

Product Number:	103789
Lot Number:	502863
Expiration:	6-Oct-2021
Platform(s):	HD-X



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

Component	Part Number	Lot Number
Bead Reagent	103776	110106
Detector Reagent	103778	110109
SBG Reagent	103780	110111
Sample Diluent	103782	110113
Calibrators	103786	109609
Control 1	103787	109610
Control 2	103788	109610
Control 3	103809	110211
RGP Reagent	103844	N/A ¹

¹ RGP is not Kit Lot Specific

Release Materials*				* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.
Sample	Lot	Result (pg/mL)	Mean Range (pg/mL)	
Control 1	109610	6.03	4.10-6.81	
Control 2	109610	128	96.0-166	
Control 3	110211	0.118	< 3.00	
Sample	Lot	Bridging Result	Kit Release Result	Pass/ Fail
Panel 1	104301	Negative	Negative	PASS
Panel 2	104302	Negative	Negative	PASS
Panel 3	104303	Negative	Negative	PASS
Panel 4	104304	Negative	Negative	PASS
Panel 5	104305	Negative	Negative	PASS
Panel 6	104306	Positive	Positive	PASS
Panel 7	104307	Positive	Positive	PASS
Panel 8	104308	Positive	Positive	PASS
Panel 9	104309	Positive	Positive	PASS
Panel 10	104310	Positive	Positive	PASS
Panel 11	104311	Positive	Positive	PASS
Panel 12	104312	Positive	Positive	PASS
Panel 13	104313	Positive	Positive	PASS
Panel 14	104314	Positive	Positive	PASS

Review/Approval

Junpil Park
Name

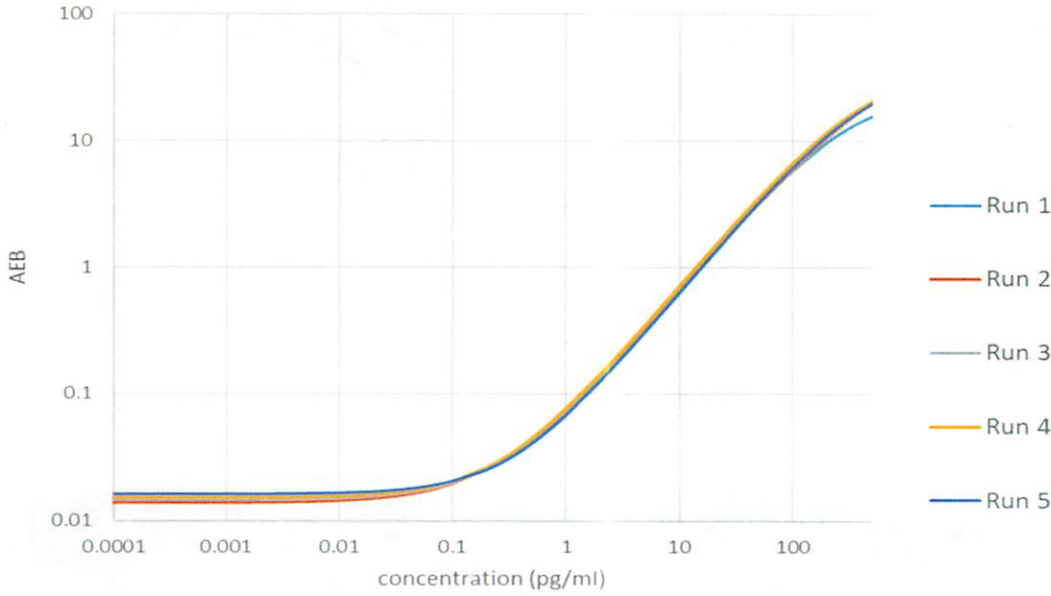
QC Supervisor
Title


Signature/Date

24 May 2021

Calibration Curve

Curve QC



Calibrator Levels
(pg/mL)

A	0.000
B	0.250
C	0.632
D	1.97
E	5.79
F	17.3
G	51.8
H	190