

Product Number:	102958
Lot Number:	502304
Expiration:	12-Feb-2021
Platform(s):	HD-X and SR-X

Component	Part Number	Lot Number
Bead Reagent	102949	008405
Detector Reagent	102951	008401
SBG Reagent	102953	005503
Sample Diluent	102954	005501
Calibrators	102960	929405
Controls	102961 & 102962	929406
RGP Reagent	103159	N/A ¹

¹ Reagents are not Kit Lot Specific



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

Review/Approval	<u>Patrizia Stadler</u>	<u>Assoc. Director, QC</u>	<u><i>P. Stadler</i></u>	<u>02 Apr 2020</u>
	Name	Title	Signature/Date	

Release Materials

IFN γ

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	2.11	1.01-2.58
Control 2	929406	55.3	28.8-62.2
Panel 1	927401	0.225	0.154-0.440
Panel 2	927703	22.4	13.8-28.6
Panel 3	927704	69.2	46.9-90.3

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.60	1.10-1.72
Control 2	929406	37.5	29.2-43.8
Panel 1	927401	5.05	3.87-5.80
Panel 2	927703	13.3	10.0-14.9
Panel 3	927704	45.5	32.3-56.5

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.11	0.700-1.27
Control 2	929406	18.6	16.8-26.7
Panel 1	927401	1.09	0.207-1.29
Panel 2	927703	12.3	6.20-14.0
Panel 3	927704	37.6	17.8-45.3

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.07	0.813-1.22
Control 2	929406	22.5	17.8-26.7
Panel 1	927401	0.236	0.161-0.287
Panel 2	927703	6.56	5.00-7.62
Panel 3	927704	21.2	17.6-26.4

IL-17A

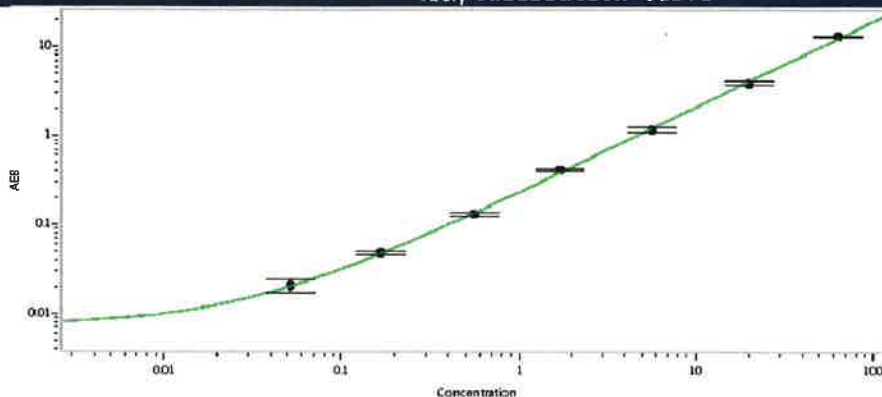
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	0.418	0.305-0.516
Control 2	929406	12.6	10.3-15.4
Panel 1	927401	0.124	0.085-0.196
Panel 2	927703	7.02	5.47-8.45
Panel 3	927704	20.6	16.9-25.4

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	0.947	0.809-1.32
Control 2	929406	45.3	34.8-52.2
Panel 1	927401	2.15	1.65-2.65
Panel 2	927703	10.2	7.22-11.6
Panel 3	927704	45.5	29.4-55.2

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

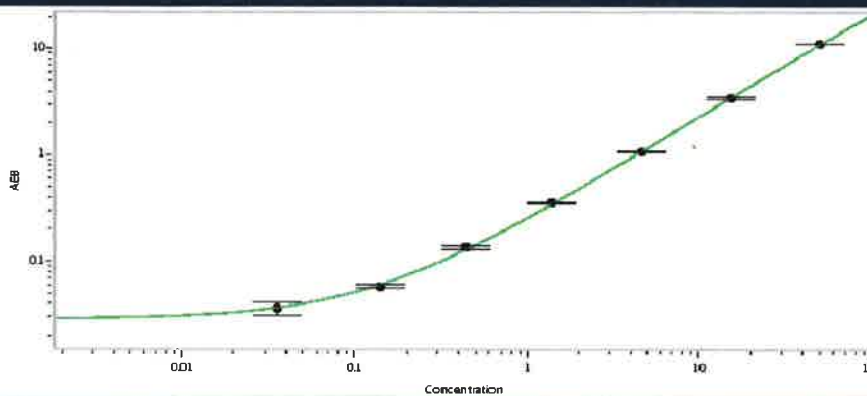
IFN γ Calibration Curve



Calibrator Levels
(pg/mL)

