

Product Number:	103769
Lot Number:	502437
Expiration:	22-Dec-2020
Platform(s):	HD-X



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

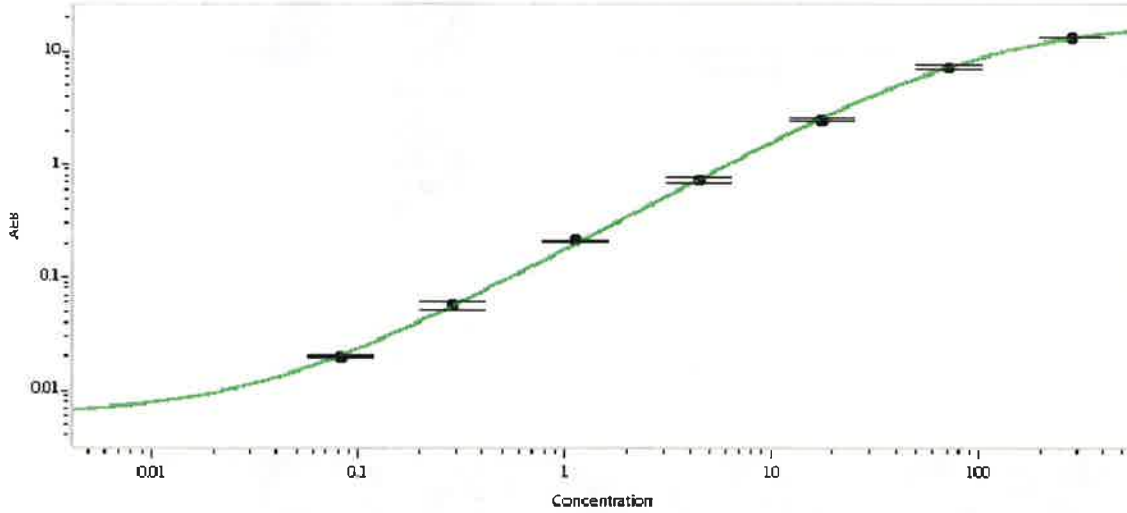
Component	Part Number	Lot Number
Bead Reagent	103758	019106
Detector Reagent	103760	017703
SBG Reagent	103762	017701
Sample Diluent	103763	017405
Calibrators	103766	017602
Control 1	103767	017603
Control 2	103768	017603
Control 3	103773	017603
RGP Reagent	103159	N/A ¹

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 (ng/mL)	Mean Range (ng/mL)	
Control 1	017603	417	234-584	
Control 2	017603	3830	2553-4367	
Control 3	017603	18330	16129-24193	
Sample	Lot	Result (ng/mL)	Cut-Off	Pass/ Fail
Positive Panel 1	016209	0.835	≥ 0.77	Pass
Positive Panel 2	016209	1.17		Pass
Positive Panel 3	016209	0.964		Pass
Positive Panel 4	016209	2.11		Pass
Positive Panel 5	016209	5.95		Pass
Positive Panel 6	016209	10.0		Pass
Positive Panel 7	016209	30.0		Pass
Positive Panel 8	016209	5.13		Pass
Positive Panel 9	013323	29.4		Pass
Positive Panel 10	013324	6.38		Pass
Negative Panel 1	016209	0.089	< 0.77	Pass
Negative Panel 2	016209	0.033		Pass
Negative Panel 3	016209	0.064		Pass
Negative Panel 4	016209	0.067		Pass
Negative Panel 5	016209	0.101		Pass
Negative Panel 6	016209	0.020		Pass
Negative Panel 7	016209	0.039		Pass
Negative Panel 8	016209	0.308		Pass
Negative Panel 9	016209	0.094		Pass
Negative Panel 10	016209	0.189		Pass

Review/Approval	Shivani Goel	QC Manager	Shivani Goel 21 Aug 2020
	Name	Title	Signature/Date

Calibration Curve



Calibrator Levels
(ng/mL)

A	0.000
B	0.082
C	0.287
D	1.11
E	4.39
F	17.5
G	69.9
H	280