

Product Number:	103293
Lot Number:	502284
Expiration:	4-Dec-2020
Platform(s):	HD-1/HD-x & SR-X



Data below represents results generated on the Simoa™ HD-1 Analyzer.

Component	Part Number	Lot Number
Bead Reagent	103281	007207
Detector Reagent	103283	007204
SBG Reagent	103285	006906
Sample Diluent	103286	005221
Calibrators Diluent	103288	006517
Calibrator Concentrate	103287	833803
SBG Diluent (SR-X)†	103158	N/A <sup>1</sup>
RGP Reagent	103159	N/A <sup>1</sup>

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

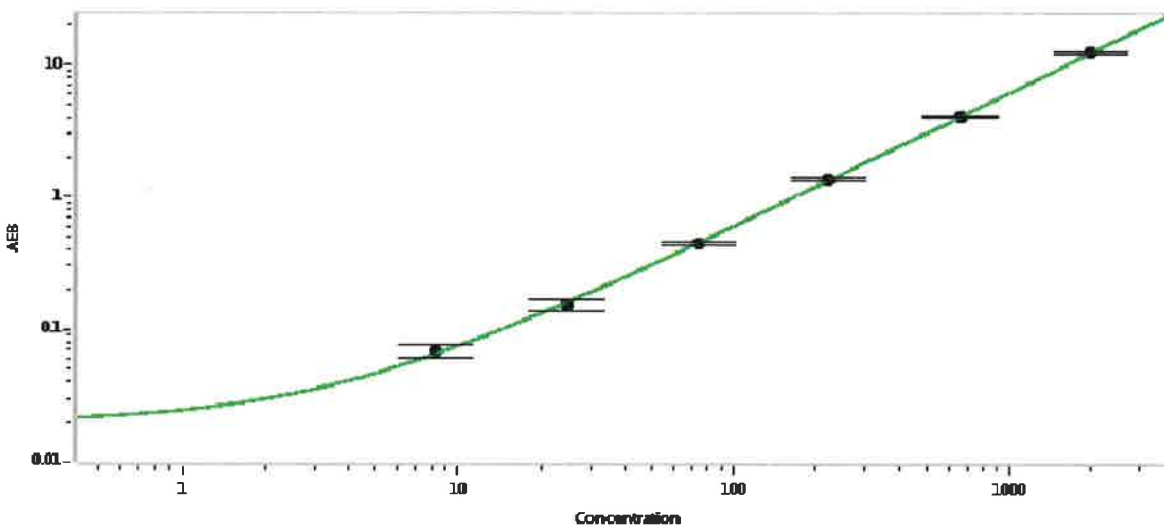
† Specific for use on the SR-X platform - refer to the Simoa™ TDP-43 SR-X Kit Instructions (KI-0132).

Release Materials*			
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	834401	191	166-249
Control 2	830401	1689	1319-1978
Panel 1	831201	34.8	24.5-73.9
Panel 2	831202	49.5	41.3-94.5
Panel 3	832006	298	203-340
Panel 4	832007	1566	1142-1746

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

Calibrator Concentrate Value Assignment (pg/mL) 34,946 pg/mL

Calibration Curve



Calibrator Levels (pg/mL)
A 0.000
B 8.23
C 24.7
D 74.1
E 222
F 667
G 2000

Review/Approval: Patrizia Stadler, Assoc. Director, QC. Signature: P. Stadler, Date: 19 Mar 2020