

Product Number:	100988
Lot Number:	502092
Expiration:	14-Mar-2020
Platform(s):	HD-1/HD-x



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

Component	Part Number	Lot Number
Bead Reagent	100974	910009
Detector Reagent	100976	908007
SBG Reagent	100987	908006
Sample Diluent	100985	907306
Calibrator Diluent	100980	908926
Calibrator Concentrate	100978	828407
RGP Reagent	103159	N/A <sup>1</sup>

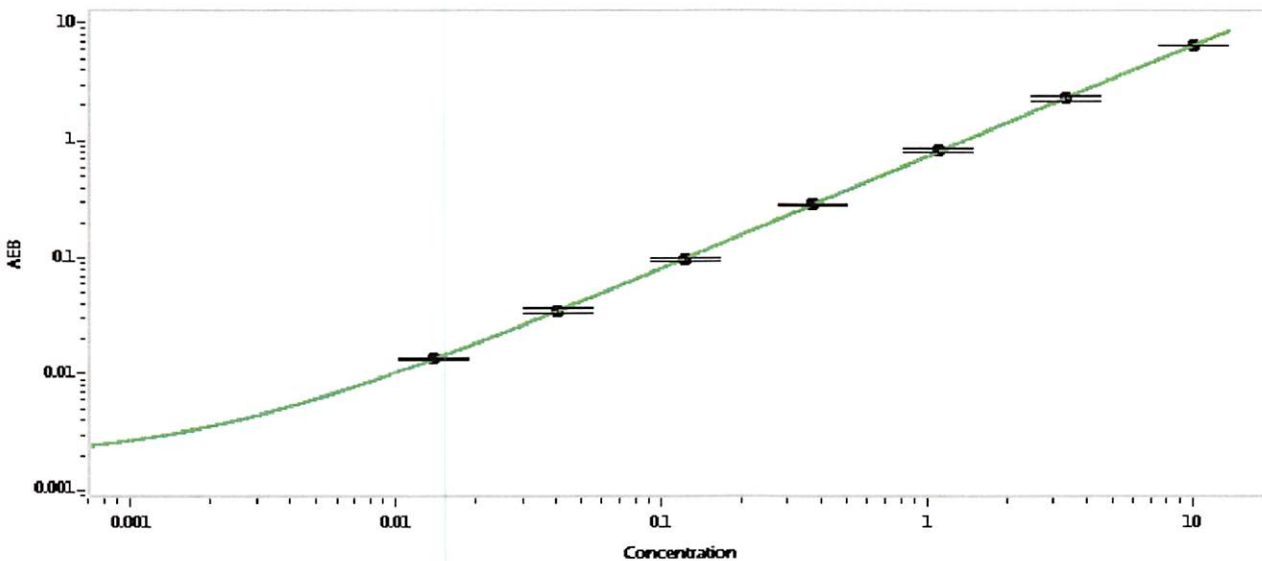
<sup>1</sup> RGP is not Kit Lot Specific

Release Materials*			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	MF-101816-02	0.117	0.068-0.161
Control 2	MF-101816-02	10.2	7.32-11.2
Panel 1	MF-101716-04	0.287	0.167-0.327
Panel 2	MF-101716-05	0.073	0.021-0.087
Panel 3	MF-101816-03	22.0	15.6-23.9
Panel 4	MF-050118-01	0.250	0.150-0.293

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

Calibrator Concentrate Value Assignment (pg/mL)	243
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Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.014
C	0.041
D	0.123
E	0.370
F	1.11
G	3.33
H	10.0

Review/Approval: Patrizia Stadler Assoc. Director, QC      P. Stadler 08 Nov 2019

Name: Patrizia Stadler      Title: Assoc. Director, QC      Signature/Date: P. Stadler 08 Nov 2019