

Product Number:	102958
Lot Number:	502360
Expiration:	24-Mar-2021
Platform(s):	HD-X and SR-X

Component	Part Number	Lot Number
Bead Reagent	102949	010415
Detector Reagent	102951	010414
SBG Reagent	102953	010002
Sample Diluent	102954	010003
Calibrators	102960	011801
Controls	102961 & 102962	011802
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	Shivani Goel	QC Manager	<i>Shivani Goel</i>	<i>07 May 2020</i>
	Name	Title	Signature/Date	

Release Materials

IFN γ

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	2.07	1.31-2.16
Control 2	011802	47.6	34.3-51.4
Panel 1	927401	0.241	0.144-0.425
Panel 2	927703	20.5	14.3-27.7
Panel 3	927704	75.1	49.0-91.0

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	2.26	1.60-2.40
Control 2	011802	45.9	39.3-59.0
Panel 1	927401	5.06	3.91-5.86
Panel 2	927703	11.9	9.87-14.8
Panel 3	927704	48.8	33.6-57.2

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	1.08	0.752-1.13
Control 2	011802	16.5	14.6-21.9
Panel 1	927401	0.647	0.237-1.21
Panel 2	927703	7.85	5.49-13.8
Panel 3	927704	25.7	16.7-43.9

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	1.02	0.798-1.20
Control 2	011802	18.9	16.5-24.8
Panel 1	927401	0.255	0.160-0.302
Panel 2	927703	5.78	4.89-7.51
Panel 3	927704	21.4	17.5-26.3

IL-17A

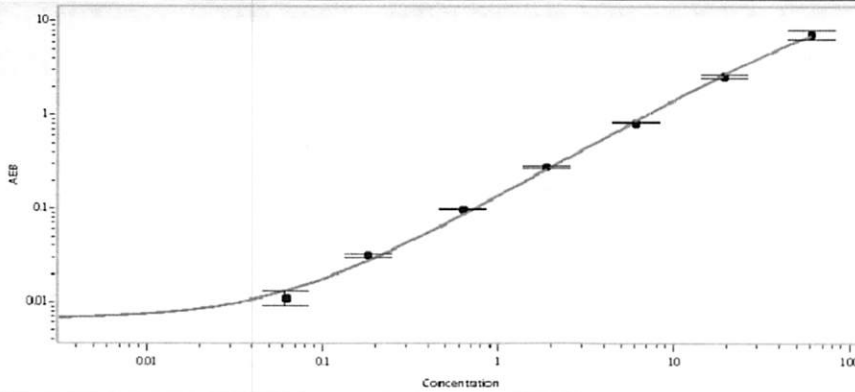
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	0.529	0.400-0.601
Control 2	011802	12.7	11.6-17.4
Panel 1	927401	0.163	0.087-0.204
Panel 2	927703	6.42	5.40-8.31
Panel 3	927704	21.4	17.0-25.5

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	011802	0.931	0.675-1.01
Control 2	011802	30.1	25.1-37.6
Panel 1	927401	2.29	1.67-2.69
Panel 2	927703	9.91	7.43-11.6
Panel 3	927704	43.1	30.9-54.0

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

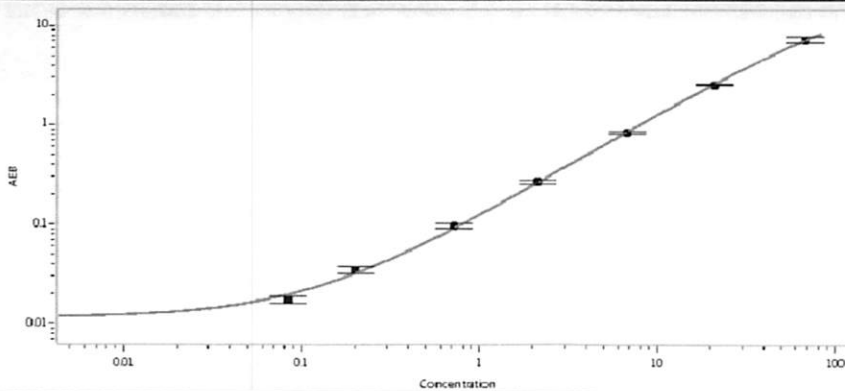
IFN γ Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.062
C	0.181
D	0.629
E	1.87
F	6.08
G	19.3
H	60.6

