

Product Number:	103670
Lot Number:	502535
Expiration:	3-Jun-2021
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	023705
Detector Reagent	103655	025209
SBG Reagent	103657	020602
Plasma Sample Diluent	103659	020904
CSF Sample Diluent	103727	020603
Calibrators	103667	021801
Control 1	103668	021802
Control 2	103669	021802
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)	Mean Range (pg/mL)
Control 1	021802	14.3	12.4-18.5
Control 2	021802	106	90.1-135
Panel 1	016412	14.3	11.4-21.3
Panel 2	018109	47.9	43.9-65.9
Panel 3	018109	130	109 - 164
<b>Abeta 42</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	021802	5.24	4.36-6.54
Control 2	021802	28.3	22.9-34.3
Panel 1	016412	1.35	0.591-2.84
Panel 2	018109	18.9	17.0-25.5
Panel 3	018109	44.5	36.0-54.1
<b>GFAP®</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	021802	228	190-285
Control 2	021802	4663	3800-5700
Panel 1	016412	29.9	22.5-45.0
Panel 2	018109	547	448-672
Panel 3	018109	2668	1861-2950
<b>NF-light®</b>			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	021802	21.8	15.6-24.3
Control 2	021802	407	327-491
Panel 1	016412	6.75	5.55-8.32
Panel 2	018109	75.0	59.1-88.6
Panel 3	018109	413	306-459

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

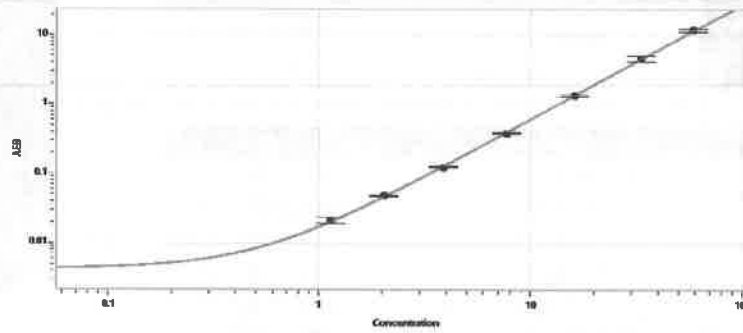
Review/Approval

Shivani Goel  
Name

QC Manager  
Title

Shivani Goel 15 Oct 2020  
Signature/Date

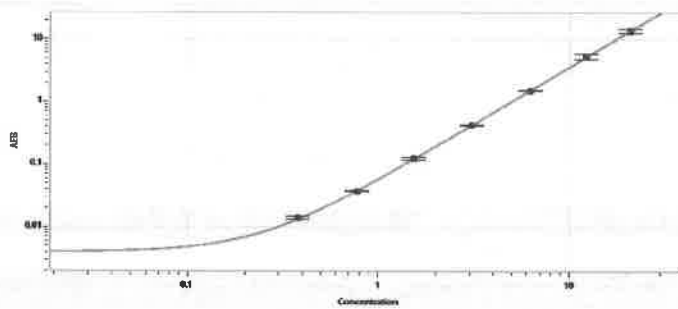
**Abeta 40 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	1.13
C	2.03
D	3.86
E	7.75
F	16.1
G	33.3
H	58.5

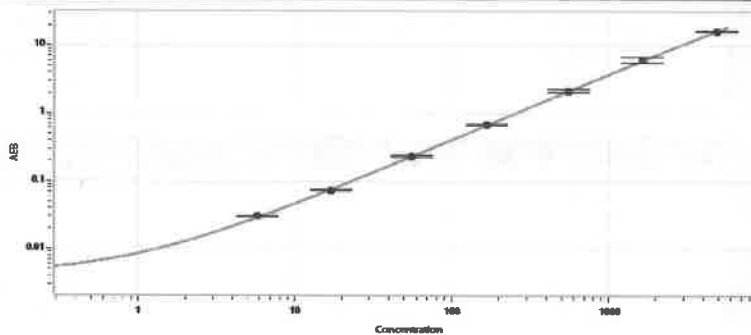
**Abeta 42 Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	0.378
C	0.780
D	1.54
E	3.09
F	6.25
G	12.2
H	20.7

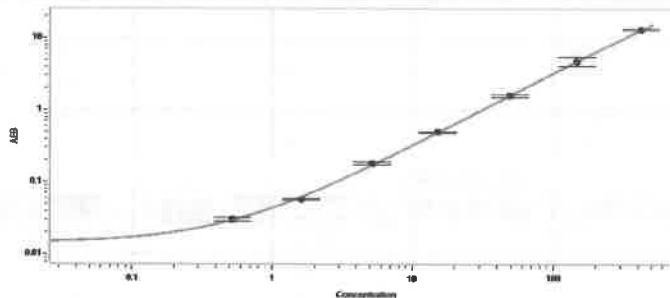
**GFAP® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	5.78
C	17.2
D	55.8
E	167
F	550
G	1642
H	4860

**NF-light® Calibration Curve**



**Calibrator Levels  
(pg/mL)**

A	0.000
B	0.519
C	1.60
D	5.10
E	15.1
F	49.3
G	148
H	420