

Product Number:	85-0329
Lot Number:	319684
Expiration:	10-May-2023
Platform(s):	SP-X

Component	Part Number	Lot Number
CorPlex Cytokine Plate	97-0329	319684P
Biotinylated Antibody Rgt	98-0329	319684B
Sample Diluent 21	1863329	319579
IL-12p70 Calibrator	18910034	319156
IL-1 β Calibrator	18910040	319564
IL-4 Calibrator	1858452	319458
IL-5 Calibrator	1858462	319223
IFN γ Calibrator	1858260	318898
IL-6 Calibrator	18910044	319484
IL-8 Calibrator	1858454	319436
IL-22 Calibrator	18910036	319459
TNF α Calibrator	1880012	319460
IL-10 Calibrator	18910043	319215
Wash Buffer (25X) ¹	1860055	N/A
Streptavidin-HRP Reagent ¹	1858263	N/A
Super Signal [®] Luminol* ¹	1858089	N/A
Super Signal [®] Peroxide* ¹	1858090	N/A

¹ Reagents are not Kit Lot Specific

*SuperSignal[®] technology is protected by US Patent #6,432,662 and is a registered trademark of ThermoFisher Scientific.

All reagents are specific for use on the SP-X platform - refer to the CorPlex Cytokine1 Kit Instructions (85A-0329).



Data below represents results generated on the SP-X Imaging and Analysis System

Release Materials

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	168.4	133.1 - 204.3
Panel 2	318935	50.40	37.09 - 66.72
Panel 3	318935	14.39	13.48 - 21.97
Panel 4	318935	5.420	3.812 - 6.073
Panel 5	318935	1.630	1.188 - 2.091

IL-1 β

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	26.41	12.49 - 32.68
Panel 2	318935	7.530	4.122 - 9.719
Panel 3	318935	2.380	1.349 - 3.475
Panel 4	318935	0.860	0.418 - 0.968
Panel 5	318935	0.300	0.133 - 0.345

IL-4

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	64.80	51.07 - 77.41
Panel 2	318935	19.22	14.17 - 24.05
Panel 3	318935	6.840	5.217 - 8.887
Panel 4	318935	2.670	1.455 - 2.760
Panel 5	318935	0.900	0.418 - 1.250

IL-5

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	68.60	43.59 - 101.9
Panel 2	318935	21.69	13.43 - 32.50
Panel 3	318935	7.290	4.948 - 11.09
Panel 4	318935	2.880	1.317 - 3.402
Panel 5	318935	0.950	0.473 - 1.224

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

Release Materials

IFN γ

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	10.21	8.190 - 14.53
Panel 2	318935	3.280	2.393 - 4.771
Panel 3	318935	1.070	0.855 - 1.720
Panel 4	318935	0.440	0.277 - 0.494
Panel 5	318935	0.160	0.114 - 0.221

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	212.3	142.9 - 214.3
Panel 2	318935	89.76	62.87 - 99.85
Panel 3	318935	16.96	13.37 - 20.05
Panel 4	318935	9.760	5.951 - 8.927
Panel 5	318935	2.880	1.992 - 3.084

IL-8

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	494.3	365.0 - 604.4
Panel 2	318935	132.2	92.02 - 191.0
Panel 3	318935	40.20	32.36 - 67.44
Panel 4	318935	16.06	9.991 - 18.54
Panel 5	318935	4.990	3.355 - 6.599

IL-22

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	75.1	50.55 - 160.4
Panel 2	318935	12.19	7.411 - 28.41
Panel 3	318935	3.710	2.237 - 9.205
Panel 4	318935	1.270	0.738 - 2.619
Panel 5	318935	0.410	0.226 - 0.888

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	322.7	250.8 - 453.3
Panel 2	318935	97.5	68.46 - 156.1
Panel 3	318935	31.47	25.97 - 51.08
Panel 4	318935	11.50	7.455 - 14.81
Panel 5	318935	3.480	2.339 - 4.887

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	114.3	76.56 - 126.0
Panel 2	318935	31.78	21.73 - 39.58
Panel 3	318935	9.86	7.682 - 13.72
Panel 4	318935	3.780	2.408 - 3.832
Panel 5	318935	1.260	0.837 - 1.442

