



## 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 24 months. The expiration date of M1010030 has been extended to 31 JUL 2022.

Function	Name	Signature	Date
Quality	Karen Hamilla		18 MAR 2021

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 Lot Number:** K0081605

**Expiration Date:** 31 Jul 2022

**Kit Catalog Numbers:** K15198-Series; K151SS-Series; K151SR-Series; K151SU-Series

### Precision and Accuracy 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	74.3	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%

### 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 Calibrator:

Spot	Name	Conc.	Units
1	SAA	4940000	pg/mL
2	CRP	3760000	pg/mL
3	VCAM-1	994000	pg/mL
4	ICAM-1	998000	pg/mL

## CERTIFICATE OF ANALYSIS


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### Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 (human) Plate	Z0056830	2-8°C	30 Apr 2023
Anti-hu SAA Antibody	D0081562	2-8°C	31 Mar 2024
Anti-hu CRP Antibody	D0081563	2-8°C	31 Mar 2024
Anti-hu VCAM-1 Antibody	D0081564	2-8°C	31 Mar 2024
Anti-hu ICAM-1 Antibody	D0081565	2-8°C	31 Mar 2024
Vascular Injury Panel 2 (human) Calibrator Blend	A0080249	≤ -70°C	30 Nov 2022
Diluent 101	M1010030	≤ -10°C	31 Jul 2022

Additional components may be provided to execute the assay. Additional components are not lot-specific.

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		18 MAR 2021