

Product Number:	103670
Lot Number:	503143
Expiration:	16-Sep-2022
Platform(s):	HD-X




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

Component	Part Number	Lot Number
Bead Reagent	103653	126101
Detector Reagent	103655	128801
SBG Reagent	103657	126105
Plasma Sample Diluent	103659	126202
CSF Sample Diluent	103727	126203
Calibrators	103667	128603
Control 1	103668	128604
Control 2	103669	128604
RGP Reagent	103159	N/A

¹ RGP is not Kit Lot Specific

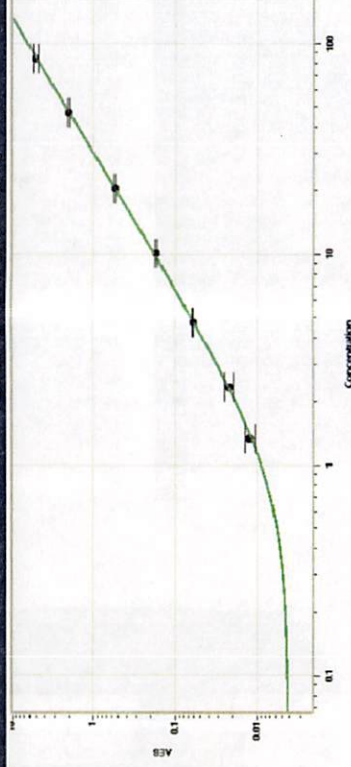
Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	128604	17.8	14.2-21.3
Control 2	128604	130	106-159
Panel 1	027301	23.6	23.3-34.9
Panel 2	124507	89.3	69.0-103
Panel 3	125905	118	91.7-138
Abeta 42			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	128604	5.87	4.59-6.88
Control 2	128604	31.3	24.9-37.3
Panel 1	027301	2.08	2.00-3.00
Panel 2	124507	12.3	10.0-15.0
Panel 3	125905	31.4	26.7-40.0
GFAP®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	128604	234	177-266
Control 2	128604	4154	3309-4963
Panel 1	027301	49.0	37.5-56.2
Panel 2	124507	165	111-180
Panel 3	125905	3137	2213-4300
NF-light®			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	128604	21.2	16.6-24.9
Control 2	128604	395	317-476
Panel 1	027301	9.28	7.10-12.6
Panel 2	124507	31.6	25.6-38.4
Panel 3	125905	232	144-415

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

Review/Approval	Wenkai Tsai	QC Supervisor	
	Name	Title	Signature/Date

04 Nov 2021

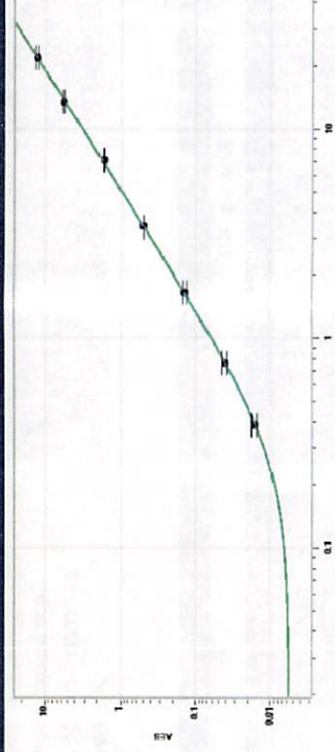
Abeta 40 Calibration Curve



Calibrator Levels
(pg/mL)

Calibrator	Level (pg/mL)
A	0.000
B	1.33
C	2.32
D	4.73
E	10.1
F	20.5
G	46.5
H	83.8

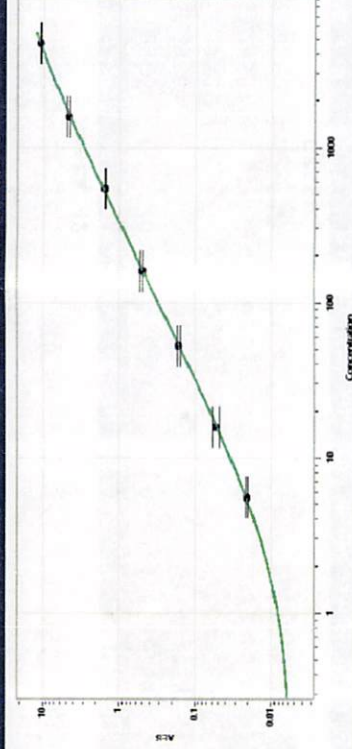
Abeta 42 Calibration Curve



Calibrator Levels
(pg/mL)

Calibrator	Level (pg/mL)
A	0.000
B	0.383
C	0.764
D	1.64
E	3.41
F	7.03
G	13.3
H	21.7

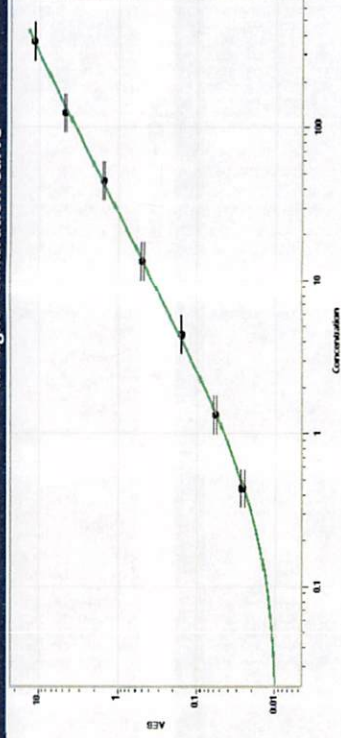
GFAP® Calibration Curve



Calibrator Levels
(pg/mL)

Calibrator	Level (pg/mL)
A	0.000
B	5.54
C	15.7
D	52.8
E	158
F	543
G	1559
H	4683

NF-light® Calibration Curve



Calibrator Levels
(pg/mL)

Calibrator	Level (pg/mL)
A	0.000
B	0.441
C	1.31
D	4.39
E	13.3
F	44.3
G	124
H	366