

Product Number:	101160
Lot Number:	502324
Expiration:	25-Nov-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 †	101263	010201
Detector Reagent	101264	011509
SBG Reagent	101296	932911
Sample Diluent	103329	932908
Calibrators	103228	005801
Controls	103229-103230	005802
SBG Diluent (SR-X)††	103158	N/A ¹
RGP Reagent	103159	N/A ¹

† Follow the Simoa™ Cytokine 3-Plex A Advantage Kit Instructions (KI-0011 - HD1/KI-0101 - SR-X) to prepare the Bead Reagent.

†† Specific for use on the SR-X platform - refer to the Simoa™ Cytokine 3-Plex A SR-X Kit Instructions (KI-0101).

¹ Reagents are not Kit Lot Specific

Release Materials

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	005802	0.837	0.661-0.991
Control 2	005802	21.1	14.1-27.3
Panel 2	MF-062818-02	1.06	0.777-1.17
Panel 3	MF-062818-03	1.74	1.37-2.06
Panel 4	MF-062818-04	13.8	10.4-15.7

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	005802	0.444	0.369-0.710
Control 2	005802	15.0	9.28-16.0
Panel 2	MF-062818-02	15.5	9.23-16.5
Panel 3	MF-062818-03	0.958	0.302-1.18
Panel 4	MF-062818-04	1.60	0.908-1.69

TNFα

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	005802	2.04	1.63-2.44
Control 2	005802	49.8	39.2-58.9
Panel 2	MF-062818-02	2.15	1.54-2.41
Panel 3	MF-062818-03	45.1	31.9-47.8
Panel 4	MF-062818-04	7.93	5.51-8.26

Ranges shown are generated internally for new lot release only.

Customer should generate their own control ranges.

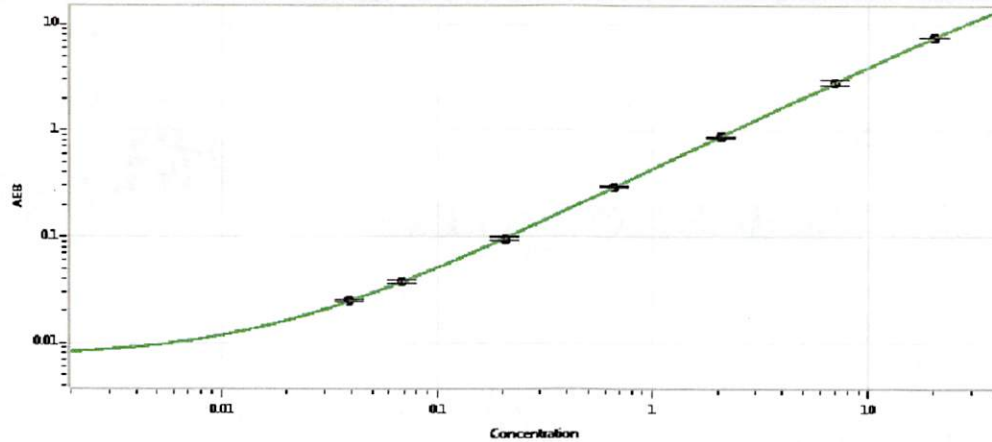
Review/Approval

Shivani Goel
Name

QC Manager
Title

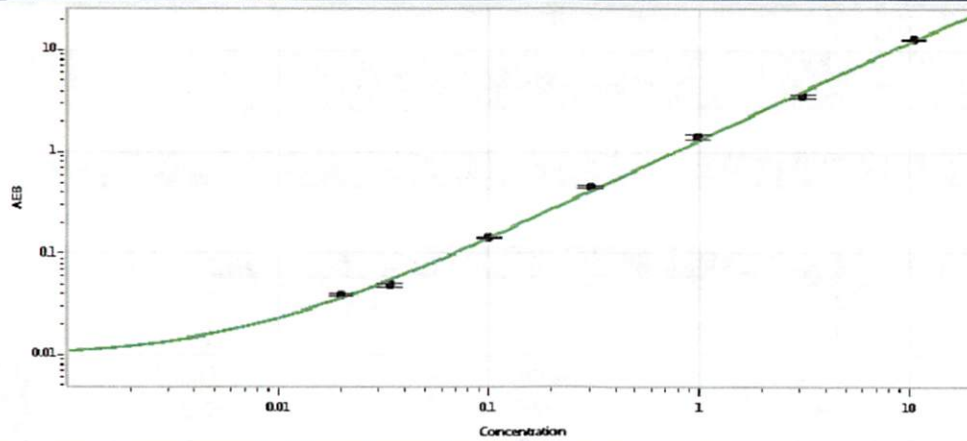
Shivani Goel 06 May 2020
Signature/Date

IL-6 Calibration Curve



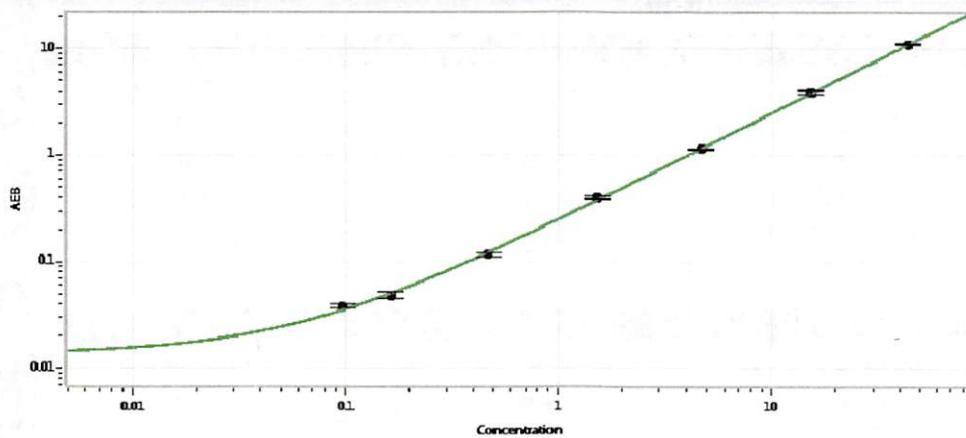
Calibrator Levels (pg/mL)	
A	0.000
B	0.039
C	0.068
D	0.206
E	0.659
F	2.06
G	6.97
H	20.3

IL-10 Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.020
C	0.034
D	0.101
E	0.307
F	0.985
G	3.12
H	10.5

TNFα Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.097
C	0.163
D	0.468
E	1.51
F	4.69
G	15.3
H	44.0