

Product Number:	100988
Lot Number:	501773
Expiration:	21-Dec-2019
Platform(s):	HD-1



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	835508
Calibrator Concentrate	100978	828407
RGP Reagent	103159	N/A <sup>1</sup>

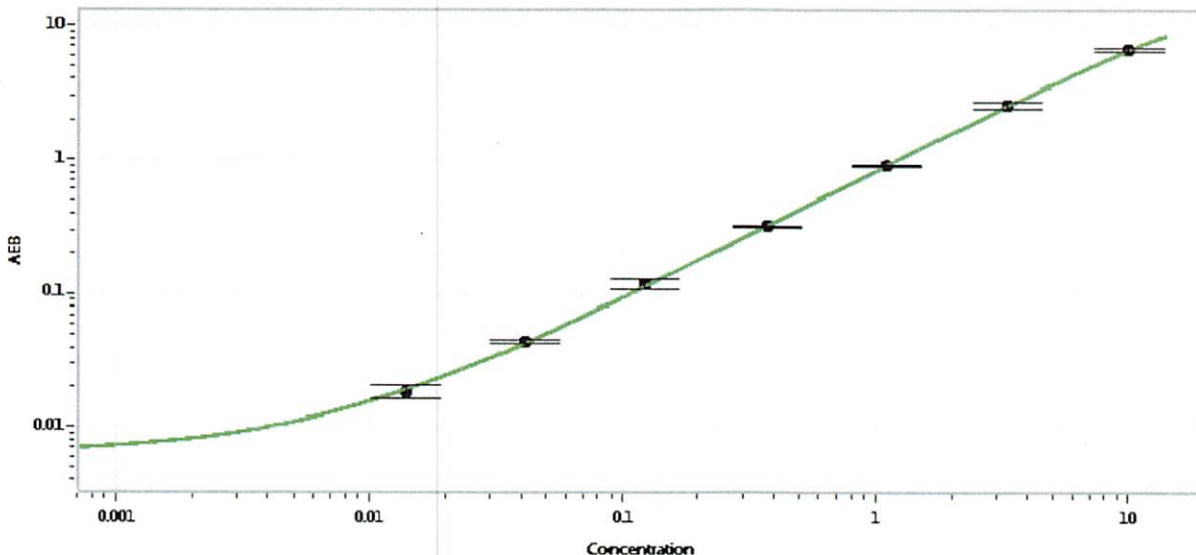
<sup>1</sup> RGP is not Kit Lot Specific

Release Materials*			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	MF-101816-02	0.112	0.066-0.163
Control 2	MF-101816-02	9.40	7.28-11.0
Panel 1	MF-101716-04	0.259	0.167-0.317
Panel 2	MF-101716-05	0.053	0.022-0.081
Panel 3	MF-101816-03	20.3	15.6-23.4
Panel 4	MF-050118-01	0.214	0.148-0.287

\* 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  
Name Title

*P. Stadler* 17 Apr 2019  
Signature/Date