

Product Number:	103670
Lot Number:	503811
Expiration:	11-Jan-2024
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	301108
Detector Reagent	103655	304706
SBG Reagent	103657	301717
Plasma Sample Diluent	103659	301304
CSF Sample Diluent	103727	301713
Calibrators	103667	304107
Control 1	103668	304108
Control 2	103669	304108
RGP Reagent	103159	N/A <sup>1</sup>

<sup>1</sup> RGP is not Kit Lot Specific

Release Materials			
<b>Abeta 40</b>			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	304108	17.9	14.2-21.3
Control 2	304108	116	96.2-144
Panel 1	226304	29.3	20.8-31.2
Panel 2	225507	57.2	44.5-66.8
Panel 3	226908	282	183-312
<b>Abeta 42</b>			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	304108	5.55	4.55-6.82
Control 2	304108	29.9	24.1-36.2
Panel 1	226304	2.19	1.65-2.97
Panel 2	225507	18.9	16.5-24.7
Panel 3	226908	49.5	41.2-61.9
<b>GFAP®</b>			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	304108	181	147-220
Control 2	304108	3461	2814-4221
Panel 1	226304	44.6	28.1 - 58.0
Panel 2	225507	266	248-372
Panel 3	226908	2259	2078-3165
<b>NF-light®</b>			
	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	304108	22.3	18.5-27.7
Control 2	304108	467	345-543
Panel 1	226304	3.43	1.38-4.84
Panel 2	225507	105	85.7-128
Panel 3	226908	503	367-698

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

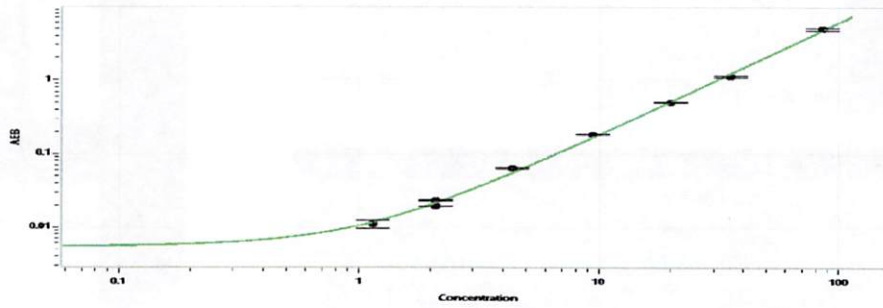
Review/Approval

ROBERT SOMOGYI  
Name

QC MANAGER  
Title

*[Signature]* 25 OCT 2023  
Signature/Date

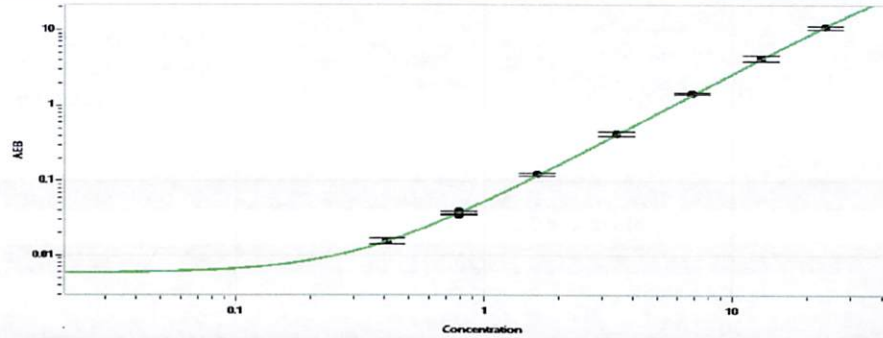
**Abeta 40 Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	1.15
C	2.10
D	4.38
E	9.40
F	19.8
G	35.2
H	85.2

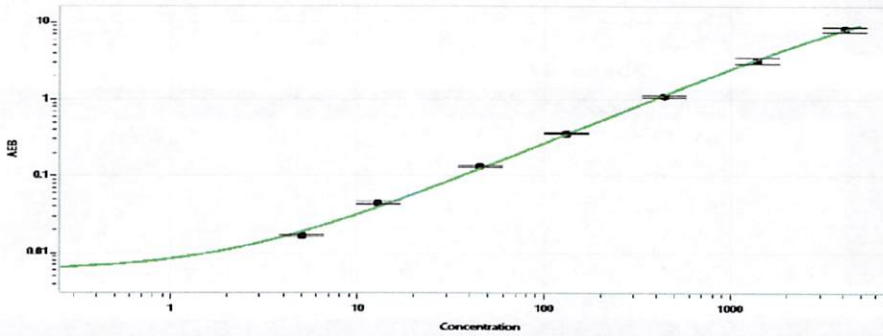
**Abeta 42 Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.407
C	0.796
D	1.63
E	3.41
F	6.89
G	13.1
H	23.6

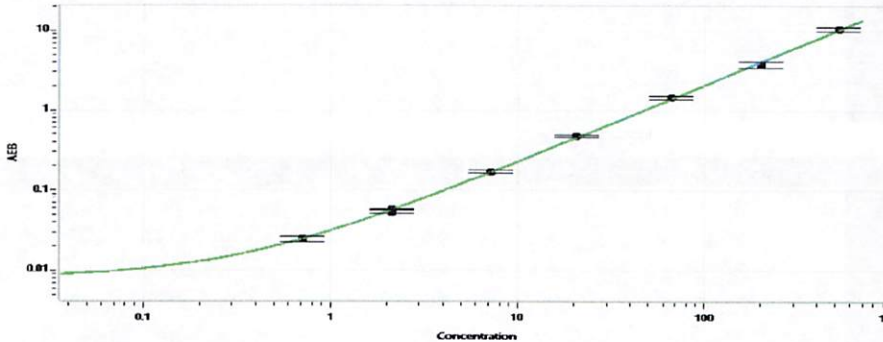
**GFAP® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	5.02
C	12.8
D	45.3
E	132
F	441
G	
H	4064

**NF-light® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.706
C	2.13
D	7.17
E	20.7
F	66.4
G	200
H	518