

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: K0081033
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	70500	pg/mL
		Vascular Injury Control 2	6620	pg/mL
		Vascular Injury Control 3	833	pg/mL
2	hu CRP	20X Calibrator	4040000	pg/mL
		Vascular Injury Control 1	24300	pg/mL
		Vascular Injury Control 2	4900	pg/mL
		Vascular Injury Control 3	604	pg/mL
3	hu VCAM-1	20X Calibrator	1038000	pg/mL
		Vascular Injury Control 1	13900	pg/mL
		Vascular Injury Control 2	1331	pg/mL
		Vascular Injury Control 3	165	pg/mL
4	hu ICAM-1	20X Calibrator	968000	pg/mL
		Vascular Injury Control 1	16300	pg/mL
		Vascular Injury Control 2	1720	pg/mL
		Vascular Injury Control 3	209	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			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
240000	974,000	3.4	202000	1,120,000	3.3	51900	534,000	2.3
48000	203,000	4.0	40400	455,000	2.6	10400	131,000	2.9
9600	35,200	5.3	8080	103,000	4.2	2080	21,100	4.7
1920	6,660	3.5	1620	20,900	4.5	415	3,110	3.5
384	1,370	2.4	323	4,140	3.8	83.0	631	2.1
76.8	340	2.7	64.6	892	3.0	16.6	178	2.7
15.4	133	3.3	12.9	241	2.9	3.32	91	5.0
0.00	80	7.0	0.00	84	9.4	0.00	68	7.3

hu ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
48400	728,000	5.6
9680	150,000	5.1
1940	30,100	7.2
387	5,720	6.9
77.4	1,210	6.1
15.5	273	3.7
3.10	99	5.8
0.00	58	7.8

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0056289	2-8°C	30 Nov 2020
Anti-hu SAA Antibody	D0081042	2-8°C	30 Apr 2020
Anti-hu CRP Antibody	D0081021	2-8°C	31 Jan 2020
Anti-hu VCAM-1 Antibody	D0080980	2-8°C	30 Sep 2019
Anti-hu ICAM-1 Antibody	D0081043	2-8°C	30 Apr 2020
Vascular Panel 2 (human) Calibrator Blend	A0080132	≤ -70°C	30 Sep 2019
Diluent 101	M1010030	≤ -10°C	31 Jul 2020
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

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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>	12 SEP 2018