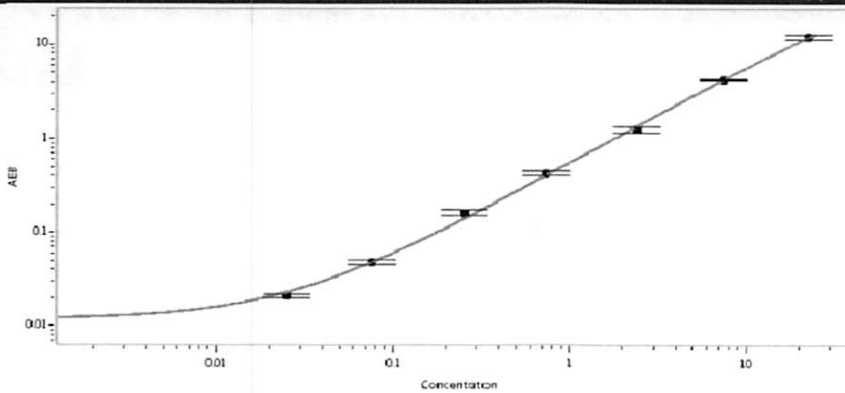
IL-6 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.084
C	0.201
D	0.713
E	2.10
F	6.78
G	20.9
H	67.5

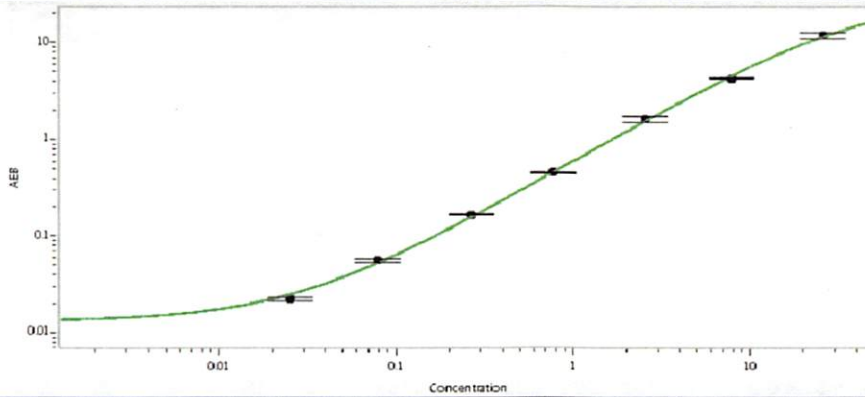
IL-10 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.025
C	0.076
D	0.252
E	0.729
F	2.40
G	7.36
H	22.6

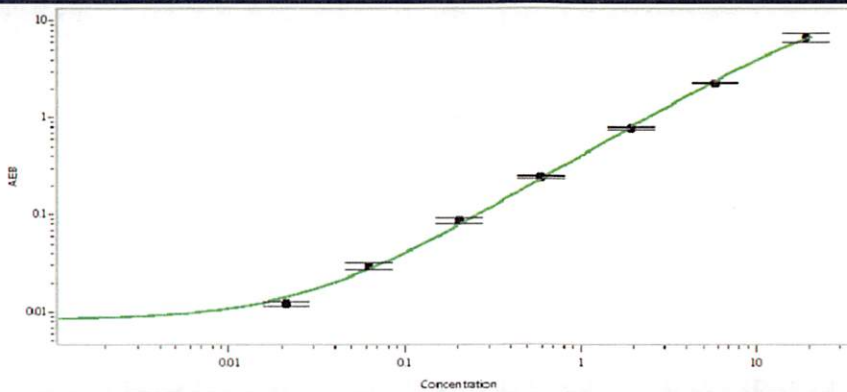
IL-12p70 Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.025
C	0.079
D	0.266
E	0.764
F	2.57
G	7.91
H	25.8

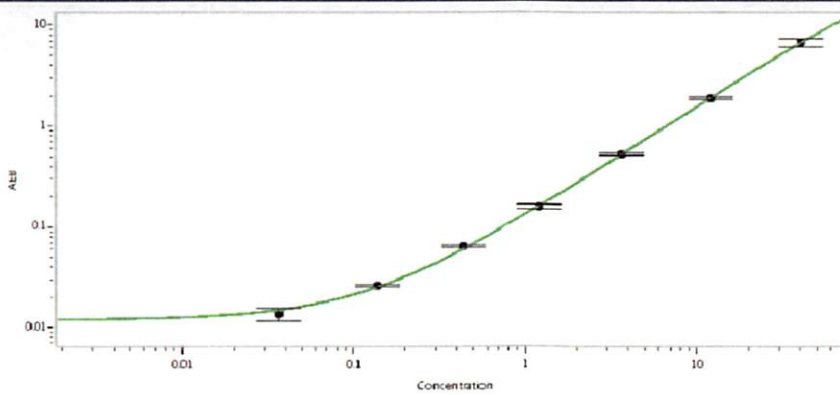
IL-17A Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.021
C	0.062
D	0.206
E	0.589
F	1.94
G	5.86
H	19.3

TNFα Calibration Curve



Calibrator Levels (pg/mL)

A	0.000
B	0.037
C	0.139
D	0.435
E	1.20
F	3.63
G	12.0
H	40.7