



RFE MEMO

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Product Description(s): V-PLEX® and V-PLEX Plus Vascular Injury Panel 2 (human) Kit

Catalog Number(s) / Size(s): K15198-Series

Lot Number: K0080664

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080664 has been extended to 31 Aug 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Vascular Injury Panel 2 Plate	Z0055645	31 Jan 2019	31 Aug 2019
Anti-hu SAA Antibody	D0080825	30 Apr 2019	31 Aug 2019
Anti-hu CRP Antibody	D0080826	30 Apr 2019	31 Aug 2019
Anti-hu VCAM-1 Antibody	D0080827	30 Apr 2019	31 Aug 2019
Anti-hu ICAM-1 Antibody	D0080828	30 Apr 2019	31 Aug 2019
Vascular Panel 2 (human) Calibrator Blend	A0040150	31 Aug 2018	31 Aug 2019
Diluent 101	M1010024	30 Nov 2018	31 Aug 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	<i>Dawn Stollar</i>	04 SEP 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 Vascular Injury Panel 2 (human) Kit
Kit Catalog Numbers: K15198-Series
Kit Lot Number: K0080664
Expiration Date: 31 Aug 2018

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Vascular Injury Control 1		Vascular Injury Control 2		Vascular Injury Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	hu SAA	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	hu CRP	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
3	hu VCAM-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	hu ICAM-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	hu SAA	54.0	80% - 120%	< 20%	138000	80% - 120%	< 20%
2	hu CRP	27.6	80% - 120%	< 20%	49600	80% - 120%	< 20%
3	hu VCAM-1	37.6	80% - 120%	< 20%	32000	80% - 120%	< 20%
4	hu ICAM-1	6.40	80% - 120%	< 20%	32700	80% - 120%	< 20%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	hu SAA	< 1.0%
2	hu CRP	< 1.0%
3	hu VCAM-1	< 1.0%
4	hu ICAM-1	< 1.0%

CERTIFICATE OF ANALYSIS

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu SAA	20X Calibrator	4440000	pg/mL
		Vascular Injury Control 1	70500	pg/mL
		Vascular Injury Control 2	6620	pg/mL
		Vascular Injury Control 3	833	pg/mL
2	hu CRP	20X Calibrator	4320000	pg/mL
		Vascular Injury Control 1	24300	pg/mL
		Vascular Injury Control 2	4900	pg/mL
		Vascular Injury Control 3	604	pg/mL
3	hu VCAM-1	20X Calibrator	1136000	pg/mL
		Vascular Injury Control 1	13900	pg/mL
		Vascular Injury Control 2	1331	pg/mL
		Vascular Injury Control 3	165	pg/mL
4	hu ICAM-1	20X Calibrator	1078000	pg/mL
		Vascular Injury Control 1	16300	pg/mL
		Vascular Injury Control 2	1720	pg/mL
		Vascular Injury Control 3	209	pg/mL

Controls tested may not be the same lot as shipped.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

Standard Curve Data:

hu SAA - Spot 1			hu CRP - Spot 2			hu VCAM-1 - Spot 3		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
222000	805,000	2.2	216000	1,110,000	3.8	56800	488,000	2.2
44400	139,000	4.7	43200	446,000	3.0	11400	125,000	2.5
8880	25,100	7.1	8640	103,000	3.4	2270	20,800	3.5
1780	4,960	7.3	1730	21,300	4.3	454	3,150	3.6
355	1,020	7.1	346	4,300	4.7	90.9	620	3.2
71.0	265	6.9	69.1	915	3.2	18.2	176	4.9
14.2	113	7.5	13.8	247	4.1	3.64	90	6.4
0.00	78	7.1	0.00	83	10.0	0.00	68	5.0

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hu ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
53900	614,000	5.2
10800	131,000	4.3
2160	27,500	7.2
431	5,450	8.3
86.2	1,130	10.0
17.2	272	6.1
3.45	101	8.3
0.00	60	12.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0055645	2-8°C	31 Jan 2019
Anti-hu SAA Antibody	D0080825	2-8°C	30 Apr 2019
Anti-hu CRP Antibody	D0080826	2-8°C	30 Apr 2019
Anti-hu VCAM-1 Antibody	D0080827	2-8°C	30 Apr 2019
Anti-hu ICAM-1 Antibody	D0080828	2-8°C	30 Apr 2019
Vascular Panel 2 (human) Calibrator Blend	A0040150	≤ -70°C	31 Aug 2018
Diluent 101	M1010024	≤ -10°C	30 Nov 2018
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
Vascular Injury Control 1	Not Kit Specific
Vascular Injury Control 2	Not Kit Specific
Vascular Injury 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>	21 MAR 2017