

Product Number:	103670
Lot Number:	503212
Expiration:	6-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	132402
Detector Reagent	103655	132403
SBG Reagent	103657	131003
Plasma Sample Diluent	103659	131004
CSF Sample Diluent	103727	131005
Calibrators	103667	131402
Control 1	103668	131403
Control 2	103669	131403
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	131403	17.0	14.1 - 21.4
Control 2	131403	122	99.6 - 149
Panel 1	027301	22.5	17.4 - 36.4
Panel 2	124507	80.3	69.2 - 104
Panel 3	125905	107	92.1-138

Abeta 42

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	6.38	5.14 - 7.70
Control 2	131403	33.0	28.2 - 42.3
Panel 1	027301	2.26	1.87 - 3.00
Panel 2	124507	12.5	10.1 - 15.1
Panel 3	125905	30.2	26.3 - 39.4

GFAP®

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	287	163 - 439
Control 2	131403	5670	4384 - 6985
Panel 1	027301	43.2	32.9 - 57.3
Panel 2	124507	140	110 - 186
Panel 3	125905	3256	2322 - 4127

NF-light®

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	131403	22.0	13.9 - 35.0
Control 2	131403	413	307 - 589
Panel 1	027301	10.5	7.13 - 12.9
Panel 2	124507	36.8	21.8 - 48.2
Panel 3	125905	289	165 - 410

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

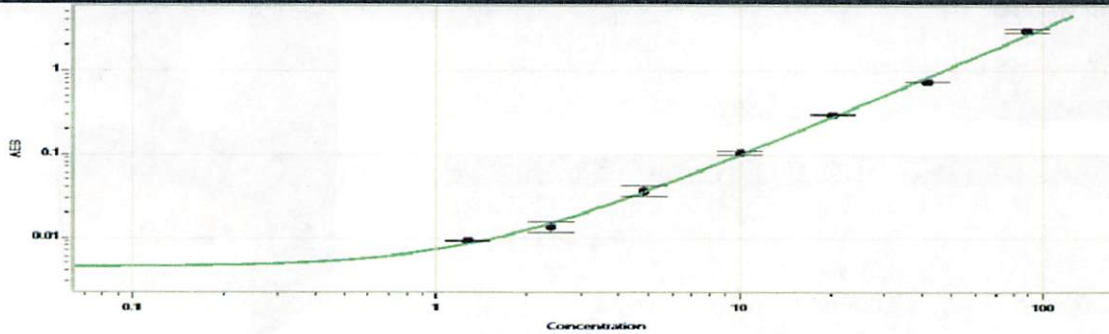
Review/Approval

Junpil Park
Name

QC Supervisor
Title

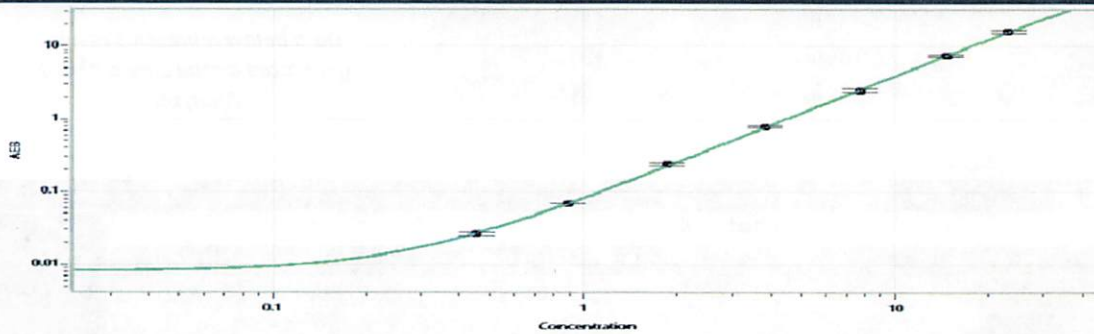
 07 Dec 2021
Signature/Date

Abeta 40 Calibration Curve



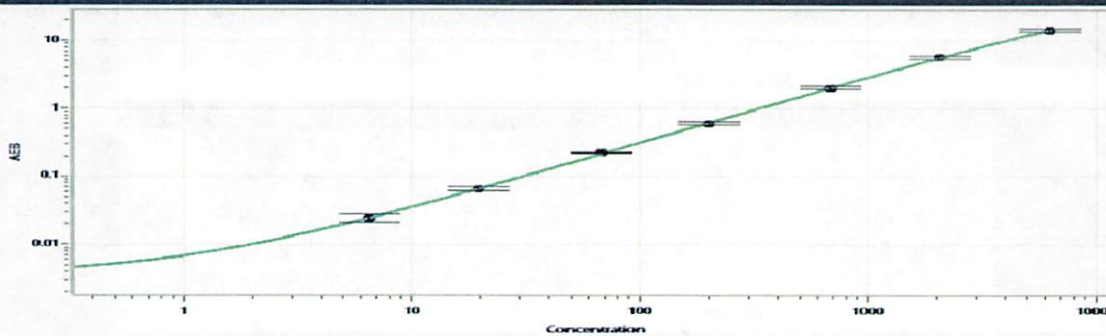
Calibrator Levels (pg/mL)	
A	0.000
B	1.27
C	2.38
D	4.86
E	10.0
F	20.4
G	41.7
H	89.0

Abeta 42 Calibration Curve



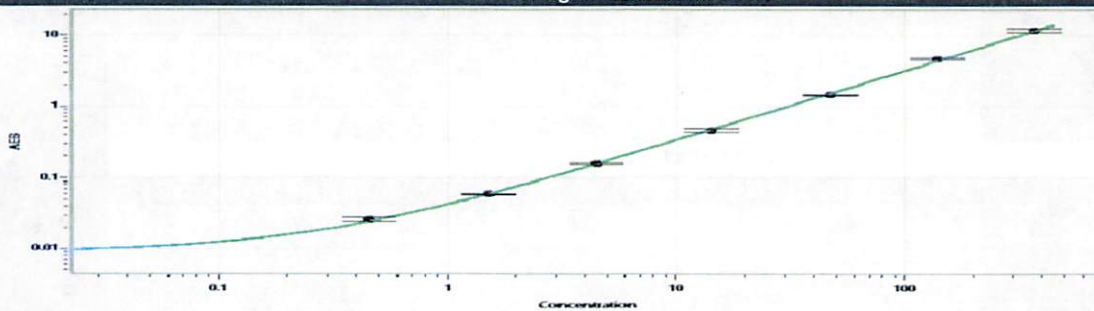
Calibrator Levels (pg/mL)	
A	0.000
B	0.452
C	0.887
D	1.85
E	3.84
F	7.75
G	14.6
H	23.2

GFAP® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	6.52
C	19.5
D	68.4
E	201
F	689
G	2050
H	6215

NF-light® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.453
C	1.52
D	4.50
E	14.3
F	46.9
G	140
H	366