

Product Number:	101995
Lot Number:	501985
Expiration:	6-May-2020
Platform(s):	HD-1/HD-X & 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	915601 & 916501
Controls	103222/103223	915602
SBG Diluent (SRX)†	103158	N/A ¹
RGP Reagent	103159	N/A ¹

¹ RGP is not Kit Lot Specific

† Specific for use on the SR-X platform - refer to the Simoa™ Neuro 3-Plex A SR-X Kit Instructions (KI-0083).

Release Materials

Tau

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	915602	1.63	1.32-1.99
Control 2	915602	62.8	55.4-83.1
Panel 1	MF-062018-04	1.46	1.18-2.03
Panel 2	MF-010818-02	181	156-234
Panel 3	MF-010818-03	3.77	1.30-5.98

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	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	915602	4.63	4.07-6.10
Control 2	915602	104	94.6-148
Panel 1	MF-062018-04	6.92	5.32-7.98
Panel 2	MF-010818-02	10.4	7.07-10.7
Panel 3	MF-010818-03	123	96.1-150

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	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	915602	11.9	11.0-16.5
Control 2	915602	207	184-275
Panel 1	MF-062018-04	111	104-159
Panel 2	MF-010818-02	144	107-200
Panel 3	MF-010818-03	88.8	71.5-124

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

Review/Approval

Daniel Ritchie QC Senior Analyst

Daniel Ritchie / 23 Aug 2019

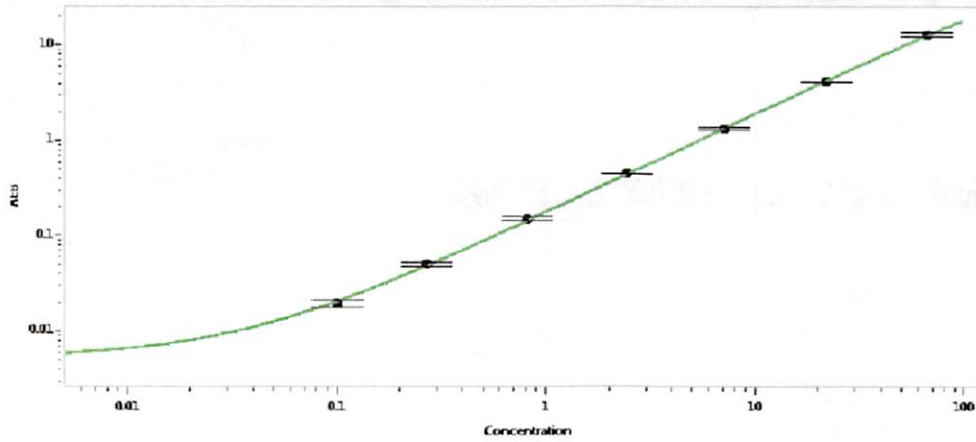
Name

Title

Signature/Date

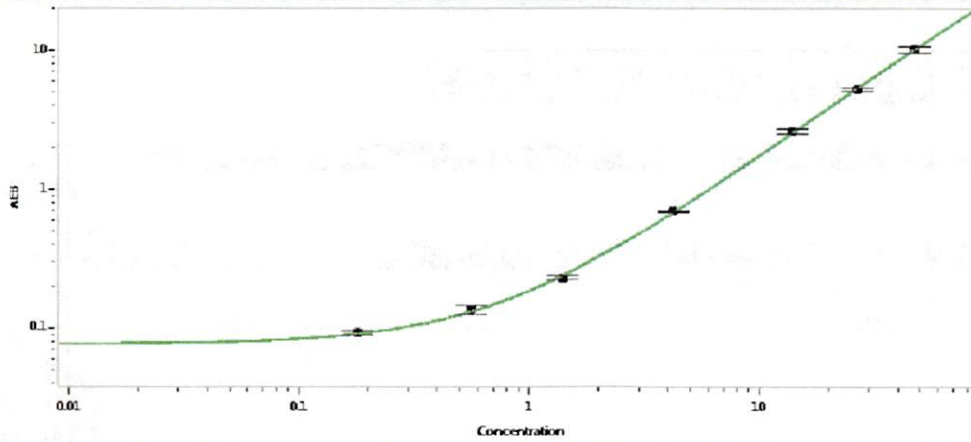
*Signing on behalf of Patrizia Stadler

Tau Calibration Curve



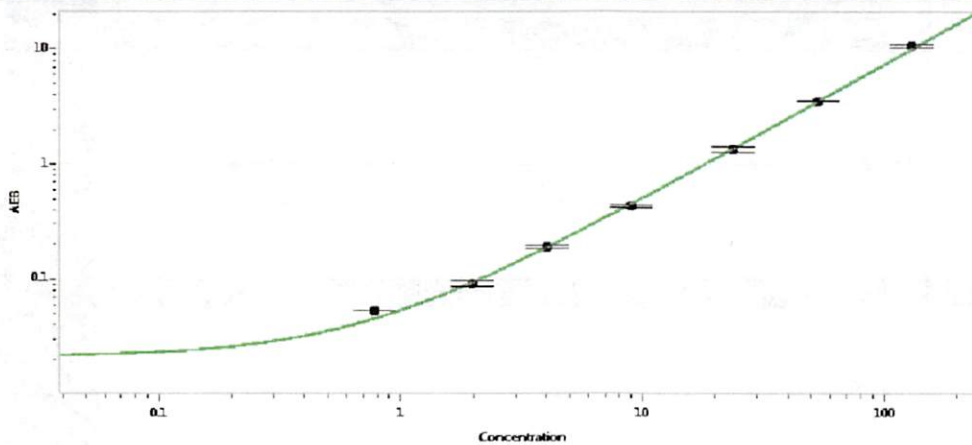
Calibrator Levels (pg/mL)	
A	0.000
B	0.100
C	0.270
D	0.814
E	2.42
F	7.17
G	21.9
H	66.3

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Calibrator Levels (pg/mL)	
A	0.000
B	0.180
C	0.555
D	1.40
E	4.22
F	14.0
G	26.5
H	46.7

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Calibrator Levels (pg/mL)	
A	0.000
B	0.777
C	1.99
D	4.07
E	9.02
F	23.6
G	53.4
H	130