

Product Number:	102153
Lot Number:	501993
Expiration:	19-Feb-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	102141	922801
Detector Reagent	102143	922803
SBG Reagent	102145	908107
Sample Diluent	102147	905012
Calibrators	102150	920401
Controls	102151-102152	920402
SBG Diluent (SR-X)†	103158	N/A <sup>1</sup>
RGP Reagent	103159	N/A <sup>1</sup>

<sup>1</sup> RGP is not Kit Lot Specific

† Specific for use on the SR-X platform - refer to the Simoa™ Neuro 4-Plex A SR-X Kit Instructions (KI-0031).

**Release Materials**

**Tau**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	920402	1.28	1.10-1.71
Control 2	920402	74.5	57.1-85.6
Panel 1	MF-101617-01	0.901	0.605-1.92
Panel 2	MF-101617-02	29.5	22.7-44.5
Panel 3	MF-101617-03	130	96.8-194

**NF-light®**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	920402	5.10	4.23-6.34
Control 2	920402	482	371-556
Panel 1	MF-101617-01	4.82	3.08-6.38
Panel 2	MF-101617-02	37.1	16.7-50.4
Panel 3	MF-101617-03	408	234-541

**GFAP®**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	920402	19.8	16.5-24.7
Control 2	920402	1080	809-1213
Panel 1	MF-101617-01	49.8	40.9-62.1
Panel 2	MF-101617-02	203	111-227
Panel 3	MF-101617-03	2622	2085-3303

**UCHL1®**

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	920402	100	78.3-138
Control 2	920402	10314	7808-11713
Panel 1	MF-101617-01	72.3	42.9-87.8
Panel 2	MF-101617-02	437	249-503
Panel 3	MF-101617-03	5674	4232-6348

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

Review/Approval

Patrizia Stadler Assoc. Director, QC

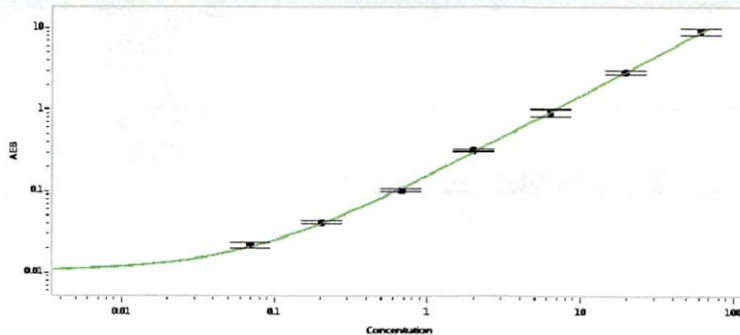
Name

Title

*P. Stadler* 28 Aug 2019

Signature/Date

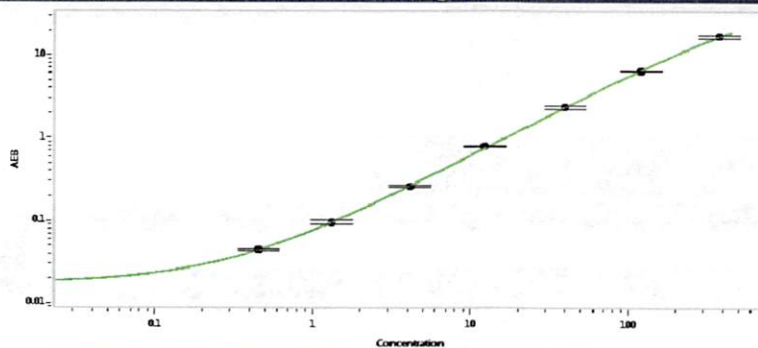
**Tau Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.070
C	0.204
D	0.679
E	1.99
F	6.34
G	19.7
H	61.3

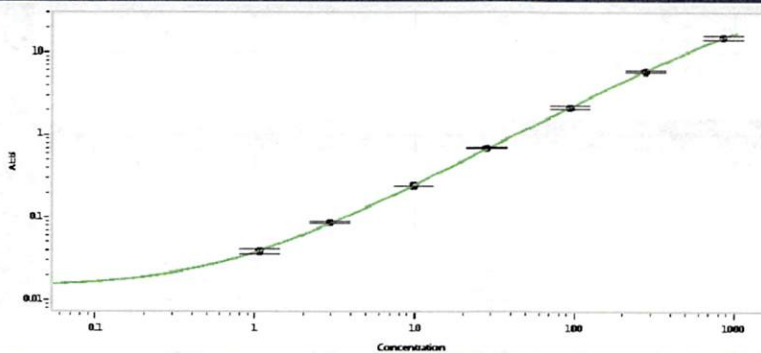
**NF-light® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	0.455
C	1.31
D	4.12
E	12.2
F	40.0
G	120
H	376

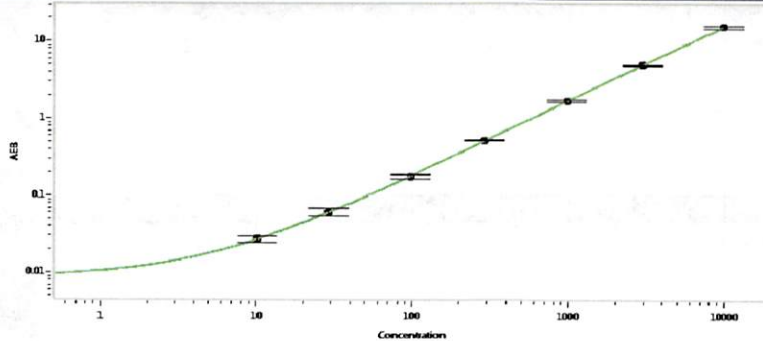
**GFAP® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	1.06
C	2.93
D	9.77
E	28.2
F	93.6
G	277
H	855

**UCHL1® Calibration Curve**



**Calibrator Levels (pg/mL)**

A	0.000
B	10.1
C	28.9
D	97.8
E	288
F	981
G	2981
H	9782