

Product Number:	102958
Lot Number:	502088
Expiration:	28-Oct-2020
Platform(s):	HD-X and SR-X

Component	Part Number	Lot Number
Bead Reagent	102949	932209
Detector Reagent	102951	932210
SBG Reagent	102953	930102
Sample Diluent	102954	930108
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	Patrizia Stadler	Assoc. Director, QC	<i>P. Stadler</i>	<i>31 Jan 2020</i>
	Name	Title	Signature/Date	

Release Materials

IFN γ

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.47	1.23-2.10
Control 2	929406	41.7	33.8-50.7
Panel 1	927401	0.238	0.160-0.448
Panel 2	927703	21.0	15.4-24.8
Panel 3	927704	71.5	52.5-78.7

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.17	1.11-1.66
Control 2	929406	34.4	28.9-43.4
Panel 1	927401	4.62	3.75-5.63
Panel 2	927703	11.5	9.71-14.6
Panel 3	927704	46.5	33.4-52.7

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	0.813	0.694-1.20
Control 2	929406	18.4	18.1-27.1
Panel 1	927401	0.622	0.492-0.776
Panel 2	927703	7.55	7.44-11.2
Panel 3	927704	24.5	23.2-34.8

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	0.913	0.804-1.21
Control 2	929406	20.8	17.7-26.5
Panel 1	927401	0.201	0.168-0.280
Panel 2	927703	5.98	4.93-7.40
Panel 3	927704	22.9	17.4-26.2

IL-17A

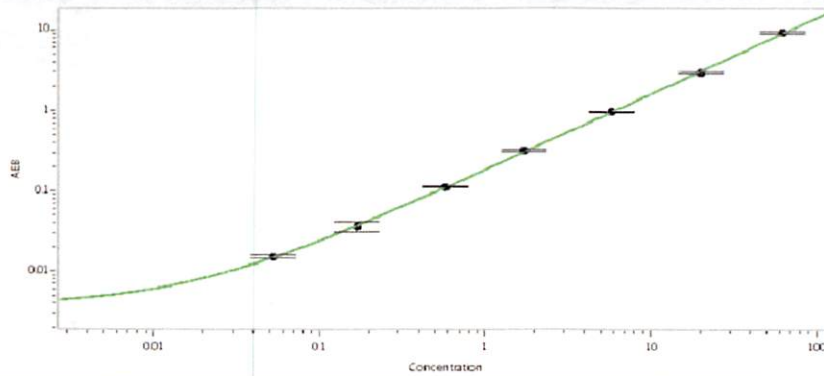
	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	0.373	0.327-0.509
Control 2	929406	13.1	10.3-15.4
Panel 1	927401	0.132	0.093-0.200
Panel 2	927703	7.53	5.51-8.27
Panel 3	927704	24.2	16.7-25.1

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Control 1	929406	1.01	0.839-1.34
Control 2	929406	45.7	34.2-51.3
Panel 1	927401	2.12	1.69-2.53
Panel 2	927703	9.46	7.22-10.8
Panel 3	927704	47.7	32.1-48.2

