



RFE MEMO


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Product Description(s): Diluent 101

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

Lot Number: M1010029

Based on additional testing, the original date of expiration for this diluent has been extended by 12 months. The expiration date of M1010029 has been extended to 31 MAR 2021.

Function	Name	Signature	Date
Quality Assurance	Karen Hamilla		09 MAR 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: K0081415
Expiration Date: 31 Mar 2021

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	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%

Spot	Name	LLOQ			ULOQ		
		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%

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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

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	854,000	2.3	200000	1,030,000	2.1	49400	519,000	2.1
48600	180,000	2.4	40000	395,000	2.0	9880	129,000	2.7
9720	32,500	3.8	8000	90,000	2.2	1980	22,400	2.7
1940	6,210	4.0	1600	18,600	2.1	395	3,470	2.5
389	1,280	3.5	320	3,730	2.1	79.0	699	2.6
77.8	310	3.5	64.0	840	2.6	15.8	188	4.1
15.6	114	5.8	12.8	250	6.8	3.16	93	6.6
0.00	64	10.0	0.00	98	11.0	0.00	63	7.4

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ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
49900	860,000	5.3
9980	185,000	4.1
2000	38,200	6.0
399	7,630	6.4
79.8	1,530	5.5
16.0	346	4.7
3.19	107	4.5
0.00	47	7.7


Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 (human) Plate	Z0056634	2-8°C	31 May 2022
Anti-hu SAA Antibody	D0081403	2-8°C	31 Jul 2023
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	M1010029	≤ -10°C	31 Mar 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
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	Karen Hamilla	Quality		06 APR 2020