

Product Number:	85-0329
Lot Number:	319682
Expiration:	12-Nov-2022
Platform(s):	SP-X



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

Component	Part Number	Lot Number
CorPlex Cytokine Plate	97-0329	319682P
Biotinylated Antibody Rgt	98-0329	319302B
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	319589
IL-6 Calibrator	18910044	319484
IL-8 Calibrator	1858454	319575
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 Cytokine Kit Instructions (85A-0329).

Release Materials

IL-12p70

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	161.3	133.1 - 204.3
Panel 2	318935	45.86	37.09 - 66.72
Panel 3	318935	16.08	13.48 - 21.97
Panel 4	318935	4.372	3.812 - 6.073
Panel 5	318935	1.511	1.188 - 2.091

IL-1 β

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	25.92	12.49 - 32.68
Panel 2	318935	7.389	4.122 - 9.719
Panel 3	318935	2.628	1.349 - 3.475
Panel 4	318935	0.744	0.418 - 0.968
Panel 5	318935	0.282	0.133 - 0.345

IL-4

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	61.45	51.07 - 77.41
Panel 2	318935	17.65	14.17 - 24.05
Panel 3	318935	6.441	5.217 - 8.887
Panel 4	318935	1.909	1.455 - 2.760
Panel 5	318935	0.749	0.418 - 1.250

IL-5

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	69.87	43.59 - 101.9
Panel 2	318935	19.98	13.43 - 32.50
Panel 3	318935	7.030	4.948 - 11.09
Panel 4	318935	1.810	1.317 - 3.402
Panel 5	318935	0.737	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	9.77	8.190 - 14.53
Panel 2	318935	3.026	2.393 - 4.771
Panel 3	318935	0.993	0.855 - 1.720
Panel 4	318935	0.326	0.277 - 0.494
Panel 5	318935	0.131	0.114 - 0.221

IL-6

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	202.5	142.9 - 214.3
Panel 2	318935	87.85	62.87 - 99.85
Panel 3	318935	16.89	13.37 - 20.05
Panel 4	318935	7.395	5.951 - 8.927
Panel 5	318935	2.485	1.992 - 3.084

IL-8

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	438.1	365.0 - 604.4
Panel 2	318935	131.0	92.02 - 191.0
Panel 3	318935	46.95	32.36 - 67.44
Panel 4	318935	13.08	9.991 - 18.54
Panel 5	318935	4.666	3.355 - 6.599

IL-22

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	80.35	50.55 - 160.4
Panel 2	318935	13.79	7.411 - 28.41
Panel 3	318935	3.734	2.237 - 9.205
Panel 4	318935	1.216	0.738 - 2.619
Panel 5	318935	0.381	0.226 - 0.888

TNF α

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	282.7	250.8 - 453.3
Panel 2	318935	81.12	68.46 - 156.1
Panel 3	318935	28.68	25.97 - 51.08
Panel 4	318935	8.669	7.455 - 14.81
Panel 5	318935	2.644	2.339 - 4.887

IL-10

	Lot	Result (pg/mL)	Mean Range (pg/mL)
Panel 1	318935	110.2	76.56 - 126.0
Panel 2	318935	32.54	21.73 - 39.58
Panel 3	318935	9.93	7.682 - 13.72
Panel 4	318935	2.993	2.408 - 3.832
Panel 5	318935	1.042	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

