



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: K0080716

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080716 has been extended to 30 Apr 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Blocker H	R0100011	30 APR 2018	30 APR 2019
Diluent 42	M0420009	31 AUG 2018	30 APR 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	16 JAN 2018

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 Proinflammatory Panel 2 (rat) Kit
Kit Catalog Numbers: K15059-Series
Kit Lot Number: K0080716
Expiration Date: 30 Apr 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	7070	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	12900	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	1200	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	9390	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	13300	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	3330	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	25600	pg/mL
		Proinflammatory Panel 1 (rat) Control 1	30052	pg/mL
		Proinflammatory Panel 1 (rat) Control 2	8606	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	1280	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
7070	1,190,000	5.6
1770	335,000	4.7
442	74,500	6.3
110	19,800	6.9
27.6	4,840	4.7
6.90	1,880	4.7
1.73	938	4.8
0.00	650	5.1

rt IL-1 β - Spot 2		
Conc. pg/mL	ECL Signal	%CV
12900	1,280,000	2.4
3230	236,000	2.0
806	40,000	2.5
202	8,430	2.3
50.4	2,370	3.4
12.6	862	3.4
3.15	498	4.9
0.00	373	6.5

rt IL-4 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
1200	1,130,000	2.3
300	294,000	2.3
75.0	55,200	2.6
18.8	11,200	2.8
4.69	2,760	3.9
1.17	986	3.6
0.293	553	5.9
0.00	391	11.0

rt IL-5 - Spot 5		
Conc. pg/mL	ECL Signal	%CV
9390	1,990,000	3.4
2350	598,000	3.6
587	108,000	3.3
147	13,300	3.4
36.7	1,690	4.7
9.17	469	3.3
2.29	345	3.6
0.00	320	8.8

rt IL-6 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
13300	234,000	4.1
3330	52,500	3.6
831	12,800	2.7
208	3,230	3.1
52.0	1,210	4.2
13.0	651	8.6
3.25	511	14.0
0.00	542	11.0

rt KC/GRO - Spot 7		
Conc. pg/mL	ECL Signal	%CV
3330	834,000	5.5
833	358,000	3.5
208	86,800	4.7
52.0	18,900	4.1
13.0	5,360	3.2
3.25	1,780	4.5
0.813	891	9.5
0.00	991	23.0

rt IL-10 - Spot 8		
Conc. pg/mL	ECL Signal	%CV
25600	698,000	3.5
6400	184,000	3.4
1600	46,400	3.4
400	11,800	2.0
100	3,480	4.4
25.0	1,320	11.0
6.25	747	11.0
0.00	758	20.0

rt IL-13 - Spot 9		
Conc. pg/mL	ECL Signal	%CV
1780	1,260,000	4.1
445	235,000	2.7
111	37,600	3.1
27.8	6,960	3.5
6.95	2,010	5.2
1.74	851	21.0
0.435	503	17.0
0.00	727	15.0

rt TNF- α - Spot 10		
Conc. pg/mL	ECL Signal	%CV
1280	965,000	1.7
320	210,000	2.0
80.0	46,200	2.2
20.0	10,900	3.9
5.00	3,480	7.4
1.25	1,400	14.0
0.313	820	14.0
0.00	1,040	22.0

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Proinflammatory Panel 2 (rat) Plate	Z0046383	2-8°C	31 Jul 2019
Anti-rat IFN- γ Antibody	D0080925	2-8°C	31 Jul 2019
Anti-rat IL-1 β Antibody	D0080927	2-8°C	31 Jul 2019
Anti-rat IL-4 Antibody	D0080926	2-8°C	31 Jul 2019
Anti-rat IL-5 Antibody	D0080928	2-8°C	31 Jul 2019
Anti-rat IL-6 Antibody	D0080929	2-8°C	31 Jul 2019
Anti-rat KC/GRO Antibody	D0080930	2-8°C	31 Jul 2019
Anti-rat IL-10 Antibody	D0080931	2-8°C	31 Aug 2019
Anti-rat IL-13 Antibody	D0080932	2-8°C	31 Jul 2019
Anti-rat TNF- α Antibody	D0080933	2-8°C	31 Jul 2019
Proinflammatory Panel 1 (rat) Calibrator Blend	A0080100	2-8°C	30 Sep 2021
Blocker H	R0100011	Room Temperature	30 Apr 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	<i>Dawn Stollar</i>	19 JUL 2017