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

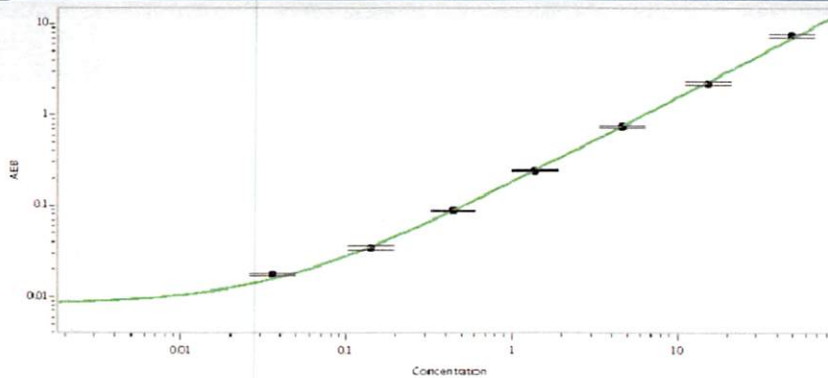
IFN γ Calibration Curve



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

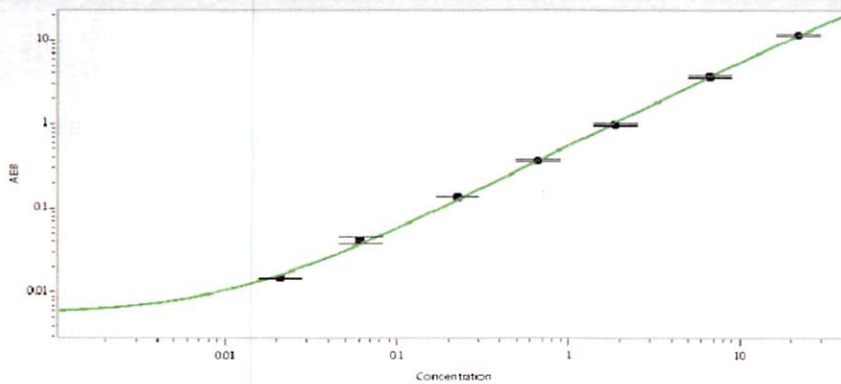
IL-6 Calibration Curve



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

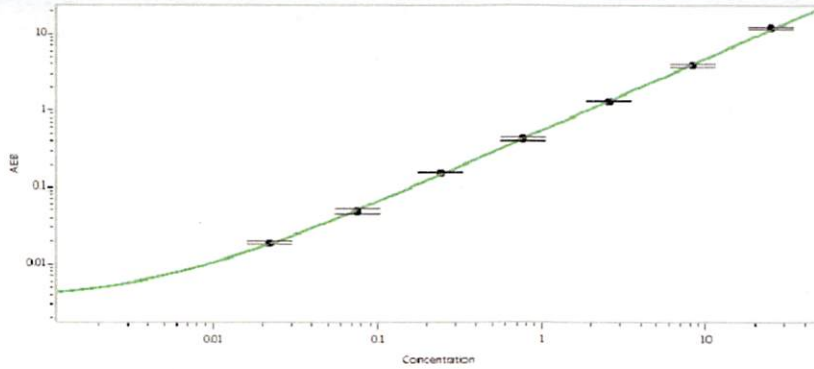
IL-10 Calibration Curve



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

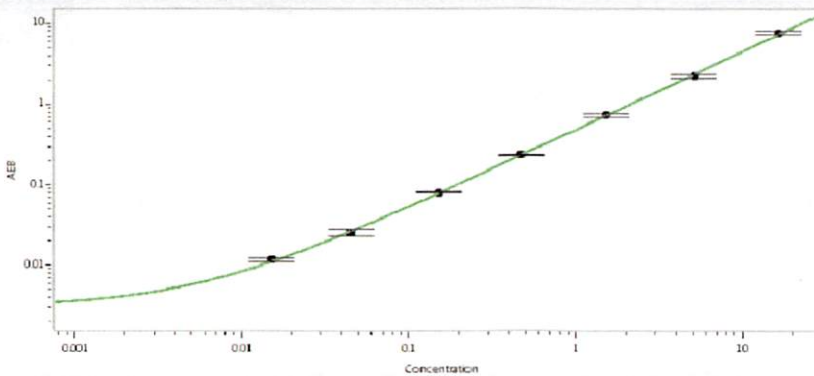
IL-12p70 Calibration Curve



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

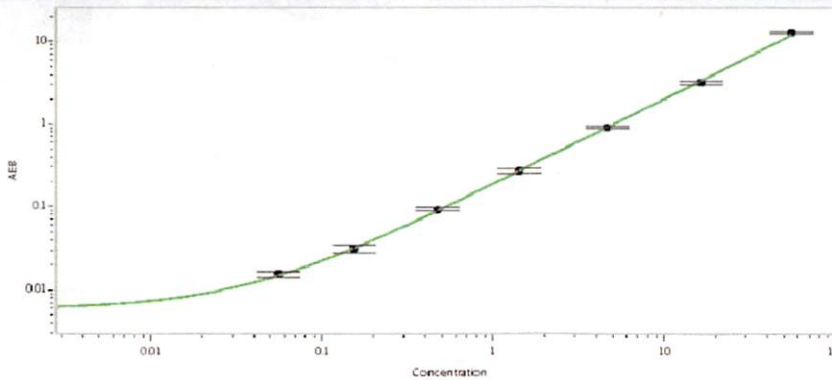
IL-17A Calibration Curve



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

Kit Certificate of Analysis Review Checklist

Kit Name:	Simoa® Human cytokine 6-plex Panel 1 Kit
Product Number:	102958
Lot Number:	502088

Content	Data Entered By (Initial/Date)	Data Checked By (Initial/Date)
		JP 09 Jan 2020
Kit Name	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Product Number	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Lot Number	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Expiration	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Platforms	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Component Names	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Component Part Numbers	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Component Lot Numbers	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
SBG Diluent (for SR-X)	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
Concentration		
• Calibrators	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
• Beads (Homebrew Kits)	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
• SBG (Homebrew Kits)	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
• Antibodies (Homebrew Kits)	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	Accept <input type="checkbox"/> Reject <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
Control Lot Numbers	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Control Ranges	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Control Results	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Panel Lot Numbers	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Panel Ranges	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Panel Results	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Calibration Curve	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Format/Typographical Errors	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>
Data Uploaded to Jira	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>	Accept <input checked="" type="checkbox"/> Reject <input type="checkbox"/> N/A <input type="checkbox"/>

Comments (Explain any N/A selections): _____

REVISION HISTORY

Revision	Detailed Description	Date	Originator
1.0	Initial release. This was FRM.019.	17Dec2015	D. Rice
1.1	DCR-16-0600: Transfer documents from QMS 2.0 to R&D vault. Archive the above docs in QMS 2.0 once released in R&D vault.	28Sep2016	S. Chin
03	DCR-18-0421: Changes were made to reflect updates made to SOP-0093 (Creating and Reviewing Certificates of Analyss). CC-17-0026	22May2018	S. Murugan
04	DCR-19-2081: Added row at end of table to ensure kit release data is uploaded to the Jira tracking system.	14Aug2019	D. Ritchie

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