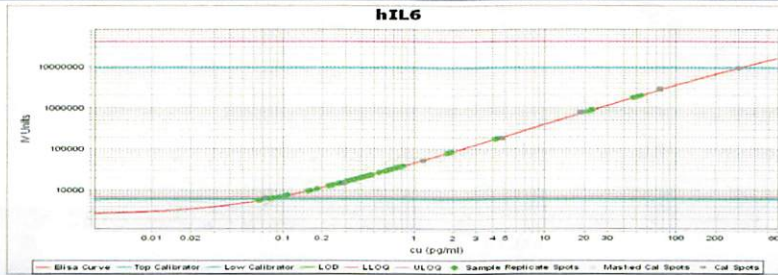
Shivani Goel 12 Apr 2022

Name

Title

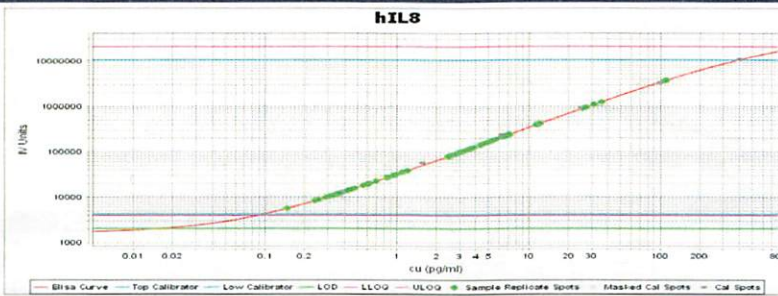
Signature/Date

IL-6 Calibration Curve



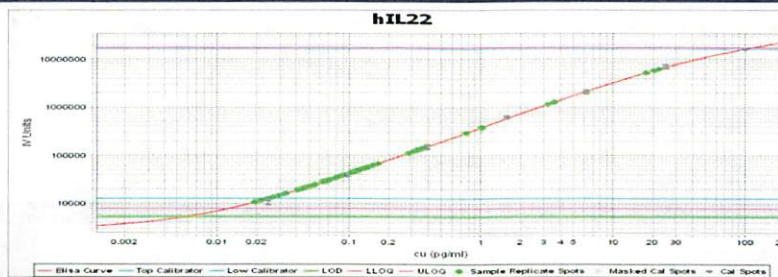
Calibrator Levels (pg/mL)	
1	300
2	75
3	18.75
4	4.688
5	1.172
6	0.293
7	0.073
8	0.000

IL-8 Calibration Curve



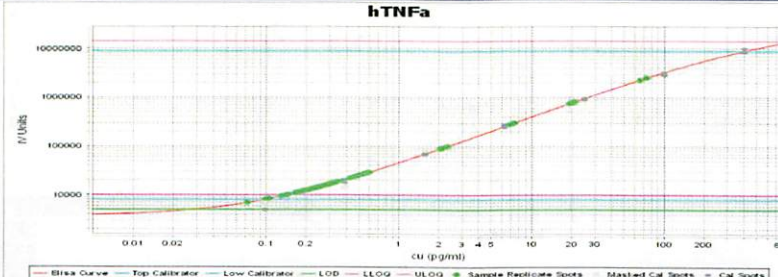
Calibrator Levels (pg/mL)	
1	400
2	100
3	25.00
4	6.250
5	1.563
6	0.391
7	0.098
8	0.000

IL-22 Calibration Curve



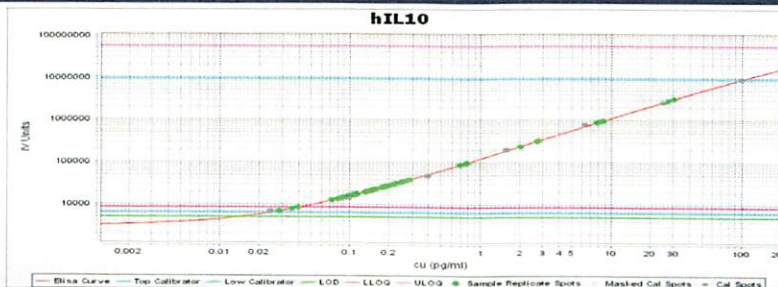
Calibrator Levels (pg/mL)	
1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

TNFα Calibration Curve



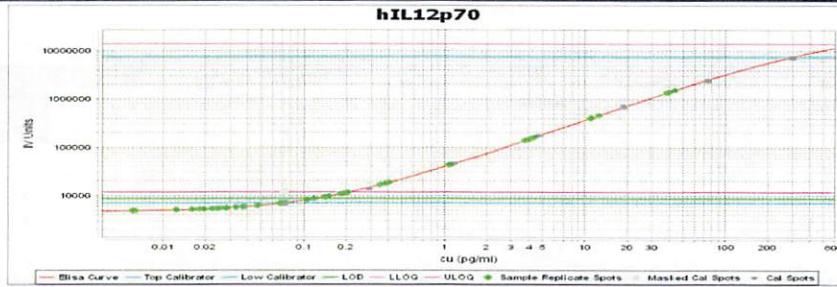
Calibrator Levels (pg/mL)	
1	400
2	100
3	25.00
4	6.250
5	1.563
6	0.391
7	0.098
8	0.000

IL-10 Calibration Curve



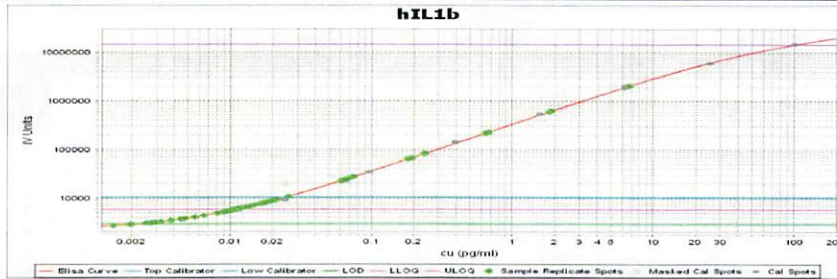
Calibrator Levels (pg/mL)	
1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

IL-12p70 Calibration Curve



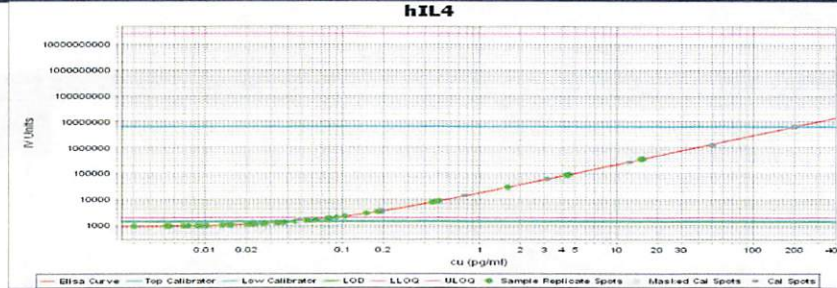
Calibrator Levels (pg/ml)	
1	300
2	75
3	18.75
4	4.688
5	1.172
6	0.293
7	0.073
8	0.000

