

CERTIFICATE OF ANALYSIS

Page 1 of 3

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: K0081420
Expiration Date: 31 Jan 2022

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%

CERTIFICATE OF ANALYSIS

Page 2 of 3

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	871,000	3.6	200000	982,000	3.8	49400	578,000	2.0
48600	193,000	3.5	40000	409,000	2.5	9880	146,000	2.9
9720	33,900	4.6	8000	92,500	3.1	1980	25,800	3.7
1940	6,710	3.0	1600	19,500	3.4	395	3,920	4.1
389	1,430	3.7	320	4,010	3.1	79.0	805	2.6
77.8	353	4.2	64.0	906	3.0	15.8	216	3.2
15.6	131	9.5	12.8	272	8.6	3.16	97	5.6
0.00	85	15.0	0.00	123	16.0	0.00	66	9.8

CERTIFICATE OF ANALYSIS

Page 3 of 3

ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
49900	856,000	5.2
9980	186,000	5.6
2000	38,500	4.4
399	7,490	3.7
79.8	1,560	4.6
16.0	355	3.7
3.19	109	7.8
0.00	48	9.5

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 (human) Plate	Z0056658	2-8°C	30 Jun 2022
Anti-hu SAA Antibody	D0081433	2-8°C	31 Jul 2023
Anti-hu CRP Antibody	D0081434	2-8°C	30 Jun 2023
Anti-hu VCAM-1 Antibody	D0081435	2-8°C	30 Jun 2023
Anti-hu ICAM-1 Antibody	D0081436	2-8°C	30 Jun 2023
Vascular Injury Panel 2 (human) Calibrator Blend	A0080234	≤ -70°C	31 May 2022
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	
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		23 APR 2020