

Product Number:	103769	
Lot Number:	503973	
Expiration Date:	8-Sep-24	
Platform(s):	HD-X	
<b>Component</b>	<b>Part Number</b>	<b>Lot Number</b>
Bead Reagent	103758	325102
Detector Reagent	103760	326906
SBG Reagent	103762	326907
Sample Diluent	103763	329621
Calibrators	103766	333503
Control 1	103767	333504
Control 2	103768	333504
Control 3	103773	333504
RGP Reagent	103159	N/A <sup>1</sup>



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

<sup>1</sup> Reagents are not Kit Lot Specific

Release Materials*				
	Lot	Result (ng/mL)	Mean Low Limit (ng/mL)	Mean High Limit (ng/mL)
Control 1	333504	260	220	331
Control 2	333504	2818	2451	3677
Control 3	333504	13891	10186	18892
	Lot	Result (ng/mL)	Mean Low Limit (ng/mL)	Mean High Limit (ng/mL)
Panel 1	319505	99.3	60.4	123
Panel 2	312101	92.0	60.2	122
Panel 3	312101	62.5	31.7	77.5
Panel 4	312101	42.5	29.8	44.7
Panel 5	312101	22.7	16.9	25.3
Panel 6	325503	8.74	7.25	10.9
Panel 7	312101	7.45	5.54	8.53
Panel 8	312101	5.06	4.06	6.09
Panel 9	312101	3.40	2.75	4.13
Panel 10	312101	2.31	1.94	2.92
Panel 11	312101	1.55	1.33	2.00
Panel 12	312101	1.05	0.840	1.26
Panel 13	312101	0.883	0.268	1.61
Panel 14	312101	0.612	0.524	0.844
Panel 15	312101	0.513	0.436	0.655
Panel 16	312101	0.376	0.336	0.504
Panel 17	312101	0.447	0.214	0.688
Panel 18	312101	0.014		
Panel 19	312101	0.040		
Panel 20	312101	0.074		

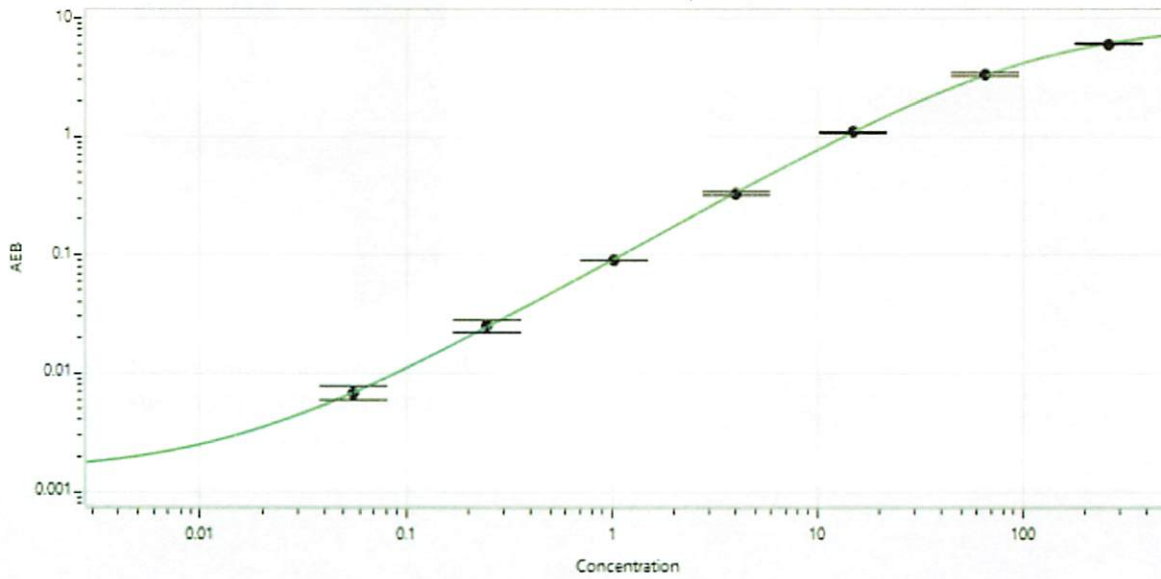
\* Ranges shown are generated internally for new lot release only. Customer should generate their own control ranges.

Review/Approval

Cody Carlson QC Manager  
Name Title

*[Signature]* 13 Dec 2023  
Signature/Date

Calibrator Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.055
C	0.247
D	1.02
E	3.99
F	15.0
G	65.0
H	263