



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Proinflammatory Panel 2 (Rat) Kit

Catalog Number(s) / Size(s): K15059-Series

Lot Number: K0080868

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080868 has been extended to 31 Jul 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Blocker H	R0100012	31 JUL 2018	31 JUL 2019
Diluent 42	M0420009	31 AUG 2018	31 JUL 2019
Diluent 40	M0400010	31 MAY 2019	31 JUL 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	12 APR 2018

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

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Product Description: V-PLEX® and V-PLEX Plus Proinflammatory Panel 2 (Rat) Kit

Kit Catalog Numbers: K15059-Series

Kit Lot Number: K0080868

Expiration Date: 31 Jul 2018

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Proinflammatory Panel 1 (Rat) Control 1		Proinflammatory Panel 1 (Rat) Control 2		Proinflammatory Panel 1 (Rat) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	rt IFN- γ	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
2	rt IL-1 β	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
4	rt IL-4	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
5	rt IL-5	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
6	rt IL-6	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
7	rt KC/GRO	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
8	rt IL-10	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
9	rt IL-13	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%
10	rt TNF- α	80% - 120%	< 20%	75% - 125%	< 25%	75% - 125%	< 25%	75% - 125%	< 25%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	rt IFN- γ	39.7	75% - 125%	< 25%	3750	75% - 125%	< 25%
2	rt IL-1 β	102	75% - 125%	< 25%	8100	75% - 125%	< 25%
4	rt IL-4	8.00	75% - 125%	< 25%	723	75% - 125%	< 25%
5	rt IL-5	82.0	75% - 125%	< 25%	3000	75% - 125%	< 25%
6	rt IL-6	96.9	75% - 125%	< 25%	8550	75% - 125%	< 25%
7	rt KC/GRO	21.7	75% - 125%	< 25%	728	75% - 125%	< 25%
8	rt IL-10	163	75% - 125%	< 25%	15700	75% - 125%	< 25%
9	rt IL-13	12.5	75% - 125%	< 25%	1080	75% - 125%	< 25%
10	rt TNF- α	9.10	75% - 125%	< 25%	793	75% - 125%	< 25%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	rt IFN- γ	< 1.0%
2	rt IL-1 β	< 1.0%
4	rt IL-4	< 1.0%
5	rt IL-5	< 1.0%
6	rt IL-6	< 1.0%
7	rt KC/GRO	< 1.0%
8	rt IL-10	< 1.0%
9	rt IL-13	< 1.0%
10	rt TNF- α	< 1.0%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	rt IFN- γ	Calibrator	6810	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	5011	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	1543	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	477	pg/mL
2	rt IL-1 β	Calibrator	12800	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	13088	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	3516	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	872	pg/mL
4	rt IL-4	Calibrator	1310	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	995	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	345	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	94.2	pg/mL
5	rt IL-5	Calibrator	10500	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	3974	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	1834	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	935	pg/mL
6	rt IL-6	Calibrator	14600	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	8425	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	2819	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	835	pg/mL
7	rt KC/GRO	Calibrator	3360	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	1033	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	550	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	284	pg/mL
8	rt IL-10	Calibrator	25000	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	30052	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	8605	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	2946	pg/mL
9	rt IL-13	Calibrator	1780	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	1502	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	485	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	170	pg/mL
10	rt TNF- α	Calibrator	1360	pg/mL
		Proinflammatory Panel 1 (Rat) Control 1	1200	pg/mL
		Proinflammatory Panel 1 (Rat) Control 2	357	pg/mL
		Proinflammatory Panel 1 (Rat) Control 3	102	pg/mL

Controls tested may not be the same lot as shipped.

