

Product Number:	103789
Lot Number:	502961
Expiration:	23-Nov-2021
Platform(s):	HD-X

Component	Part Number	Lot Number
Bead Reagent	103776	114405
Detector Reagent	103778	114308
SBG Reagent	103780	114407
Sample Diluent	103782	114409
Calibrators	103786	114505
Control 1	103787	114506
Control 2	103788	114506
Control 3	103809	114508
RGP Reagent	103844	N/A ¹



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

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	114506	7.57	4.91-9.51	
Control 2	114506	144	90.6-187	
Control 3	114508	0.067	< 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

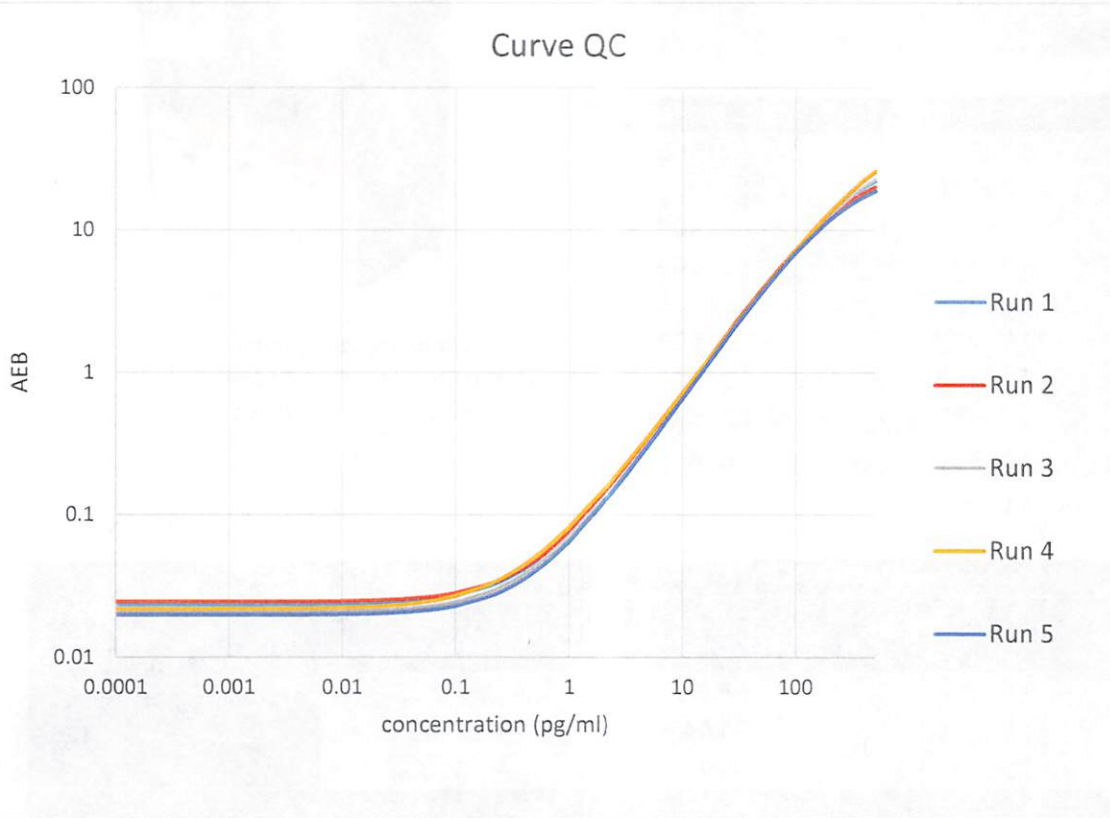
Review/Approval

Junpil Park
Name

QC Supervisor
Title

 30 Jun 2021
Signature/Date

Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.301
C	0.762
D	2.38
E	6.98
F	17.4
G	52.0
H	191