



## RFE MEMO


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**Product Description(s):** Diluent 101

**Catalog Number(s) / Size(s):** R51AD-Series

**Lot Number:** M1010030

Based on additional testing, the original date of expiration for this diluent has been extended by 12 months. The expiration date of M1010030 has been extended to 31 JUL 2021.

Function	Name	Signature	Date
Quality	Karen Hamilla		11 JUN 2020

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; K151SS-Series, K151SR-Series; K151SU-Series  
**Kit Lot Number:** K0081478  
**Expiration Date:** 31 Jul 2021

### Acceptance Data/ Percent Recovery Specifications:

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

		LLOQ			ULOQ		
Spot	Name	Value	Recovery	CV	Value	Recovery	CV
1	SAA	54.0	80% - 120%	< 20%	138000	80% - 120%	< 20%
2	CRP	27.6	80% - 120%	< 20%	49600	80% - 120%	< 20%
3	VCAM-1	37.6	80% - 120%	< 20%	32000	80% - 120%	< 20%
4	ICAM-1	15.0	80% - 120%	< 20%	32700	80% - 120%	< 20%

### Acceptance Data/ Non Specific Binding Specifications:

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

### Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	SAA	20X Calibrator	4860000	pg/mL
		Vascular Injury Control 1	47400	pg/mL
		Vascular Injury Control 2	4560	pg/mL
		Vascular Injury Control 3	601	pg/mL
2	CRP	20X Calibrator	4000000	pg/mL
		Vascular Injury Control 1	23700	pg/mL
		Vascular Injury Control 2	4620	pg/mL
		Vascular Injury Control 3	613	pg/mL
3	VCAM-1	20X Calibrator	988000	pg/mL
		Vascular Injury Control 1	16200	pg/mL
		Vascular Injury Control 2	1530	pg/mL
		Vascular Injury Control 3	195	pg/mL
4	ICAM-1	20X Calibrator	998000	pg/mL
		Vascular Injury Control 1	12300	pg/mL
		Vascular Injury Control 2	1250	pg/mL
		Vascular Injury Control 3	148	pg/mL

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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:

SAA - Spot 1			CRP - Spot 2			VCAM-1 - Spot 3		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
243000	860,000	2.6	200000	996,000	2.4	49400	462,000	2.4
48600	175,000	2.7	40000	364,000	3.0	9880	109,000	2.4
9720	31,000	3.0	8000	83,300	3.0	1980	18,800	2.8
1940	5,970	2.6	1600	17,600	4.7	395	3,130	1.9
389	1,250	4.1	320	3,620	4.2	79.0	656	3.4
77.8	327	4.2	64.0	810	4.8	15.8	186	3.7
15.6	142	7.3	12.8	241	7.8	3.16	98	5.3
0.00	101	14.0	0.00	91	15.0	0.00	72	6.5

ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
49900	761,000	3.8
9980	165,000	4.7
2000	34,800	4.9
399	7,070	3.8
79.8	1,490	5.3
16.0	338	5.9
3.19	113	5.8
0.00	56	8.1

### Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 (human) Plate	Z0056594	2-8°C	28 Feb 2022
Anti-hu SAA Antibody	D0081298	2-8°C	30 Sep 2022
Anti-hu CRP Antibody	D0081404	2-8°C	31 May 2023
Anti-hu VCAM-1 Antibody	D0081356	2-8°C	30 Apr 2023
Anti-hu ICAM-1 Antibody	D0081357	2-8°C	30 Apr 2023
Vascular Injury Panel 2 (human) Calibrator Blend	A0080234	≤ -70°C	31 May 2022
Diluent 101	M1010030	≤ -10°C	31 Jul 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A


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Additional Components Included in V-PLEX Plus	
Plate Seals	Not Kit Specific
Wash Buffer (20X), 100 mL	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
<b>Review/Approval</b>	Karen Hamilla	Quality		30 JUL 2020