



RFE MEMO


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Product Description(s): V-PLEX® and V-PLEX Plus TH17 Panel 1 (human) Kit
Catalog Number(s) / Size(s): K15085-Series
Lot Number: K0081134

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0081134 has been extended to 30 APR 2020.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
TH17 Panel 1 (human) Plate	Z0046290	30 APR 2019	30 APR 2020

Function	Name	Signature	Date
Quality	Karen Hamilla		11 JUN 2019

This memo supersedes all other statements regarding date of expiration for this product.

CERTIFICATE OF ANALYSIS

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Product Description: V-PLEX® and V-PLEX Plus TH17 Panel 1 (human) Kit

Kit Catalog Numbers: K15085-Series

Kit Lot Number: K0081134

Expiration Date: 30 Apr 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		TH17 Panel 1 (human) Control 1		TH17 Panel 1 (human) Control 2		TH17 Panel 1 (human) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu IL-17A Gen B.	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	hu IL-21	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
5	hu IL-31	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
6	hu IL-27	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
7	hu IL-23	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
8	hu IL-22	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
10	hu MIP-3α	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu IL-17A Gen B.	5.86	80% - 120%	< 20%	1950	80% - 120%	< 20%
4	hu IL-21	1.65	80% - 120%	< 20%	650	80% - 120%	< 20%
5	hu IL-31	4.22	80% - 120%	< 20%	650	80% - 120%	< 20%
6	hu IL-27	38.7	80% - 120%	< 20%	13000	80% - 120%	< 20%
7	hu IL-23	4.60	80% - 120%	< 20%	3250	80% - 120%	< 20%
8	hu IL-22	2.78	80% - 120%	< 20%	325	80% - 120%	< 20%
10	hu MIP-3α	0.590	80% - 120%*	< 20%	325	80% - 120%	< 20%

* See Additional Comments.

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	hu IL-17A Gen B.	< 1.0%
4	hu IL-21	< 1.0%
5	hu IL-31	< 1.0%
6	hu IL-27	< 1.0%
7	hu IL-23	< 1.0%
8	hu IL-22	< 1.0%
10	hu MIP-3α	< 1.0%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu IL-17A Gen B.	Calibrator	2900	pg/mL
		TH17 Panel 1 (human) Control 1	2690	pg/mL
		TH17 Panel 1 (human) Control 2	429	pg/mL
		TH17 Panel 1 (human) Control 3	61.4	pg/mL
4	hu IL-21	Calibrator	1020	pg/mL
		TH17 Panel 1 (human) Control 1	929	pg/mL
		TH17 Panel 1 (human) Control 2	145	pg/mL
		TH17 Panel 1 (human) Control 3	25	pg/mL
5	hu IL-31	Calibrator	962	pg/mL
		TH17 Panel 1 (human) Control 1	931	pg/mL
		TH17 Panel 1 (human) Control 2	145	pg/mL
		TH17 Panel 1 (human) Control 3	21.9	pg/mL
6	hu IL-27	Calibrator	16100	pg/mL
		TH17 Panel 1 (human) Control 1	18400	pg/mL
		TH17 Panel 1 (human) Control 2	3450	pg/mL
		TH17 Panel 1 (human) Control 3	790	pg/mL
7	hu IL-23	Calibrator	4600	pg/mL
		TH17 Panel 1 (human) Control 1	4190	pg/mL
		TH17 Panel 1 (human) Control 2	487	pg/mL
		TH17 Panel 1 (human) Control 3	58.2	pg/mL
8	hu IL-22	Calibrator	551	pg/mL
		TH17 Panel 1 (human) Control 1	547	pg/mL
		TH17 Panel 1 (human) Control 2	103	pg/mL
		TH17 Panel 1 (human) Control 3	17.7	pg/mL
10	hu MIP-3α	Calibrator	463	pg/mL
		TH17 Panel 1 (human) Control 1	531	pg/mL
		TH17 Panel 1 (human) Control 2	214	pg/mL
		TH17 Panel 1 (human) Control 3	82.3	pg/mL

Controls tested may not be the same lot as shipped.

