

Product Number:	101995
Lot Number:	501543
Expiration:	21-Sep-2019
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	832312
Detector Reagent	101996	832313
SBG Reagent	102000	826412
Sample Diluent	102002	826503
Calibrators	103221	820001
Controls	103222-103223	834609
SBG Diluent (SR-X)†	103158	N/A ¹
RGP Reagent	103159	N/A ¹

¹ Reagents are not Kit Lot Specific

† Specific for use on the SR-X platform - refer to the SR-X Kit Instructions (KI-0083).

Release Materials

Tau

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	834609	2.11	1.58-2.37
Control 2	834609	90.2	66.6-99.9
Panel 1	MF-062018-04	1.72	1.29-2.00
Panel 2	MF-010818-02	170	156-234
Panel 3	MF-010818-03	4.23	1.30-5.98

Abeta 42

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	834609	4.96	3.21-6.66
Control 2	834609	112	86.4-132
Panel 1	MF-062018-04	5.71	5.28-7.93
Panel 2	MF-010818-02	8.94	7.07-10.7
Panel 3	MF-010818-03	109	96.1-150

Abeta 40

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	834609	15.1	10.8-16.2
Control 2	834609	237	170-255
Panel 1	MF-062018-04	128	106-159
Panel 2	MF-010818-02	154	107-200
Panel 3	MF-010818-03	100	71.5-124

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

Review/Approval

Bud Drummey

Senior Director,
Manufacturing
Operations

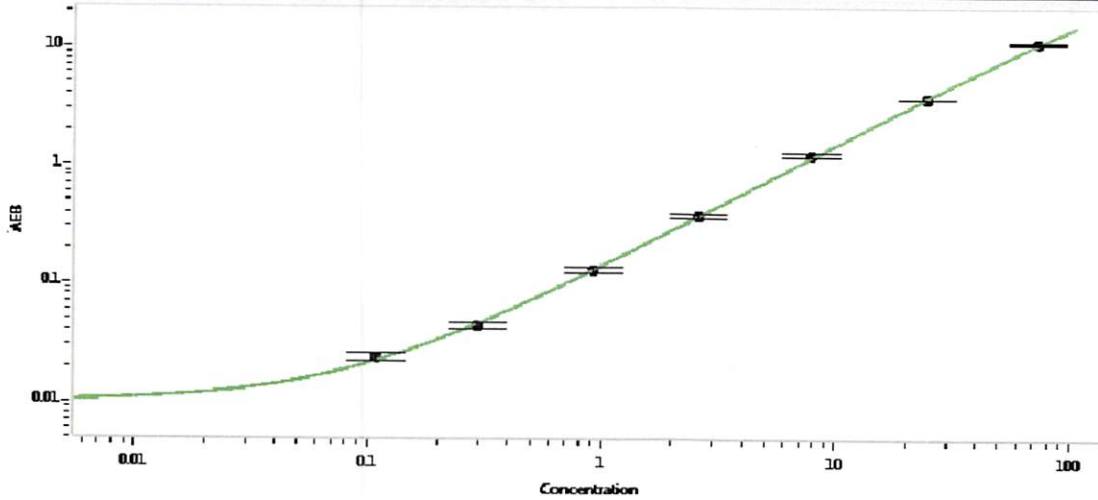
[Signature]
31-Dec-2018

Name

Title

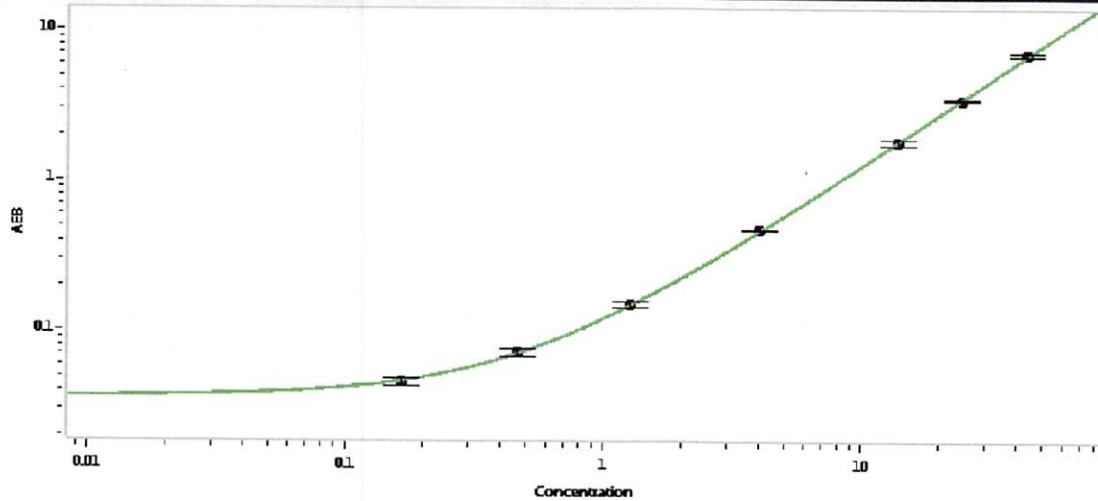
Signature/Date

Tau Calibration Curve



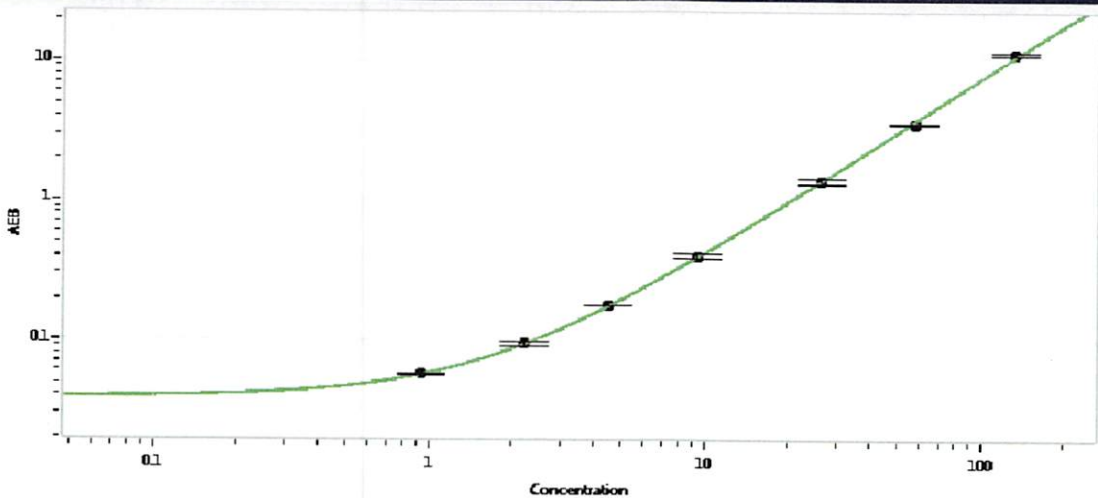
Calibrator Levels (pg/mL)	
A	0.000
B	0.109
C	0.294
D	0.919
E	2.59
F	7.88
G	24.7
H	73.5

Abeta 42 Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.165
C	0.462
D	1.27
E	4.03
F	13.7
G	24.2
H	43.1

Abeta 40 Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.938
C	2.22
D	4.48
E	9.43
F	26.3
G	57.3
H	133