A	0.000
B	0.052
C	0.165
D	0.566
E	1.70
F	5.75
G	20.1
H	63.4

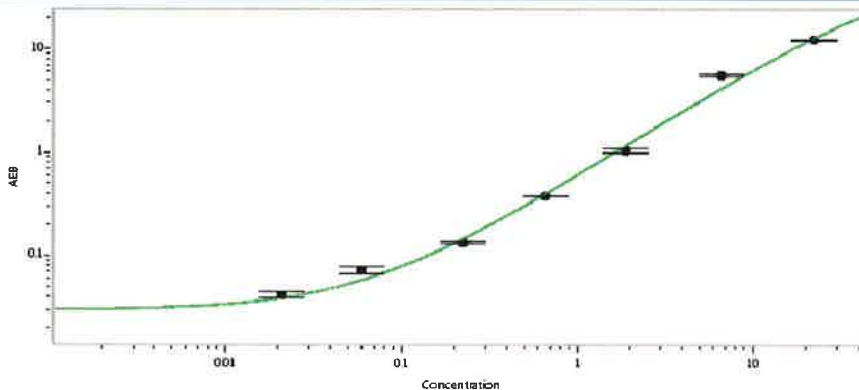
IL-6 Calibration Curve



Calibrator Levels
(pg/mL)

A	0.000
B	0.036
C	0.141
D	0.440
E	1.37
F	4.68
G	15.4
H	50.4

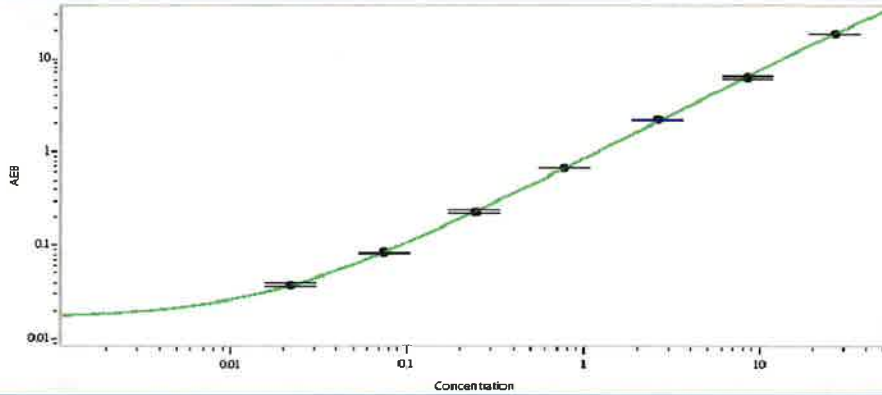
IL-10 Calibration Curve



Calibrator Levels
(pg/mL)

A	0.000
B	0.021
C	0.060
D	0.224
E	0.661
F	1.89
G	6.71
H	22.4

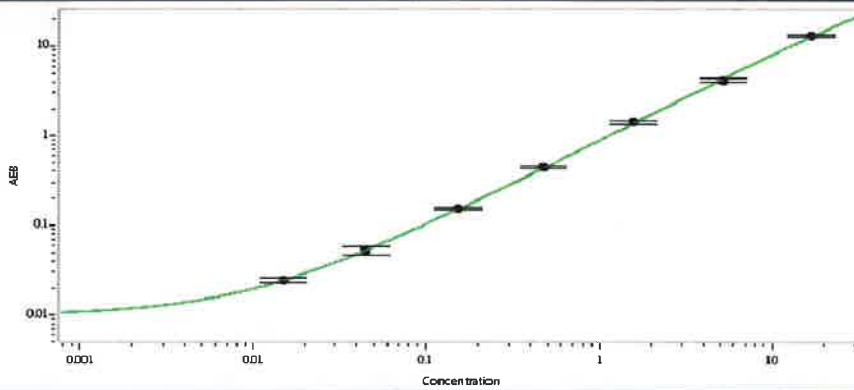
IL-12p70 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.022
C	0.075
D	0.243
E	0.766
F	2.59
G	8.39
H	26.4

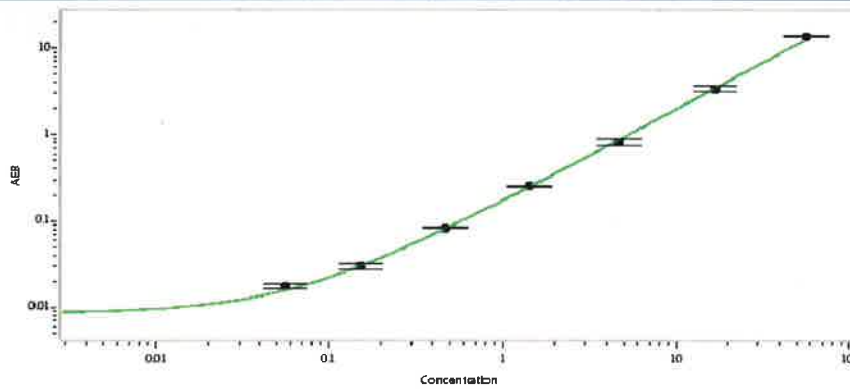
IL-17A Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.015
C	0.045
D	0.153
E	0.468
F	1.55
G	5.16
H	16.8

TNFα Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.056
C	0.153
D	0.468
E	1.42
F	4.64
G	16.7
H	56.0