

Product Number:	103670
Lot Number:	503864
Expiration:	5-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	318614	318614A
Detector Reagent	103655	318707	318707A
SBG Reagent	103657	318710	318710A
Plasma Sample Diluent	103659	318714	318714A
CSF Sample Diluent	103727	318713	318713A
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	20.5	14.8 - 22.2
Control 2	321305	111	86.8 - 130
Panel 1	226304	28.6	20.8 - 31.2
Panel 2	225507	53.0	44.5 - 66.8
Panel 3	226908	229	183 - 312
Abeta 42			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	8.84	6.58 - 9.87
Control 2	321305	42.4	32.3 - 48.4
Panel 1	226304	2.49	1.65 - 2.97
Panel 2	225507	19.7	16.5 - 24.7
Panel 3	226908	56.4	41.2 - 61.9
GFAP®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	182	134 - 201
Control 2	321305	3653	2719 - 4078
Panel 1	226304	48.9	28.1 - 58.0
Panel 2	225507	318	248 - 372
Panel 3	226908	2851	2078 - 3165
NF-light®			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	321305	23.3	19.0 - 28.5
Control 2	321305	536	403 - 604
Panel 1	226304	3.08	1.38 - 4.84
Panel 2	225507	102	85.7 - 128
Panel 3	226908	591	367 - 698

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

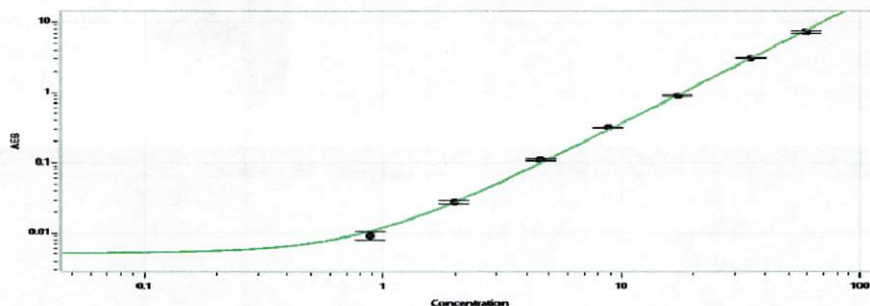
Review/Approval

Sonia Khilka
Name

Senior QC Analyst
Title

Sonia 12/1/23 14/NOV2023
Signature/Date

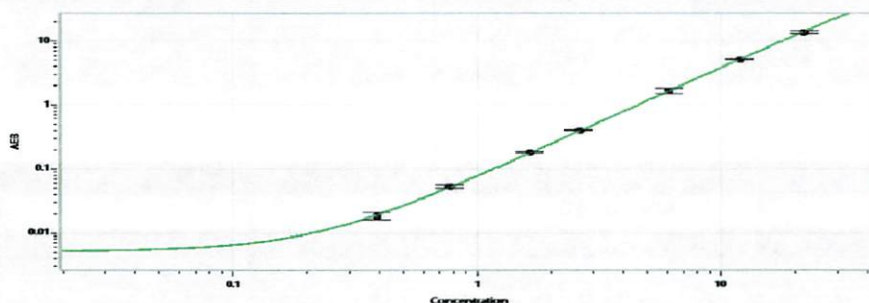
Abeta 40 Calibration Curve



**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

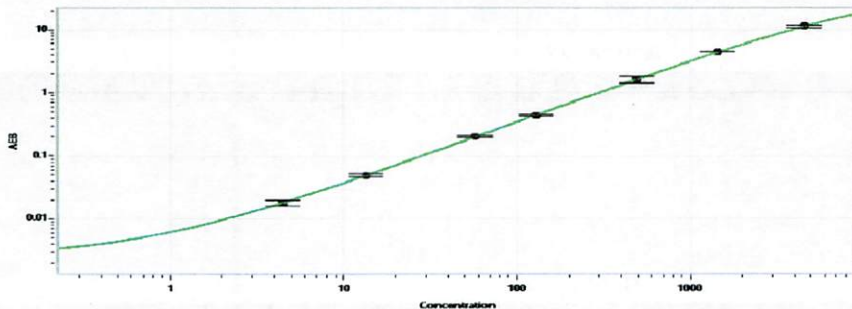
Abeta 42 Calibration Curve



**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

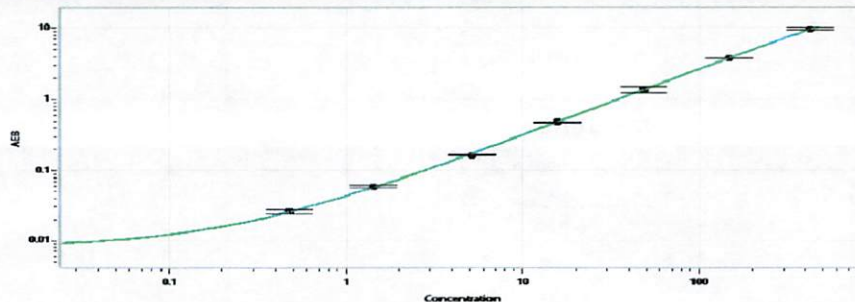
GFAP® Calibration Curve



**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