

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; K151SU-Series, K151SR-Series
Kit Lot Number: K0081336
Expiration Date: 31 Jul 2020

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	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%

Spot	Name	LLOQ			ULOQ		
		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%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	SAA	20X Calibrator	4860000	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	4000000	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	988000	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	998000	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.

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
243000	852,000	3.8	200000	906,000	11.0	49400	407,000	8.0
48600	195,000	4.7	40000	364,000	4.4	9880	103,000	3.0
9720	35,700	2.7	8000	83,500	4.7	1980	17,800	3.1
1940	7,060	1.9	1600	17,700	5.0	395	2,990	2.0
389	1,520	2.7	320	3,680	5.7	79.0	637	1.8
77.8	385	9.4	64.0	807	4.6	15.8	182	5.7
15.6	149	8.4	12.8	220	4.0	3.16	98	9.7
0.00	146	19.0	0.00	74	15.0	0.00	72	13.0

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ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
49900	732,000	6.0
9980	173,000	4.0
2000	37,100	3.7
399	7,650	5.2
79.8	1,650	4.9
16.0	372	4.0
3.19	115	5.9
0.00	50	11.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 Plate	Z0056594	2-8°C	28 Feb 2022
Anti-hu SAA Antibody	D0081298	2-8°C	30 Sep 2022
Anti-hu CRP Antibody	D0081404	2-8°C	31 May 2023
Anti-hu VCAM-1 Antibody	D0081356	2-8°C	30 Apr 2023
Anti-hu ICAM-1 Antibody	D0081357	2-8°C	30 Apr 2023
Vascular Panel 2 (human) Calibrator Blend	A0080234	≤ -70°C	31 May 2022
Diluent 101	M1010030	≤ -10°C	31 Jul 2020
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	Karen Hamilla	Quality		14 JAN 2020