

Product Number:	102958
Lot Number:	502366
Expiration:	4-May-2021
Platform(s):	HD-X and SR-X

Component	Part Number	Lot Number
Bead Reagent	102949	012505
Detector Reagent	102951	023008
SBG Reagent	102953	012602
Sample Diluent	102954	012601
Calibrators	102960	012701
Control 1	102961	012702
Control 2	102962	012702
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	Shivani Goel	28 Aug 2020
	Name	Title	Signature/Date	

Release Materials

IFN γ

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	1.63	1.36-2.05
Control 2	012702	44.1	36.8-55.2
Panel 1	927401	0.238	0.138-0.417
Panel 2	927703	17.1	13.1-27.7
Panel 3	927704	68.7	49.7-89.9

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	2.06	1.69-2.54
Control 2	012702	50.1	42.5-63.8
Panel 1	927401	4.48	3.86-5.79
Panel 2	927703	10.3	9.15-14.9
Panel 3	927704	40.9	32.4-56.5

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	0.860	0.728-1.09
Control 2	012702	19.2	15.3-26.7
Panel 1	927401	0.596	0.500-0.760
Panel 2	927703	6.91	5.76-11.3
Panel 3	927704	27.5	22.0-34.0

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	0.986	0.817-1.22
Control 2	012702	21.5	17.4-26.1
Panel 1	927401	0.275	0.153-0.324
Panel 2	927703	5.57	4.71-7.48
Panel 3	927704	22.3	17.6-26.4

IL-17A

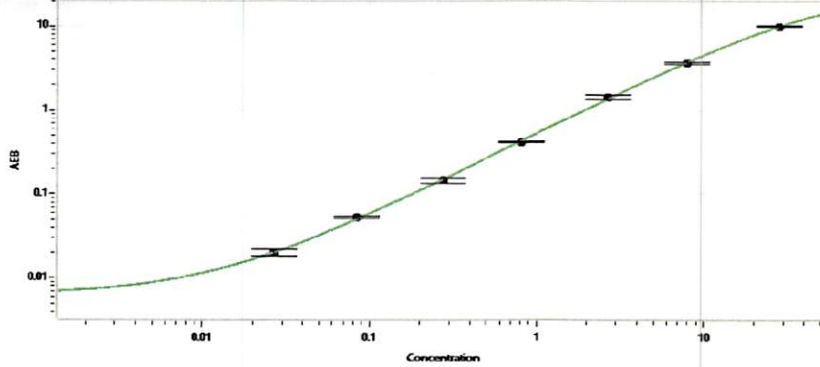
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	0.472	0.338-0.582
Control 2	012702	15.7	12.3-18.4
Panel 1	927401	0.129	0.086-0.199
Panel 2	927703	6.66	5.38-8.27
Panel 3	927704	22.8	17.2-25.9

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	012702	0.986	0.749-1.12
Control 2	012702	36.6	29.9-44.8
Panel 1	927401	2.38	1.70-2.72
Panel 2	927703	8.51	7.19-11.5
Panel 3	927704	40.6	31.2-53.0

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

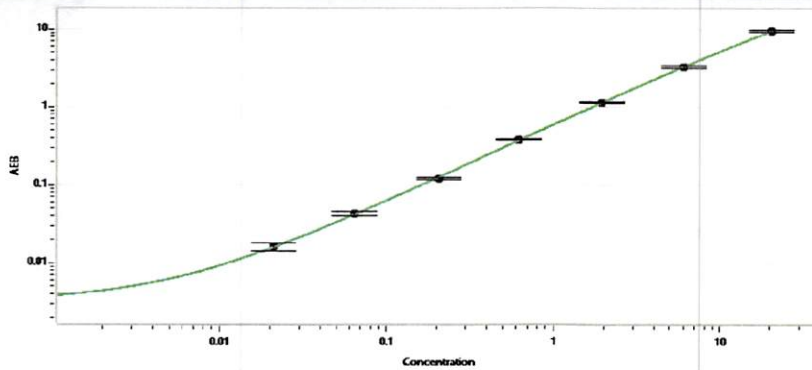
IL-12p70 Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.027
C	0.084
D	0.275
E	0.805
F	2.66
G	7.96
H	28.3

