

Product Number:	101995
Lot Number:	501651
Expiration:	22-Jan-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	903807
Detector Reagent	101996	903901
SBG Reagent (HD-1)	102000	902802
Sample Diluent	102002	902803
Calibrators	103221	903702/904203
Controls	103222/103223	903703
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	903703	1.18	0.922-1.38
Control 2	903703	50.3	35.8-53.7
Panel 1	MF-062018-04	1.49	1.16-2.04
Panel 2	MF-010818-02	215	156-234
Panel 3	MF-010818-03	3.83	1.30-5.98

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	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	903703	4.12	3.60-5.43
Control 2	903703	86.7	67.3-101
Panel 1	MF-062018-04	6.70	5.28-7.92
Panel 2	MF-010818-02	8.90	7.07-10.7
Panel 3	MF-010818-03	134	96.1-150

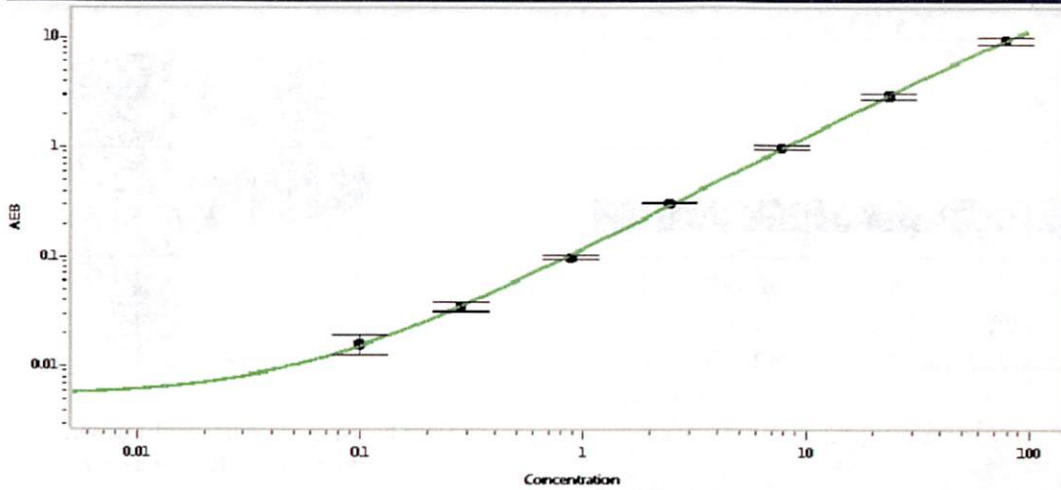
Abeta 40

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	903703	15.7	12.9-20.9
Control 2	903703	245	182-273
Panel 1	MF-062018-04	129	102-158
Panel 2	MF-010818-02	150	107-200
Panel 3	MF-010818-03	98.9	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	<i>P. Stadler</i> 19 Feb 2019
	Name Title	Signature/Date

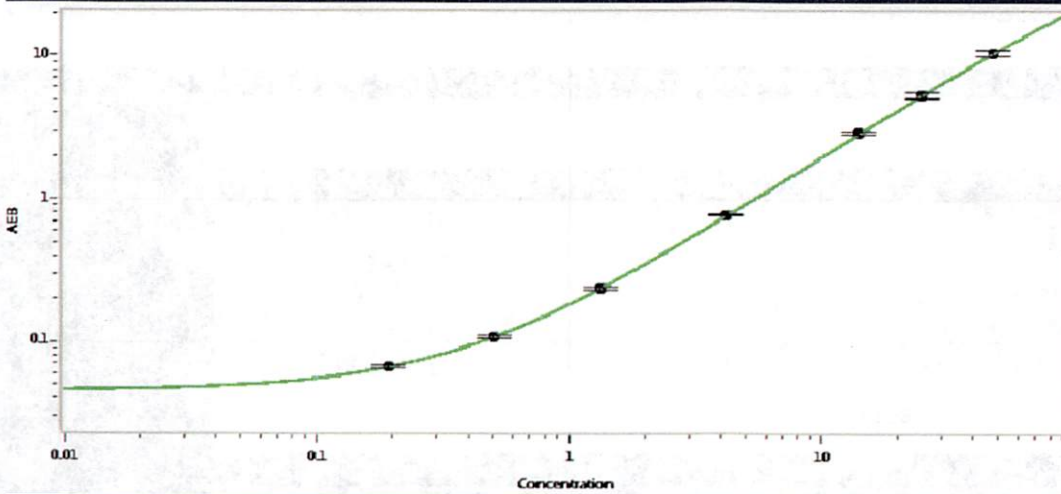
Tau Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.100
C	0.283
D	0.886
E	2.44
F	7.82
G	23.8
H	79.0

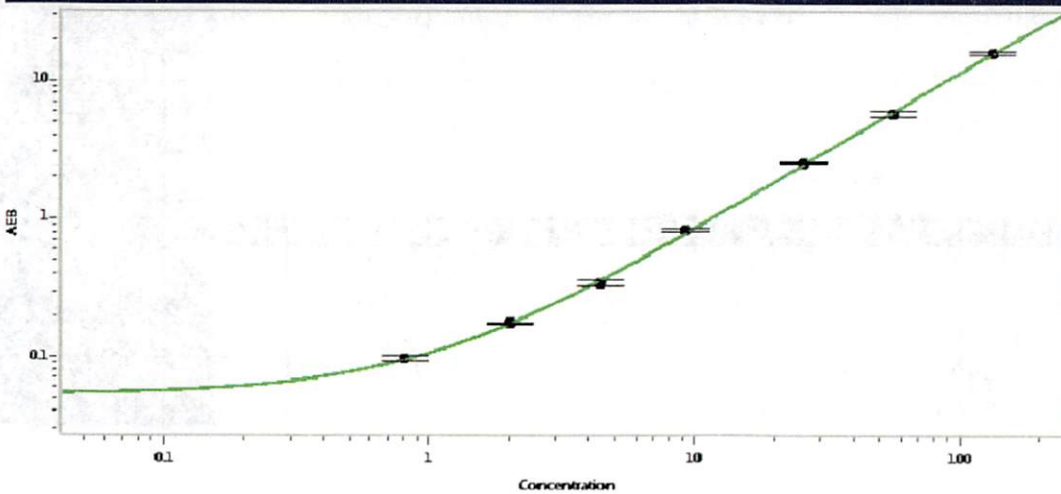
Abeta 42



Calibrator Levels (pg/mL)

A	0.000
B	0.194
C	0.507
D	1.34
E	4.20
F	14.1
G	25.1
H	47.9

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Calibrator Levels (pg/mL)

A	0.000
B	0.814
C	2.04
D	4.45
E	9.27
F	25.9
G	56.1
H	133