

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: K0081395
Expiration Date: 30 Nov 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	4960000	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	3920000	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	958000	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	1002000	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.

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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
248000	851,000	3.3	196000	971,000	2.0	47900	390,000	3.1
49600	188,000	2.7	39200	385,000	2.8	9580	94,200	2.3
9920	34,200	2.9	7840	87,500	2.7	1920	16,200	3.2
1980	6,560	6.2	1570	18,100	4.8	383	2,740	4.4
397	1,390	3.2	314	3,700	3.6	76.6	566	2.5
79.4	329	3.4	62.7	855	3.6	15.3	162	3.5
15.9	115	5.2	12.5	286	13.0	3.07	85	5.5
0.00	60	7.9	0.00	110	24.0	0.00	63	5.8

ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
50100	696,000	4.4
10000	158,000	3.9
2000	33,300	5.1
401	6,630	5.1
80.2	1,400	2.5
16.0	322	3.2
3.21	117	9.4
0.00	62	17.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0056550	2-8°C	31 Dec 2021
Anti-hu SAA Antibody	D0081230	2-8°C	30 Jun 2022
Anti-hu CRP Antibody	D0081355	2-8°C	28 Feb 2023
Anti-hu VCAM-1 Antibody	D0081299	2-8°C	30 Nov 2022
Anti-hu ICAM-1 Antibody	D0081300	2-8°C	30 Sep 2022
Vascular Injury Panel 2 (human) Calibrator Blend	A0080212	≤ -70°C	30 Nov 2021
Diluent 101	M1010037	≤ -10°C	31 Jan 2022
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Components Included in V-PLEX Plus	
MSD Wash Buffer (20x), 100mL	Not Kit Specific
Plate Seals	Not Kit Specific
Vascular Injury Control 1	Not Kit Specific
Vascular Injury Control 2	Not Kit Specific
Vascular Injury Control 3	Not Kit Specific

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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		12 DEC 2019