

Product Number: 101995
Lot Number: 501824
Expiration: 6-May-2020
Platform(s): HD-1 & SR-X



Data below represents results generated on the Simoa™ HD-1 Analyzer.

Component	Part Number	Lot Number
Bead Reagent	101998	913701
Detector Reagent	101996	913703
SBG Reagent (HD-1)	102000	912605
Sample Diluent	102002	912604
Calibrators	103221	911201
Controls	103222/103223	911202
SBG Diluent (SRX)	103158	N/A ¹
RGP Reagent	103159	N/A ¹

¹ Reagents are not Kit Lot Specific

Release Materials

Tau

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	911202	2.03	1.49-2.24
Control 2	911202	77.3	58.8-88.1
Panel 1	MF-062018-04	1.62	1.18-2.03
Panel 2	MF-010818-02	197	156-234
Panel 3	MF-010818-03	3.86	1.30-5.98

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	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	911202	5.00	3.80-5.71
Control 2	911202	106	79.7-119
Panel 1	MF-062018-04	7.77	5.32-7.98
Panel 2	MF-010818-02	10.7	7.07-10.7
Panel 3	MF-010818-03	120	96.1-150

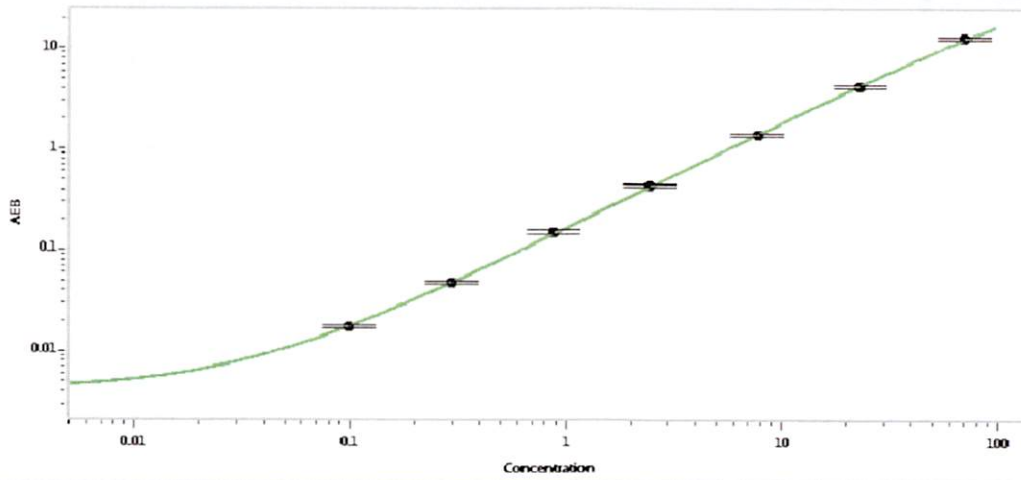
Abeta 40

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	911202	15.7	11.8-17.6
Control 2	911202	230	182-273
Panel 1	MF-062018-04	138	104-159
Panel 2	MF-010818-02	167	107-200
Panel 3	MF-010818-03	90.0	71.5-124

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

Review/Approval: Patrizia Stadler Assoc. Director, QC P. Stadler 28 May 2019
Name Title Signature/Date

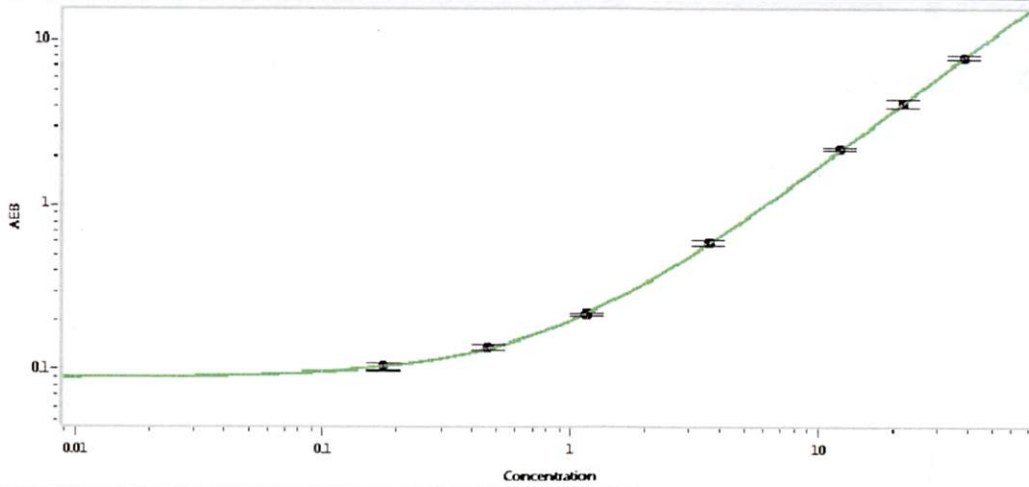
Tau Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.099
C	0.296
D	0.879
E	2.42
F	7.70
G	23.0
H	70.3

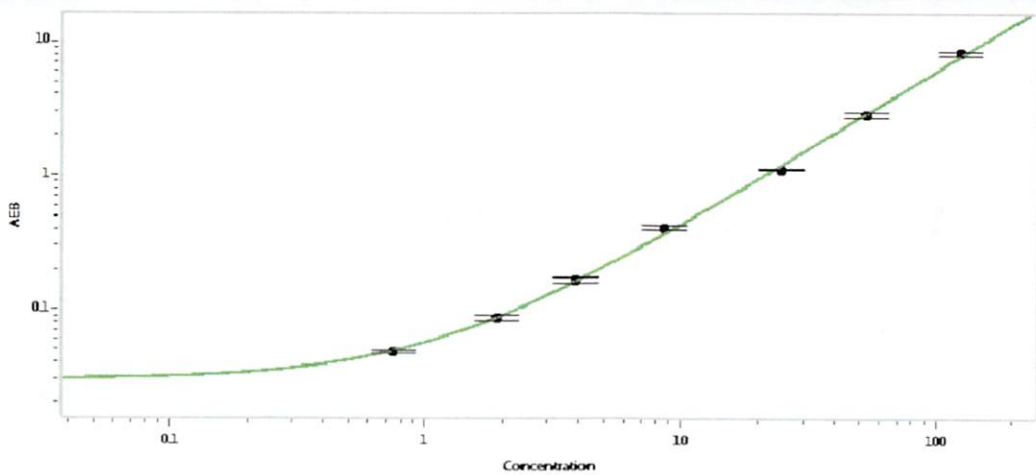
Abeta 42



Calibrator Levels (pg/mL)

A	0.000
B	0.176
C	0.463
D	1.16
E	3.60
F	12.2
G	21.8
H	38.2

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Calibrator Levels (pg/mL)

A	0.000
B	0.752
C	1.90
D	3.88
E	8.62
F	24.6
G	52.9
H	124