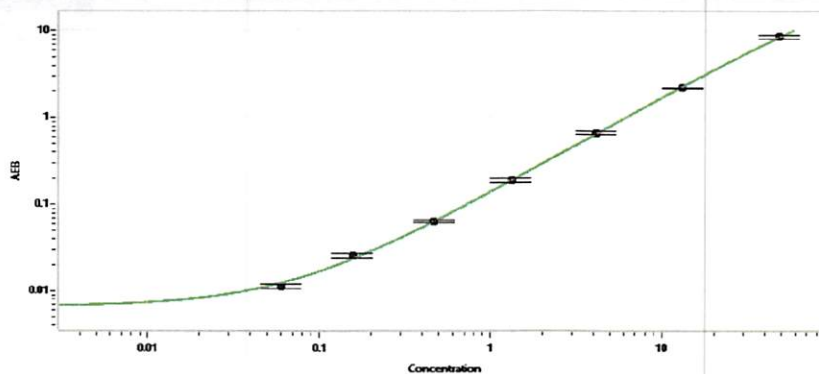
IL-17A Calibration Curve



**Calibrator Levels
(pg/mL)**

A	0.000
B	0.021
C	0.064
D	0.207
E	0.612
F	1.94
G	6.02
H	20.1

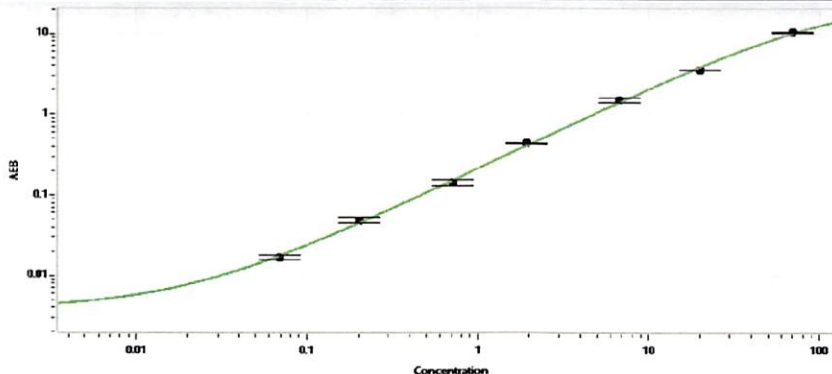
TNFα Calibration Curve



**Calibrator Levels
(pg/mL)**

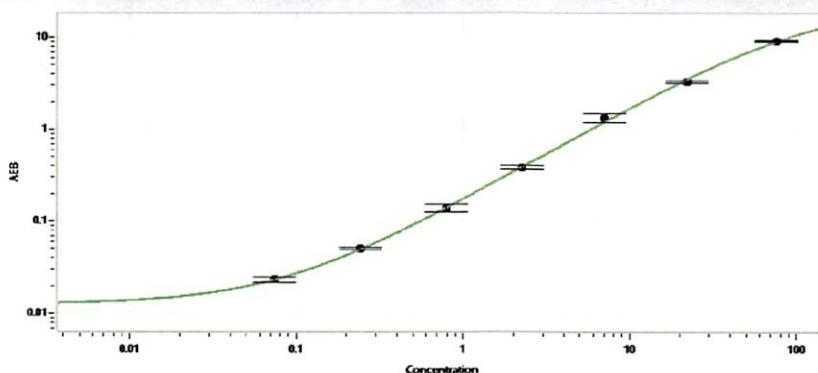
A	0.000
B	0.060
C	0.157
D	0.468
E	1.32
F	4.09
G	13.2
H	48.2

IFN γ Calibration Curve



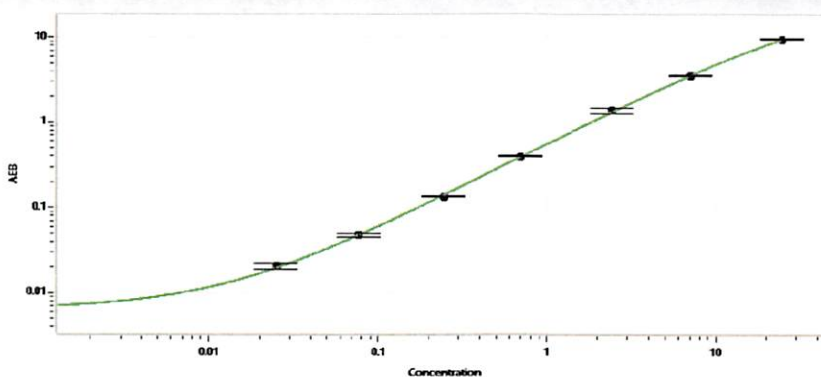
Calibrator Levels (pg/mL)	
A	0.000
B	0.069
C	0.203
D	0.720
E	1.93
F	6.72
G	20.1
H	69.4

IL-6 Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.073
C	0.242
D	0.796
E	2.23
F	7.05
G	21.9
H	75.2

IL-10 Calibration Curve



Calibrator Levels (pg/mL)	
A	0.000
B	0.025
C	0.077
D	0.245
E	0.697
F	2.41
G	7.08
H	24.4