

Product Number:	104465
Lot Number:	504032
Expiration:	28-Jul-2024
Platform(s):	HD-X



Component	Part Number	Lot Number
Bead Reagent	104448	330506
Detector Reagent	104450	330505
SBG Reagent	104452	330504
Calibrator Diluent	104453	320908
Plasma Sample Diluent	104647	327915
CSF Sample Diluent	104648	329623
Control Diluent	104649	320909
Calibrator Concentrate	104466	335404
Control 1 Concentrate	104468	335405
Control 2 Concentrate	104469	335406
RGP 2.0 Reagent	104321	N/A ¹
Activation Buffer Reagent	104324	N/A ¹

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

¹ Reagents are not Kit Lot Specific

Review/Approval

<i>Cody Carlson</i>	<i>QC Manager</i>	<i>[Signature]</i> 18 JAN 2024
Name	Title	Signature/Date

Release Materials*

Abeta 40

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	335405	3.69	2.20 - 4.98
Control 2	335406	61.7	45.0 - 83.6
Panel 1	327811	3.68	2.44 - 4.53
Panel 2	327811	42.2	24.9 - 50.3

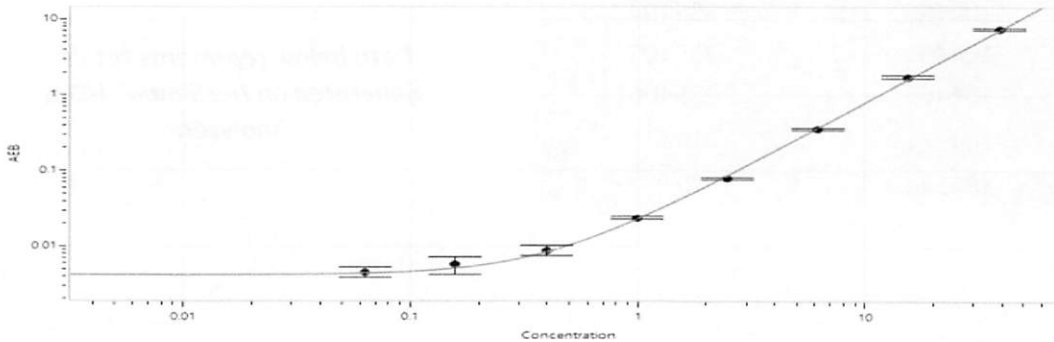
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibrator Levels (pg/mL)

A	0.000
B	0.063
C	0.158
D	0.395
E	0.987
F	2.47
G	6.17
H	15.4
I	38.6

Calibration Curve



Release Materials*

Abeta 42

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	335405	2.12	1.02 - 2.90
Control 2	335406	31.4	23.2 - 43.0
Panel 1	327811	3.57	2.58 - 4.79
Panel 2	327811	31.9	19.7 - 42.3

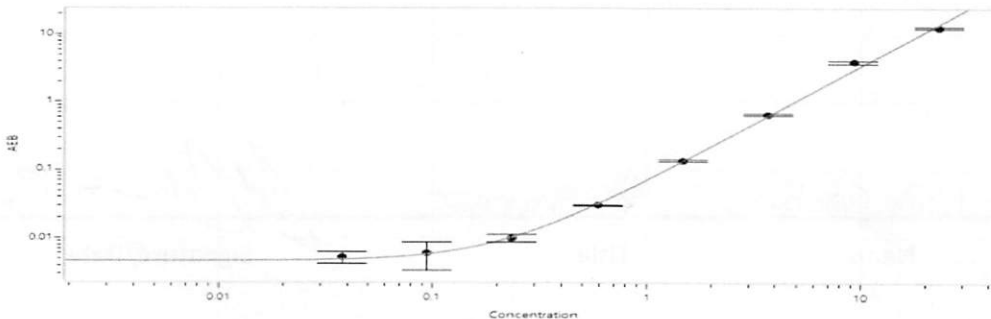
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibrator Levels (pg/mL)

A	0.000
B	0.038
C	0.094
D	0.236
E	0.590
F	1.47
G	3.69
H	9.22
I	23.0

Calibration Curve



Release Materials*

GFAP®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	335405	93.5	59.9 - 115
Control 2	335406	1097	816 - 1516
Panel 1	327811	64.9	34.6 - 77.2
Panel 2	327811	1685	461 - 2266

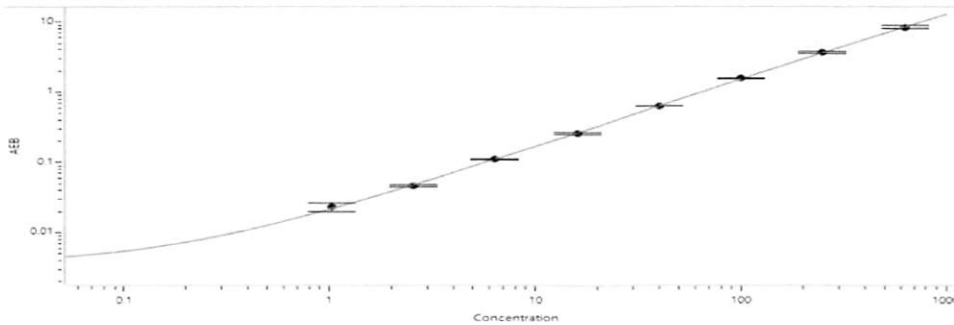
* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibrator Levels (pg/mL)

A	0.000
B	1.03
C	2.57
D	6.42
E	16.1
F	40.1
G	100
H	251
I	627

Calibration Curve



Release Materials*

NF-Light®

	Lot	Result (pg/mL)	Spec. Range (pg/mL)
Control 1	335405	86.0	52.9 - 105
Control 2	335406	1011	738 - 1371
Panel 1	327811	10.6	5.56 - 12.6
Panel 2	327811	304	77.2 - 395

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

Calibrator Concentrate Reconstitution Volume (uL)	1144
Control 1 Concentrate Reconstitution Volume (uL)	1144
Control 2 Concentrate Reconstitution Volume (uL)	1144

Calibrator Levels (pg/mL)

A	0.000
B	0.866
C	2.17
D	5.41
E	13.5
F	33.8
G	84.6
H	211
I	529

Calibration Curve

