

Product Number:	103337
Lot Number:	502162
Expiration:	7-Oct-2020
Platform(s):	HD-1/HD-X & SR-X



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

Component	Item Number	Lot Number
Bead Reagent	103334	928409
Detector Reagent	101091	929011
SBG Reagent	101101	934407
Sample Diluent	103336	928308
Calibrator Diluent	101095	928020
Calibrator Concentrate	101093	906801
RGP Reagent	103159	N/A <sup>1</sup>

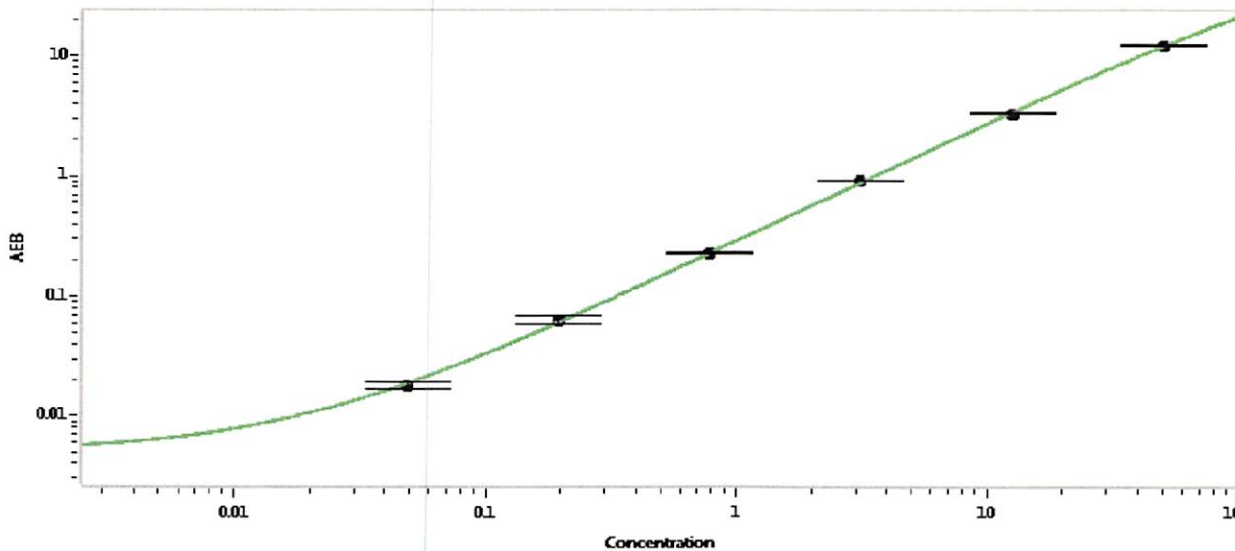
<sup>1</sup> RGP is not Kit Lot Specific

Release Materials*			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	911603	1.42	1.22-1.83
Control 2	911603	27.2	22.8-34.2
Panel 1	MF-033018-03	2.80	2.51-3.76
Panel 2	MF-033018-04	4.95	4.20-6.96
Panel 3	MF-033018-05	47.4	44.1-66.1

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

Calibrator Concentrate Value Assignment (pg/mL)	1,325
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Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.049
C	0.195
D	0.781
E	3.13
F	12.5
G	50.0

Review/Approval

Patrizia Stadler Assoc. Director, QC

*P. Stadler* 12 DEC 2019

Name Title Signature/Date