

Product Number:	103769
Lot Number:	503844α
Expiration:	15-Mar-2024
Platform(s):	HD-X



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

Component	Part Number	Lot Number	Control Lot Number
Bead Reagent	103758	307417	N/A
Detector Reagent	103760	307514	N/A
SBG Reagent	103762	318709	318709A
Sample Diluent	103763	329621	N/A
Calibrators	103766	318711	318711A
Control 1	103767	318712	318712A
Control 2	103768	318712	318712A
Control 3	103773	318712	318712A
RGP Reagent	103159	N/A <sup>1</sup>	N/A <sup>1</sup>

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

Release Materials*				
Sample	Lot	Result (ng/mL)	Mean Low limit (ng/mL)	Mean High Limit (ng/mL)
Control 1	318712A	72.6	47.2	117
Control 2	318712A	3133	2027	3293
Control 3	318712A	14466	7712	18355

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

Sample	Lot	Result (ng/mL)	Mean Low limit (ng/mL)	Mean High Limit (ng/mL)
Panel 1	319505A	103	60.4	123
Panel 2	312101	85.0	60.2	122
Panel 3	312101	63.5	31.7	77.5
Panel 4	312101	41.6	29.8	44.7
Panel 5	312101	21.1	16.9	25.3
Panel 6	325503	9.21	7.3	10.9
Panel 7	312101	7.46	5.54	8.53
Panel 8	312101	5.32	4.06	6.09
Panel 9	312101	3.51	2.75	4.13
Panel 10	312101	2.12	1.94	2.92
Panel 11	312101	1.68	1.33	2.00
Panel 12	312101	1.05	0.840	1.26
Panel 13	312101	0.685	0.268	1.61
Panel 14	312101	0.592	0.524	0.844
Panel 15	312101	0.530	0.436	0.655
Panel 16	312101	0.384	0.336	0.504
Panel 17	312101	0.504	0.214	0.688
Panel 18	312101	0.0121		
Panel 19	312101	0.0319		
Panel 20	312101	0.0634		

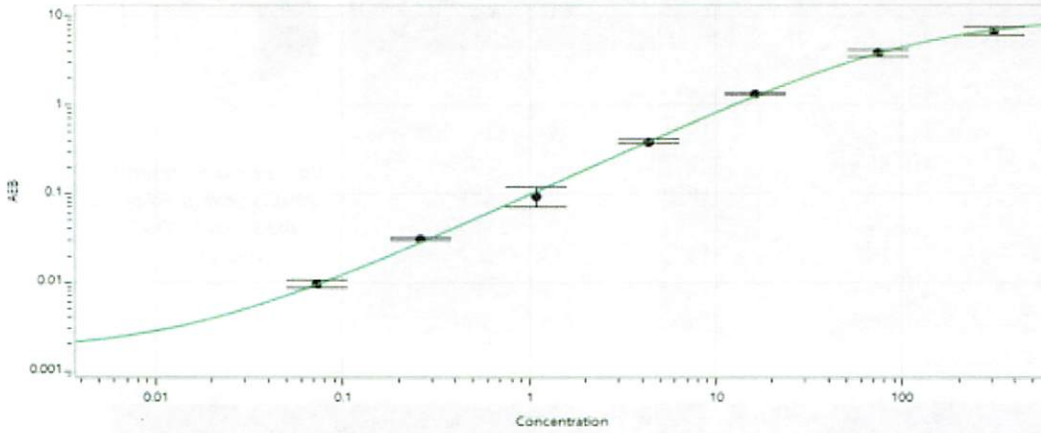
Review/Approval

Sonia Khillan QC  
Name Title

Sonia Della 14 NOV 2023  
Signature/Date



Calibration Curve



**Calibrator Levels  
(ng/mL)**

<b>A</b>	0.000
<b>B</b>	0.073
<b>C</b>	0.259
<b>D</b>	1.09
<b>E</b>	4.33
<b>F</b>	16.3
<b>G</b>	74.2
<b>H</b>	307