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Standard Curve Data:

rt IFN- γ - Spot 1		
Conc. pg/mL	ECL Signal	%CV
6810	1,000,000	4.9
1700	279,000	6.8
426	60,800	8.4
106	15,900	6.5
26.6	4,650	5.2
6.65	2,050	3.5
1.66	1,290	3.1
0.00	1,080	3.5

rt IL-1 β - Spot 2		
Conc. pg/mL	ECL Signal	%CV
12800	1,450,000	3.1
3200	287,000	2.2
800	48,900	2.7
200	10,300	2.4
50.0	2,880	2.6
12.5	1,050	2.4
3.13	613	3.8
0.00	465	4.1

rt IL-4 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
1310	1,190,000	2.9
328	319,000	2.4
81.9	60,100	2.8
20.5	12,300	3.1
5.12	3,240	4.2
1.28	1,200	3.2
0.320	704	4.9
0.00	528	4.5

rt IL-5 - Spot 5		
Conc. pg/mL	ECL Signal	%CV
10500	2,030,000	3.0
2630	641,000	2.5
656	114,000	3.6
164	15,100	3.6
41.0	2,080	3.4
10.3	617	4.6
2.56	454	5.8
0.00	416	7.0

rt IL-6 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
14600	136,000	3.5
3650	29,900	3.0
913	7,270	4.4
228	2,080	5.5
57.0	1,010	3.9
14.3	670	5.2
3.56	607	5.5
0.00	559	4.6

rt KC/GRO - Spot 7		
Conc. pg/mL	ECL Signal	%CV
3360	992,000	3.3
840	432,000	3.4
210	104,000	4.0
52.5	23,000	3.0
13.1	6,070	3.9
3.28	1,870	3.4
0.820	845	6.3
0.00	505	8.0

rt IL-10 - Spot 8		
Conc. pg/mL	ECL Signal	%CV
25000	801,000	3.6
6250	212,000	2.8
1560	50,800	2.6
391	13,000	3.6
97.7	3,970	5.1
24.4	1,570	7.1
6.10	1,160	14.0
0.00	920	18.0

rt IL-13 - Spot 9		
Conc. pg/mL	ECL Signal	%CV
1780	1,140,000	2.6
445	215,000	2.2
111	34,800	1.9
27.8	7,020	2.8
6.95	2,120	3.0
1.74	912	4.4
0.435	645	6.6
0.00	532	6.2

rt TNF- α - Spot 10		
Conc. pg/mL	ECL Signal	%CV
1360	920,000	3.2
340	196,000	2.0
85.0	39,100	3.0
21.3	9,050	2.4
5.31	2,850	4.7
1.33	1,220	5.6
0.332	796	7.6
0.00	707	7.6

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Proinflammatory Panel 2 (rat) Plate	Z0046604	2-8°C	28 Feb 2020
Anti-rat IFN- γ Antibody	D0081025	2-8°C	29 Feb 2020
Anti-rat IL-1 β Antibody	D0081027	2-8°C	29 Feb 2020
Anti-rat IL-4 Antibody	D0081026	2-8°C	29 Feb 2020
Anti-rat IL-5 Antibody	D0081028	2-8°C	29 Feb 2020
Anti-rat IL-6 Antibody	D0081029	2-8°C	29 Feb 2020
Anti-rat KC/GRO Antibody	D0081030	2-8°C	29 Feb 2020
Anti-rat IL-10 Antibody	D0081031	2-8°C	29 Feb 2020
Anti-rat IL-13 Antibody	D0081032	2-8°C	31 Mar 2020
Anti-rat TNF- α Antibody	D0081033	2-8°C	29 Feb 2020
Proinflammatory Panel 1 (rat) Calibrator Blend	A0080124	2-8°C	31 Mar 2022
Blocker H	R0100012	Room Temperature	31 Jul 2018
Diluent 42	M0420009	$\leq -10^{\circ}\text{C}$	31 Aug 2018
Diluent 40	M0400010	$\leq -10^{\circ}\text{C}$	31 May 2019
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), 100mL	Not Kit Specific
Proinflammatory Panel 1 (rat) Control 1	Not Kit Specific
Proinflammatory Panel 1 (rat) Control 2	Not Kit Specific
Proinflammatory Panel 1 (rat) Control 3	Not Kit Specific

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		11 JAN 2018