Standard Curve Data:

hu IL-17A Gen B. - Spot 1			hu IL-21 - Spot 4			hu IL-31 - Spot 5		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
2900	533,000	2.3	1020	330,000	3.2	962	456,000	2.4
725	128,000	3.7	255	99,900	2.7	241	143,000	2.0
181	30,400	4.4	63.8	25,100	2.9	60.1	36,600	2.6
45.3	8,100	4.8	15.9	6,880	2.6	15.0	9,770	3.1
11.3	2,490	4.3	3.98	2,240	2.5	3.76	2,580	2.2
2.83	1,240	2.5	0.996	1,150	4.2	0.939	844	3.3
0.708	881	4.2	0.249	852	3.3	0.235	386	5.6
0.00	781	3.2	0.00	779	3.3	0.00	243	7.1

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hu IL-27 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
16100	265,000	3.5
4030	53,400	2.2
1010	12,300	4.7
252	3,350	4.8
62.9	1,310	3.7
15.7	751	4.1
3.93	595	4.4
0.00	555	5.3

hu IL-23 - Spot 7		
Conc. pg/mL	ECL Signal	%CV
4600	334,000	4.2
1150	103,000	3.7
288	27,200	6.5
71.9	7,270	2.8
18.0	2,290	3.5
4.49	1,000	4.6
1.12	689	3.9
0.00	582	4.8

hu IL-22 - Spot 8		
Conc. pg/mL	ECL Signal	%CV
551	393,000	2.9
138	110,000	1.7
34.4	28,000	2.4
8.61	7,930	2.6
2.15	2,750	3.2
0.538	1,560	2.1
0.135	1,190	2.5
0.00	1,110	3.1

hu MIP-3 α - Spot 10		
Conc. pg/mL	ECL Signal	%CV
463	440,000	2.1
116	116,000	2.7
28.9	23,500	6.0
7.23	5,730	5.8
1.81	2,020	2.7
0.452	1,100	3.2
0.113	867	3.8
0.00	775	3.4

Components:

Description	Lot Number	Storage Temperature	Expiration Date
TH17 Panel 1 (human) Plate	Z0046290	2-8°C	30 Apr 2019
Anti-hu IL-17A Antibody	D0081135	2-8°C	30 Apr 2022
Anti-hu IL-21 Antibody	D0081136	2-8°C	31 Mar 2022
Anti-hu IL-31 Antibody	D0081140	2-8°C	28 Feb 2022
Anti-hu IL-27 Antibody	D0081139	2-8°C	28 Feb 2022
Anti-hu IL-23 Antibody	D0081138	2-8°C	31 Mar 2022
Anti-hu IL-22 Antibody	D0081137	2-8°C	28 Feb 2022
Anti-hu MIP-3 α Antibody	D0081141	2-8°C	30 Apr 2022
TH17 Panel 1 (human) Calibrator Blend	A0080119	2-8°C	31 Jan 2022
Diluent 43	M0430028	≤ -10°C	31 Jan 2021
Diluent 3	M0030085	≤ -10°C	28 Feb 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Components Included in V-PLEX Plus	
Plate Seals	Not Kit Specific
Wash Buffer (20X), 100 mL	Not Kit Specific
TH17 Panel 1 (human) Control 1	Not Kit Specific
TH17 Panel 1 (human) Control 2	Not Kit Specific
TH17 Panel 1 (human) Control 3	Not Kit Specific

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Additional Comments:

	Assay	Spot	Specification	Comment
1	hu MIP-3 α	10	LLOQ Conc.	Measured Recovery = 121.9%. LLOQ meets specification at 0.75 pg/mL

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance	<i>Dawn Stollar</i>	20 DEC 2018