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

Review/Approval

Shivani Goel

Quality Control
Manager

Shivani Goel 09 May 2022

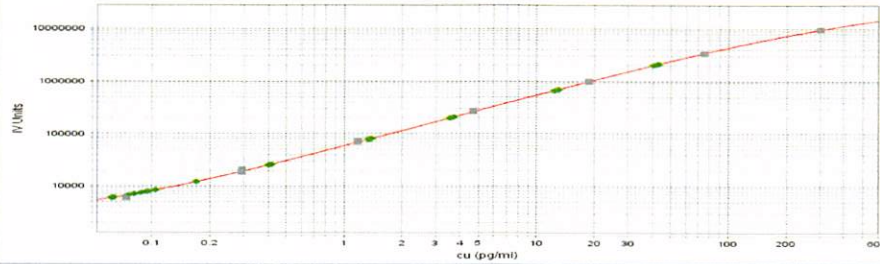
Name

Title

Signature/Date

IL-12p70 Calibration Curve

hIL12p70

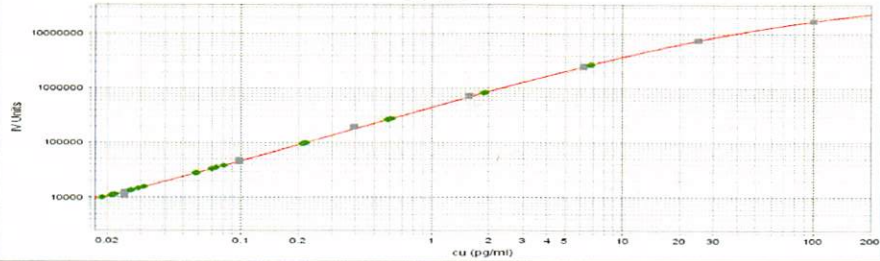


Calibrator Levels (pg/ml)

1	300
2	75
3	18.75
4	4.688
5	1.172
6	0.293
7	0.073
8	0.000

IL-1β Calibration Curve

hIL1β

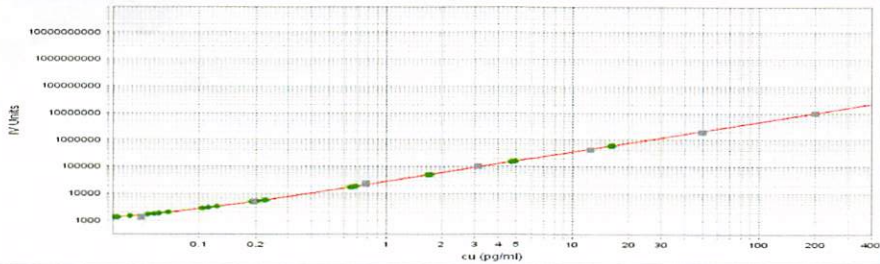


Calibrator Levels (pg/mL)

1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

IL-4 Calibration Curve

hIL4

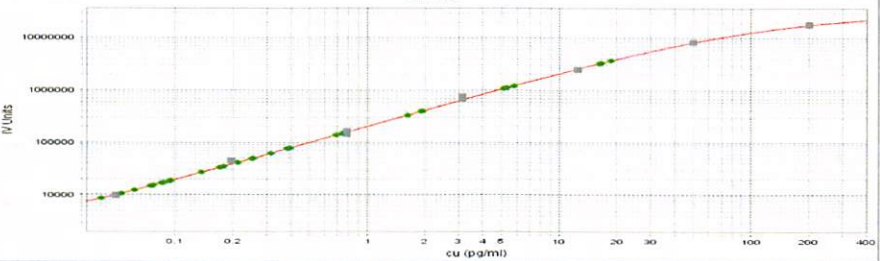


Calibrator Levels (pg/mL)

1	200
2	50
3	12.50
4	3.125
5	0.781
6	0.195
7	0.049
8	0.000

IL-5 Calibration Curve

hIL5

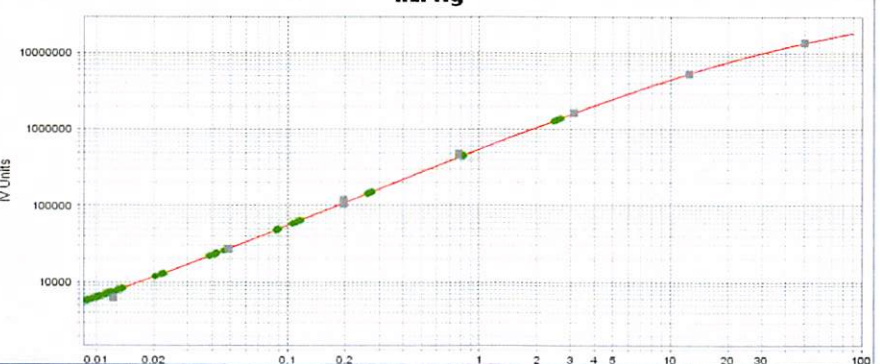


Calibrator Levels (pg/mL)