IL-1β Calibration Curve



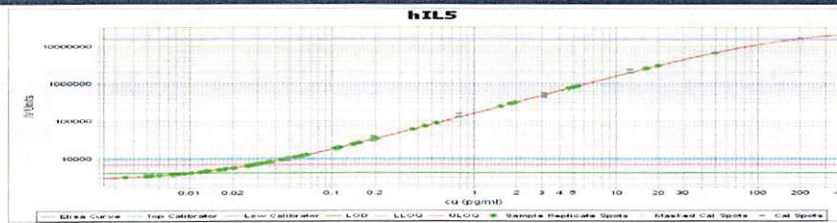
Calibrator Levels (pg/mL)	
1	100
2	25
3	6.25
4	1.563
5	0.391
6	0.098
7	0.024
8	0.000

IL-4 Calibration Curve



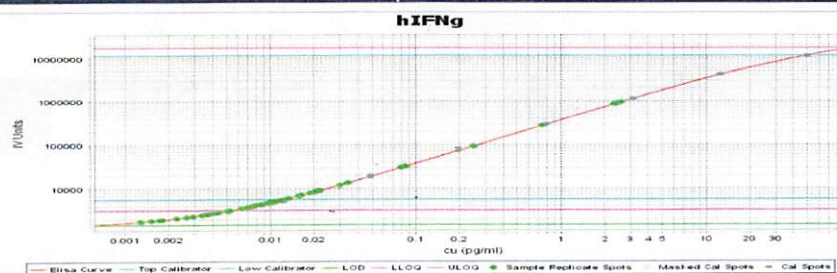
Calibrator Levels (pg/mL)	
1	200
2	50
3	12.50
4	3.125
5	0.781
6	0.195
7	0.049
8	0.000

IL-5 Calibration Curve



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



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

Kit Certificate of Analysis Review Checklist

Kit Name:	Simoa® Complex Cytokine Panel 1 Kit
Product Number:	85-0329
Lot Number:	319682

Content	Data Entered By (Initial/Date)	Data Checked By (Initial/Date)
		KC 11 Apr 2022

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"/>
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 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 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 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"/>
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 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"/>

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

*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: NA Data Reviewed by: NA
QC Operator ATS/ QC Manager

Comments (Explain any N/A selections):
Not Discovery Kit

Corplex CP1 Kit Panels Lot 318935 Ranges Established 28Mar2022

External (C of A)

IL12p70		-		IL6					
	Panel 1	133.1	-	204.3	Panel 1	142.9	-	214.3	
	Panel 2	37.09	-	66.72	Panel 2	62.87	-	99.85	
	Panel 3	13.48	-	21.97	Panel 3	13.37	-	20.05	
	Panel 4	3.812	-	6.073	Panel 4	5.951	-	8.927	
	Panel 5	1.188	-	2.091	Panel 5	1.992	-	3.084	
IL1b				IL8					
	Panel 1	12.49	-	32.68	Panel 1	365.0	-	604.4	
	Panel 2	4.122	-	9.719	Panel 2	92.02	-	191.0	
	Panel 3	1.349	-	3.475	Panel 3	32.36	-	67.44	
	Panel 4	0.418	-	0.968	Panel 4	9.991	-	18.54	
	Panel 5	0.133	-	0.345	Panel 5	3.355	-	6.599	
IL4	Panel 1	51.07	-	77.41	IL22	Panel 1	50.55	-	160.4
	Panel 2	14.17	-	24.05		Panel 2	7.411	-	28.41
	Panel 3	5.217	-	8.887		Panel 3	2.237	-	9.205
	Panel 4	1.455	-	2.760		Panel 4	0.738	-	2.619
	Panel 5	0.418	-	1.250		Panel 5	0.226	-	0.888
IL5	Panel 1	43.59	-	101.85	TNFa	Panel 1	250.8	-	453.3
	Panel 2	13.43	-	32.50		Panel 2	68.46	-	156.1
	Panel 3	4.948	-	11.09		Panel 3	25.97	-	51.08
	Panel 4	1.317	-	3.402		Panel 4	7.455	-	14.81
	Panel 5	0.473	-	1.224		Panel 5	2.339	-	4.887
IFNg	Panel 1	8.190	-	14.53	IL10	Panel 1	76.56	-	126.0
	Panel 2	2.393	-	4.771		Panel 2	21.73	-	39.58
	Panel 3	0.855	-	1.720		Panel 3	7.682	-	13.72
	Panel 4	0.277	-	0.494		Panel 4	2.408	-	3.832
	Panel 5	0.114	-	0.221		Panel 5	0.837	-	1.442