

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: K0081122
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	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	15.0	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%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	hu SAA	20X Calibrator	3680000	pg/mL
		Vascular Injury Control 1	49800	pg/mL
		Vascular Injury Control 2	4640	pg/mL
		Vascular Injury Control 3	597	pg/mL
2	hu CRP	20X Calibrator	3680000	pg/mL
		Vascular Injury Control 1	25100	pg/mL
		Vascular Injury Control 2	5060	pg/mL
		Vascular Injury Control 3	639	pg/mL
3	hu VCAM-1	20X Calibrator	932000	pg/mL
		Vascular Injury Control 1	13900	pg/mL
		Vascular Injury Control 2	1290	pg/mL
		Vascular Injury Control 3	160	pg/mL
4	hu ICAM-1	20X Calibrator	940000	pg/mL
		Vascular Injury Control 1	12900	pg/mL
		Vascular Injury Control 2	1320	pg/mL
		Vascular Injury Control 3	160	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
184000	699,000	3.2	184000	873,000	3.6	46600	367,000	2.0
36800	138,000	3.3	36800	352,000	3.0	9320	92,700	2.6
7360	25,100	3.3	7360	81,900	2.5	1860	16,000	2.9
1470	5,020	3.8	1470	17,400	3.8	373	2,710	2.2
294	1,050	4.0	294	3,530	3.7	74.6	553	1.9
58.9	269	5.4	58.9	804	4.4	14.9	164	4.0
11.8	110	6.1	11.8	232	4.3	2.98	85	4.7
0.00	72	9.0	0.00	91	18.0	0.00	63	8.6

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hu ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
47000	633,000	5.2
9400	139,000	3.0
1880	29,800	3.9
376	6,100	5.4
75.2	1,310	6.5
15.0	306	7.0
3.01	104	6.2
0.00	52	8.4

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0056391	2-8°C	31 Mar 2021
Anti-hu SAA Antibody	D0081155	2-8°C	31 Mar 2022
Anti-hu CRP Antibody	D0081156	2-8°C	28 Feb 2022
Anti-hu VCAM-1 Antibody	D0081188	2-8°C	30 Apr 2022
Anti-hu ICAM-1 Antibody	D0081189	2-8°C	30 Apr 2022
Vascular Injury Panel 2 (human) Calibrator Blend	A0080184	≤ -70°C	31 Mar 2021
Diluent 101	M1010033	≤ -10°C	30 Apr 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), 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>	09 JAN 2019