

Product Number:	103670
Lot Number:	503940
Expiration:	24-Apr-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	311407	311407A
Detector Reagent	103655	311506	311506A
SBG Reagent	103657	311501	311501A
Plasma Sample Diluent	103659	311504	311504A
CSF Sample Diluent	103727	311505	311505A
Calibrators	103667	321303	N/A
Control 1	103668	321305	N/A
Control 2	103669	321305	N/A
RGP Reagent	103159	N/A ¹	N/A ¹

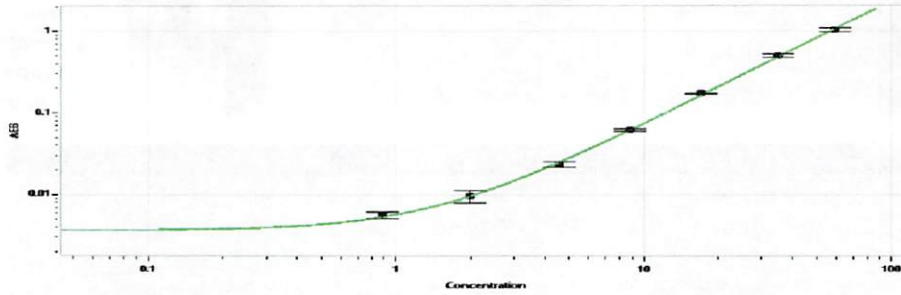
¹ RGP is not Kit Lot Specific

Release Materials			
Abeta 40			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	18.9	14.8 - 22.2
Control 2	321305	112	86.8 - 130
Panel 1	226304	24.3	20.8 - 31.2
Panel 2	225507	52.9	44.5 - 66.8
Panel 3	226908	217	183 - 312
Abeta 42			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	8.11	6.58 - 9.87
Control 2	321305	40.5	32.3 - 48.4
Panel 1	226304	2.18	1.65 - 2.97
Panel 2	225507	19.0	16.5 - 24.7
Panel 3	226908	48.7	41.2 - 61.9
GFAP®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	182	134 - 201
Control 2	321305	3275	2719 - 4078
Panel 1	226304	46.2	28.1 - 58.0
Panel 2	225507	292	248 - 372
Panel 3	226908	2120	2078 - 3165
NF-light®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	23.2	19.0 - 28.5
Control 2	321305	526	403 - 604
Panel 1	226304	3.08	1.38 - 4.84
Panel 2	225507	98.4	85.7 - 128
Panel 3	226908	551	367 - 698

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

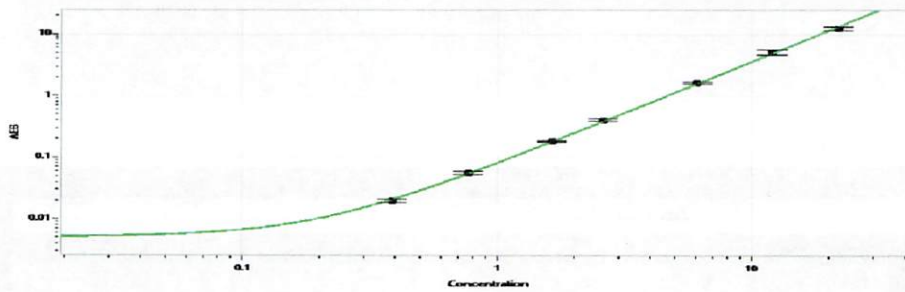
Review/Approval: Sonia Khillan Senior QC Analyst Sonia Della 14 NOV 2023
Name Title Signature/Date

Abeta 40 Calibration Curve



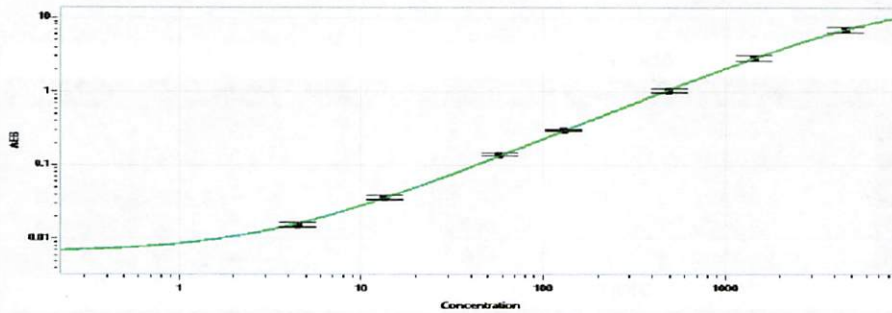
Calibrator Levels (pg/mL)	
A	0.000
B	0.887
C	1.99
D	4.56
E	8.77
F	17.2
G	34.7
H	59.5

Abeta 42 Calibration Curve



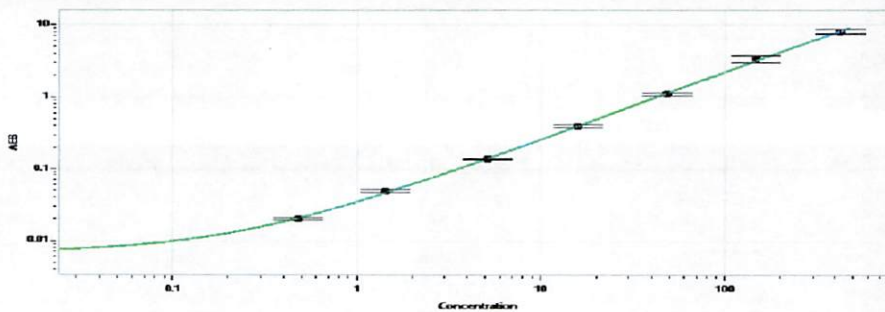
Calibrator Levels (pg/mL)	
A	0.000
B	0.389
C	0.773
D	1.65
E	2.62
F	6.08
G	11.9
H	22.1

GFAP® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	4.45
C	13.6
D	57.5
E	130
F	493
G	1432
H	4565

NF-light® Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.482
C	1.42
D	5.17
E	15.9
F	48.3
G	147
H	425