

Product Number:	103670
Lot Number:	503248
Expiration:	22-Nov-2022
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	134108
Detector Reagent	103655	132809
SBG Reagent	103657	132812
Plasma Sample Diluent	103659	132817
CSF Sample Diluent	103727	132818
Calibrators	103667	133201
Control 1	103668	133202
Control 2	103669	133202
RGP Reagent	103159	N/A

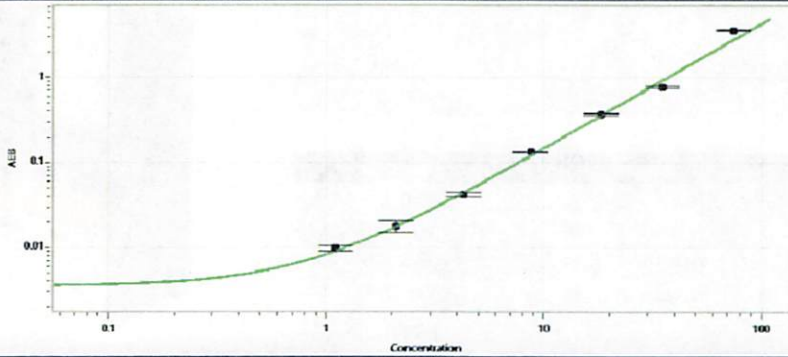
¹ RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	133202	16.8	12.6-19.0
Control 2	133202	112	76.0-139
Panel 1	027301	26.3	17.4-36.4
Panel 2	124507	87.5	69.2-104
Panel 3	125905	109	92.1-138
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	133202	5.17	4.15-6.22
Control 2	133202	28.0	19.5-33.1
Panel 1	027301	2.05	1.87-3.00
Panel 2	124507	12.6	10.1-15.1
Panel 3	125905	31.8	26.3-39.4
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	133202	179	143-215
Control 2	133202	3417	2044-4164
Panel 1	027301	46.0	32.9-57.3
Panel 2	124507	152	110-186
Panel 3	125905	3169	2322-4127
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	133202	22.4	18.9-28.3
Control 2	133202	443	308-567
Panel 1	027301	11.2	7.13-12.9
Panel 2	124507	41.1	21.8-48.2
Panel 3	125905	300	165-410

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

Review/Approval	<u>Shivani Goel</u>	<u>QC</u>	<u>Shivani Goel</u>	<u>14Jan2022</u>
	Name	Title	Signature/Date	

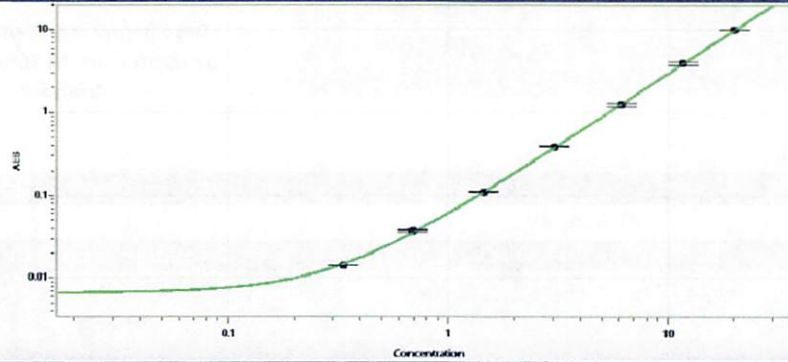
Abeta 40 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	1.11
C	2.09
D	4.30
E	8.68
F	18.3
G	35.1
H	74.3

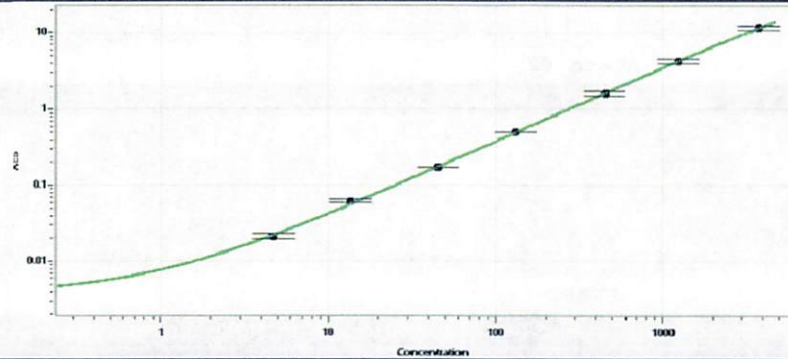
Abeta 42 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.332
C	0.690
D	1.45
E	3.01
F	6.14
G	11.6
H	20.0

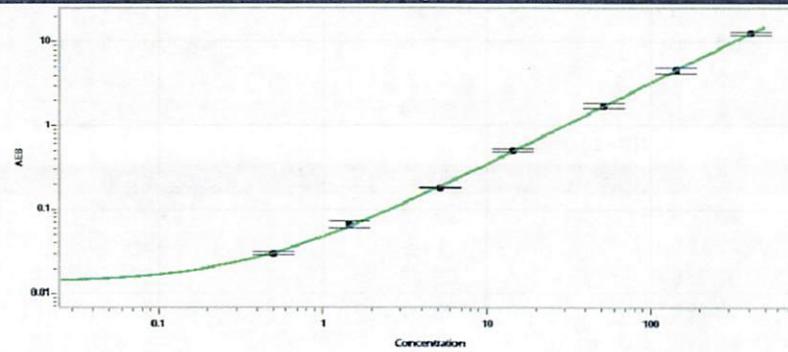
GFAP® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	4.72
C	13.6
D	45.7
E	131
F	449
G	1224
H	3719

NF-light® Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.497
C	1.46
D	5.20
E	14.5
F	51.8
G	142
H	408