1	200
2	50
3	12.50
4	3.125
5	0.781
6	0.195
7	0.049
8	0.000

IFNγ Calibration Curve

hIFNγ

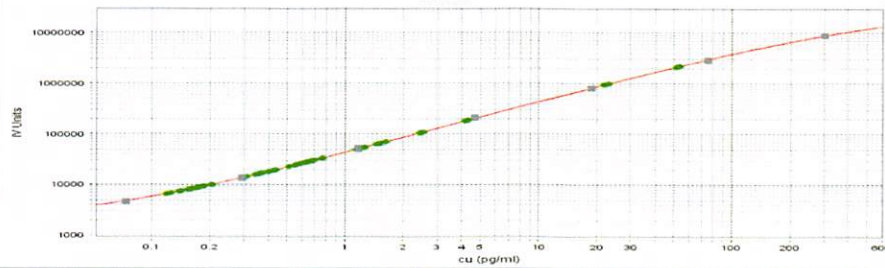


Calibrator Levels (pg/mL)

1	50
2	12.5
3	3.13
4	0.781
5	0.195
6	0.049
7	0.012
8	0.000

IL-6 Calibration Curve

hIL6

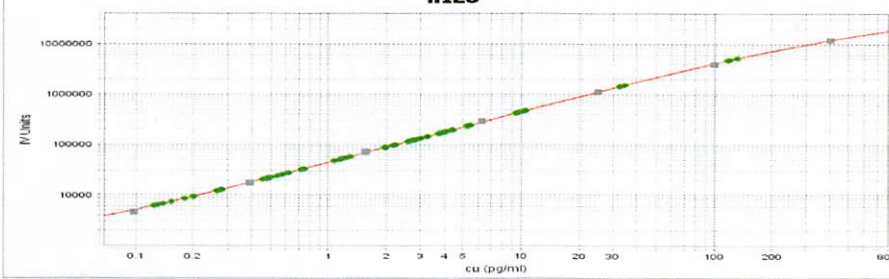


Calibrator Levels (pg/mL)

1	300
2	75
3	18.75
4	4.688
5	1.172
6	0.293
7	0.073
8	0.000

IL-8 Calibration Curve

hIL8

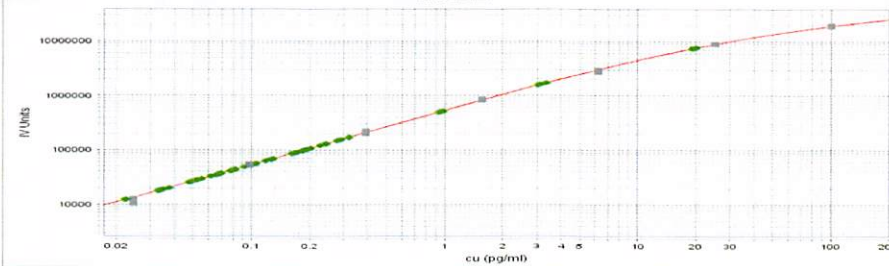


Calibrator Levels (pg/mL)

1	400
2	100
3	25.00
4	6.250
5	1.563
6	0.391
7	0.098
8	0.000

IL-22 Calibration Curve

hIL22

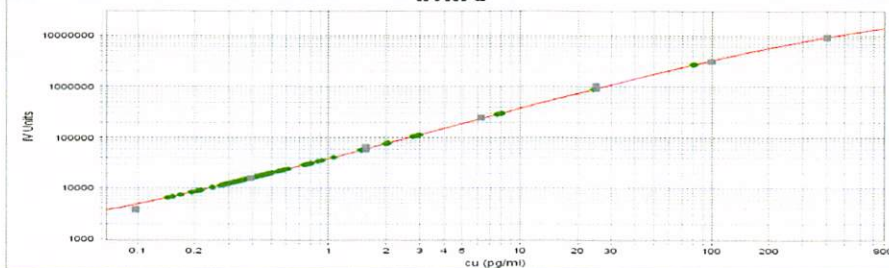


Calibrator Levels (pg/mL)

