73.9	64.2-96.2
Panel 2	921102	1.23	0.312 - 2.93
Panel 3	921103	27.2	20.3 - 34.0
Panel 4	921104	43.0	29.9 - 61.1

NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	034501	7.44	6.18-9.51
Control 2	034501	646	541-837
Panel 2	921102	6.24	5.75 - 8.63
Panel 3	921103	168	147 - 221
Panel 4	921104	575	555 - 832

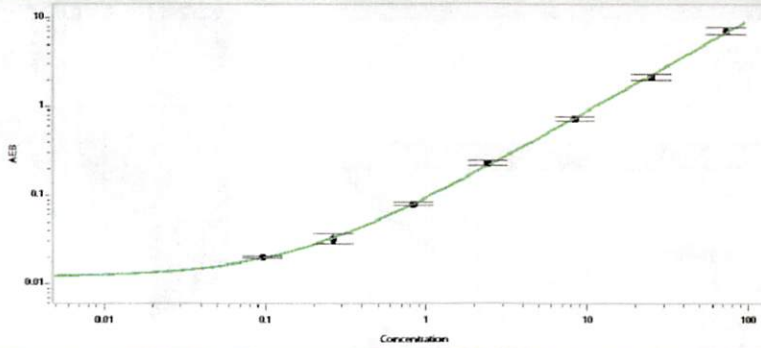
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	034501	144	109-184
Control 2	034501	9563	7644-12407
Panel 2	921102	31.5	27.8 - 53.1
Panel 3	921103	847	638 - 1195
Panel 4	921104	5026	3584 - 6789

UCH-L1®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	034501	134	112-168
Control 2	034501	10585	9114-13671
Panel 2	921102	104	84.5 - 127
Panel 3	921103	3115	2398 - 4156
Panel 4	921104	7881	6436 - 10728

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

Review/Approval	Junpil Park	QC Supervisor	 22 Jan 2021
	Name	Title	Signature/Date

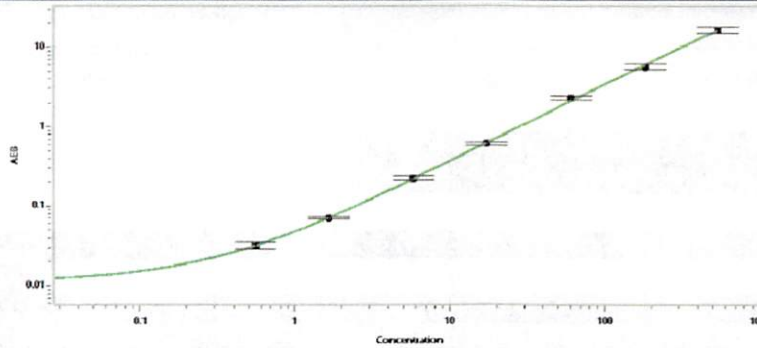
Tau Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.096
C	0.263
D	0.833
E	2.41
F	8.42
G	24.9
H	72.6

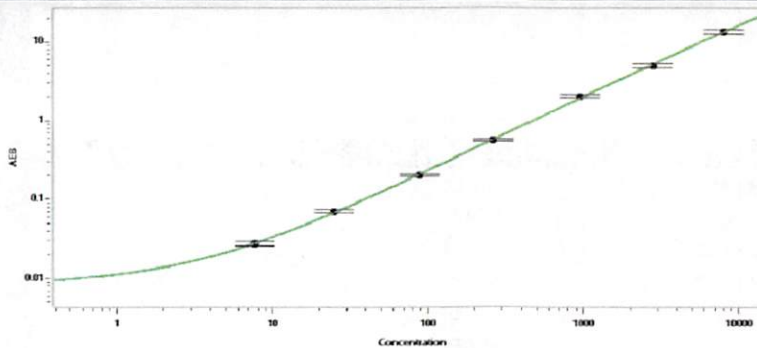
NF-light® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.552
C	1.64
D	5.78
E	17.2
F	60.7
G	181
H	535

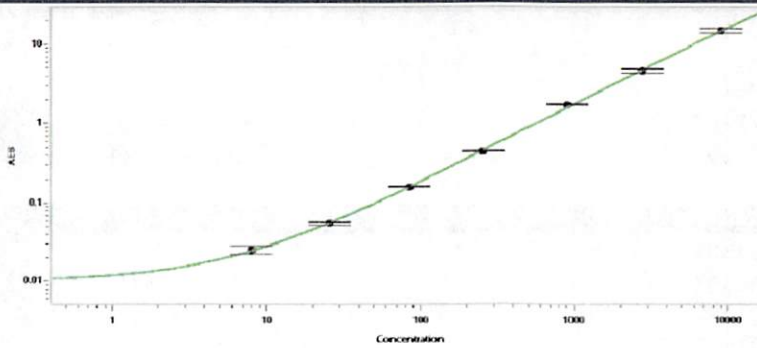
GFAP® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	7.72
C	24.9
D	87.8
E	261
F	951
G	2808
H	8016

UCHL1® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	8.04
C	25.9
D	85.4
E	256
F	910
G	2778
H	9075