

Product Number:	103670
Lot Number:	502807
Expiration:	16-Mar-2022
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103653	107508
Detector Reagent	103655	107509
SBG Reagent	103657	107512
Plasma Sample Diluent	103659	107513
CSF Sample Diluent	103727	107514
Calibrators	103667	107703
Control 1	103668	107704
Control 2	103669	107704
RGP Reagent	103159	N/A <sup>1</sup>

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

**Release Materials**

**Abeta 40**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	15.1	11.8-17.7
Control 2	107704	117	77.8-130
Panel 1	027301	29.0	23.3-34.9
Panel 2	018109	52.4	42.3-64.6
Panel 3	018109	143	100-163

**Abeta 42**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	5.16	4.01-6.01
Control 2	107704	29.6	22.3-33.5
Panel 1	027301	2.41	2.00-3.00
Panel 2	018109	21.3	16.6-24.8
Panel 3	018109	48.2	36.0-54.0

**GFAP®**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	184	147-220
Control 2	107704	3903	3007-4511
Panel 1	027301	45.1	37.5-56.2
Panel 2	018109	504	446-668
Panel 3	018109	2200	1916-2948

**NF-light®**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	107704	23.6	19.8-29.7
Control 2	107704	572	438-656
Panel 1	027301	8.35	7.10-12.6
Panel 2	018109	66.8	59.5-89.3
Panel 3	018109	388	310-474

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

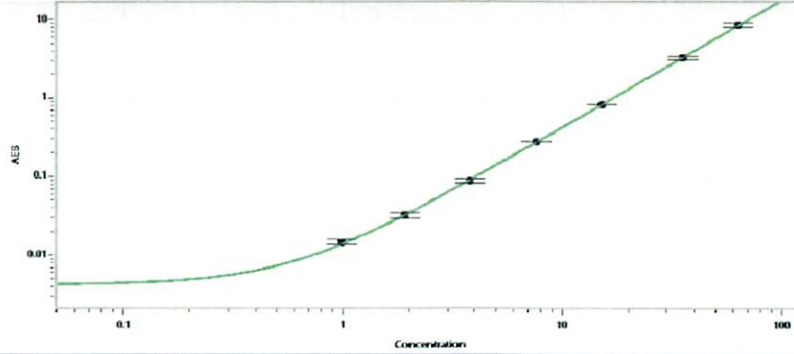
Review/Approval

Shivani Goel  
Name

QC Manager  
Title

*Shivani Goel* 05 Apr 2022  
Signature/Date

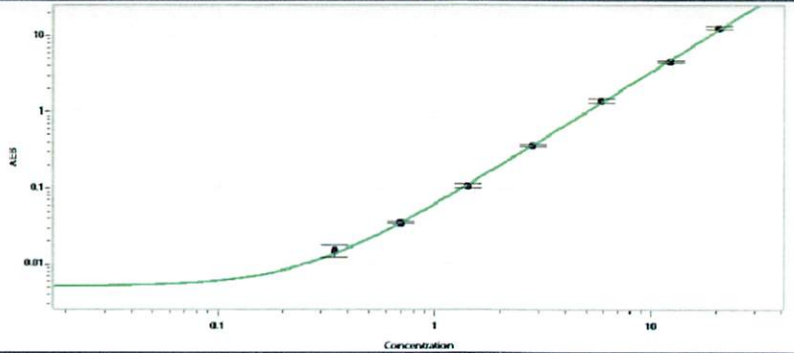
**Abeta 40 Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.990
C	1.92
D	3.77
E	7.61
F	15.0
G	35.2
H	62.6

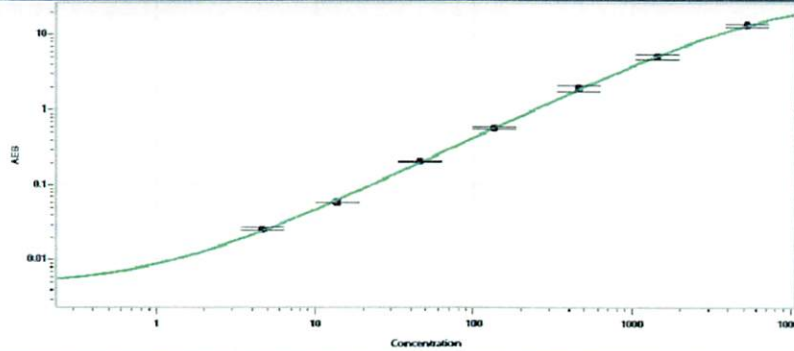
**Abeta 42 Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.347
C	0.695
D	1.42
E	2.84
F	5.84
G	12.2
H	20.5

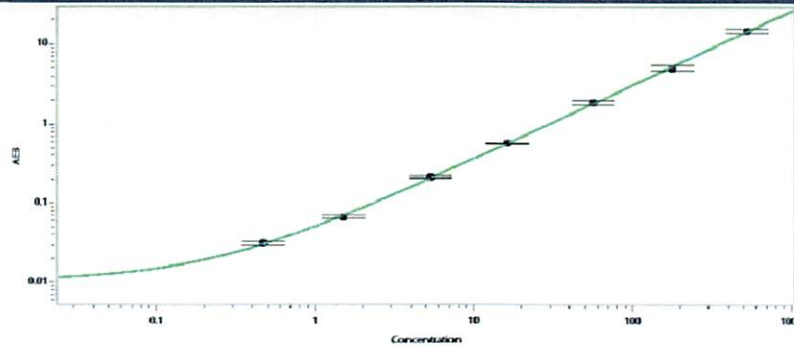
**GFAP® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	4.66
C	13.9
D	46.1
E	135
F	460
G	1444
H	5309

**NF-light® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.473
C	1.51
D	5.30
E	16.3
F	56.1
G	177
H	524