1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

TNFα Calibration Curve

hTNFα

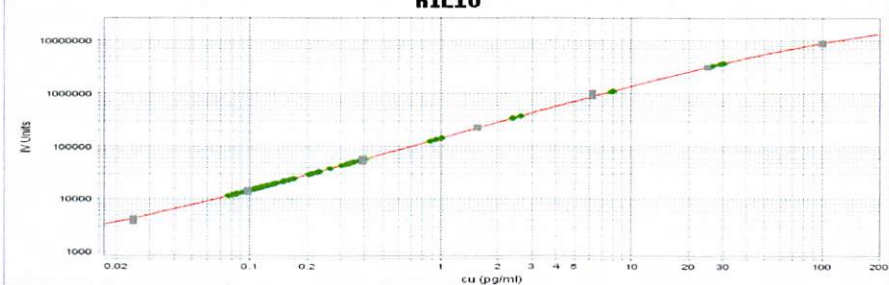


Calibrator Levels (pg/mL)

1	400
2	100
3	25.00
4	6.250
5	1.563
6	0.391
7	0.098
8	0.000

IL-10 Calibration Curve

hIL10



Calibrator Levels (pg/mL)

1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

Quanterix	Form	
	Document No: FRM-0110	Revision No: 06
	Name: Kit Certificate of Analysis Review Checklist	Effective: 24 Jun 2021 Page 1 of 4

Kit Certificate of Analysis Review Checklist

Kit Name:	Simoa® Complex Cytokine Panel 1 Kit
Product Number:	85-0329
Lot Number:	319684

Content	Data Entered By (Initial/Date)	Data Checked By (Initial/Date)
	JC 05 May 2022	SG 09 May 2022

① See note p.3

Kit Name	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"/>
Product Number	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"/>
Lot Number	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"/>
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 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"/>
Component Names	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"/>
Component Part Numbers	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"/>
Component Lot Numbers	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"/>
Is this a Discovery Kit (If Yes See *Note)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input type="checkbox"/> No <input checked="" 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 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"/>
• 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 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 Ranges	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 Results	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"/>
Are all replicates of at least one control read with $F_{on} < 0.7$?	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"/>
Are all replicates of at least one control read with $F_{on} > 0.7$?	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"/>
Panel Lot Numbers	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"/>
Panel Ranges	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"/>
Panel Results	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"/>
Are all replicates of at least one panel read with $F_{on} < 0.7$?	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"/>
Are all replicates of at least one panel read with $F_{on} > 0.7$?	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"/>
Calibration Curve	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"/>
Format/Typographical Errors	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"/>
Data Uploaded to Jira	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"/>

*Note: 1.) Discovery Kit temporary specification: If discovery kit has an endpoint less than 8 AEB or greater than 19.5 AEB update the google document in ATSI- 150 and add a comment to ATSI-150 once data is entered into the google sheet. ATS/QC Manager will review and suggest outcome based on review. In the comments include the outcome of the ATS/QC Manager review.

2.) Control and Panel specification: Ensure all replicates of at least one control and at least one panel have Fon of <0.7. Ensure all replicates of at least one control and at least one panel have Fon of >0.7. If this criteria is not met at Kit Release testing, then please update the "Controls / Panels Close to Digital / Analog Cutoff Tracking Sheet" google spreadsheet and add a comment on ATSI-179. ATS / QC management will review and suggest outcome based on review. In the comments include the outcome of the ATS/ QC Management review.

Initial and date below:

Data entered by:

Data Reviewed by:

QC Operator

ATS/ QC Manager

N/A SG 09 May 2022

Comments (Explain any N/A selections): _____

1 CofA was previously checked against original data/folder. The only change is to update expiration date based on new lot of shortest dated component (SuperSignal Luminol/Peroxide)

[Signature]
05 May 2022

REVISION HISTORY

Revision	Detailed Description	Date	Originator
01	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
05	DCR-20-2864: Adding temporary specifications for discovery kits per CC-20-0060.	20Oct2020	N. Barrett
06	DCR-21-0953: Added temporary digital / analog Fon monitoring evaluation at kit release.	03Jun2021	S. Kaur

End of Document