

Product Number:	103670
Lot Number:	503893
Expiration:	6-Jul-2024
Platform(s):	HD-X



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

Component	Part Number	Lot Number	Control Number
Bead Reagent	103653	323402	N/A
Detector Reagent	103655	323610	N/A
SBG Reagent	103657	323409	N/A
Plasma Sample Diluent	103659	318704	318704A
CSF Sample Diluent	103727	323502	N/A
Calibrators	103667	324402	N/A
Control 1	103668	324403	N/A
Control 2	103669	324403	N/A
RGP Reagent	103159	N/A ¹	N/A ¹

¹ RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	19.1	15.6-23.4
Control 2	324403	116	86.9-134
Panel 1	226304	25.6	20.8-31.2
Panel 2	225507	56.6	44.5-66.8
Panel 3	226908	259	183-312
Abeta 42			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	8.47	6.79-10.2
Control 2	324403	40.1	31.2-46.8
Panel 1	226304	2.36	1.65-2.97
Panel 2	225507	20.9	16.5-24.7
Panel 3	226908	58.7	41.2-61.9
GFAP®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	186	150-225
Control 2	324403	3971	2980-4470
Panel 1	226304	40.3	28.1 - 58.2
Panel 2	225507	291	248-372
Panel 3	226908	2599	2078-3165
NF-light®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	324403	23.6	19.5-29.2
Control 2	324403	563	429-643
Panel 1	226304	2.63	1.38-4.84
Panel 2	225507	95.5	85.7-128
Panel 3	226908	535	367-698

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

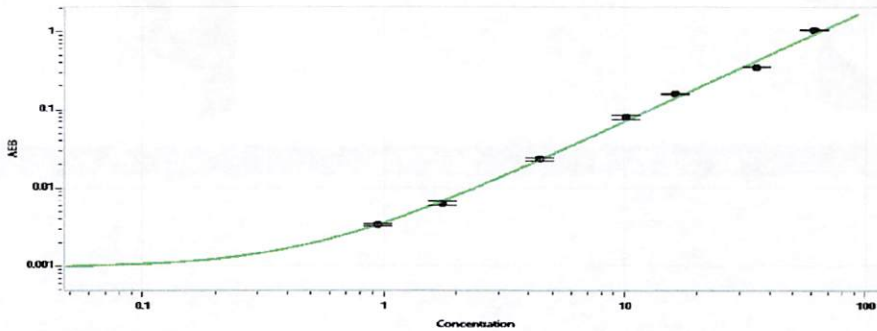
Review/Approval

ROBERT SOMOGYI
Name

QC, MANAGER
Title

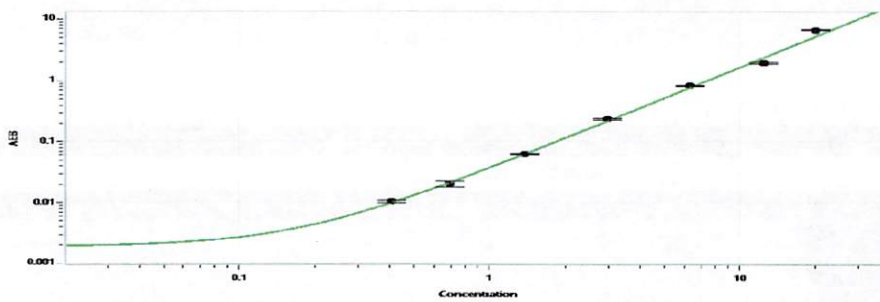
Signature/Date 25 OCT 2023

Abeta 40 Calibration Curve



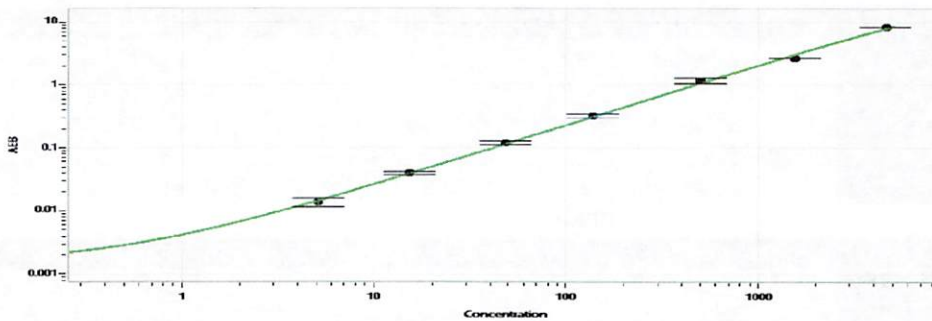
Calibrator Levels (pg/mL)	
A	0.000
B	0.947
C	1.75
D	4.46
E	10.1
F	16.2
G	35.2
H	61.4

Abeta 42 Calibration Curve



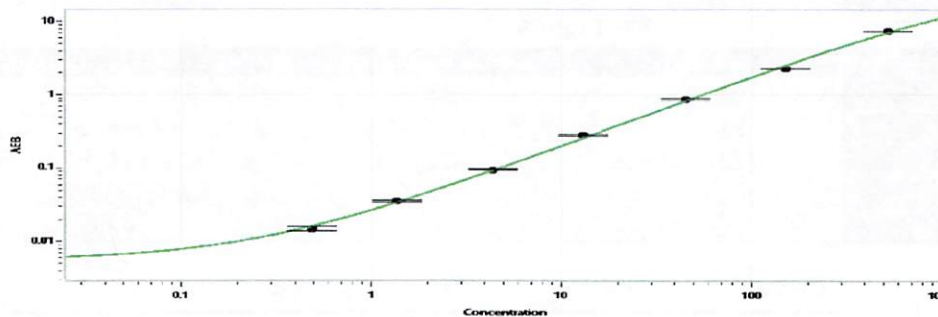
Calibrator Levels (pg/mL)	
A	0.000
B	0.405
C	0.692
D	1.39
E	2.97
F	6.31
G	12.4
H	20.1

GFAP® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	5.13
C	15.2
D	48.3
E	138
F	501
G	1529
H	4577

NF-light® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.489
C	1.38
D	4.38
E	13.0
F	45.5
G	152
H	525