

**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:** K0081082

**Expiration Date:** 30 Sep 2019

**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%

**Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
1	hu SAA	20X Calibrator	4800000	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	4040000	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	1038000	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	968000	pg/mL
		Vascular Injury Control 1	12900	pg/mL
		Vascular Injury Control 2	1320	pg/mL
		Vascular Injury Control 3	160	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:

hu SAA - Spot 1		
Conc. pg/mL	ECL Signal	%CV
240000	960,000	2.0
48000	209,000	4.0
9600	37,600	2.5
1920	7,260	3.3
384	1,540	3.8
76.8	371	3.7
15.4	136	5.6
0.00	88	30.0

hu CRP - Spot 2		
Conc. pg/mL	ECL Signal	%CV
202000	1,030,000	1.9
40400	422,000	1.9
8080	98,600	1.4
1620	20,600	1.7
323	4,280	1.8
64.6	957	2.8
12.9	287	7.9
0.00	120	17.0

hu VCAM-1 - Spot 3		
Conc. pg/mL	ECL Signal	%CV
51900	472,000	3.3
10400	118,000	3.4
2080	20,800	2.3
415	3,240	4.1
83.0	662	3.0
16.6	184	3.8
3.32	92	5.3
0.00	68	6.6

hu ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
48400	985,000	5.8
9680	214,000	8.7
1940	45,000	6.2
387	8,630	7.5
77.4	1,870	9.3
15.5	399	6.1
3.10	123	5.1
0.00	58	5.9

### Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0056364	2-8°C	28 Feb 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	D0081157	2-8°C	28 Feb 2022
Anti-hu ICAM-1 Antibody	D0081158	2-8°C	31 Mar 2022
Vascular Panel 2 (human) Calibrator Blend	A0080132	≤ -70°C	30 Sep 2019
Diluent 101	M1010032	≤ -10°C	31 Jan 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

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Additional Components Included in V-PLEX Plus	
Wash Buffer (20x)	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

**Statement:**

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

	Name	Function	Signature	Date
<b>Review/Approval</b>	Dawn Stollar	Quality Assurance	<i>Dawn Stollar</i>	22 OCT 2018