

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; K151SR-Series; K151SU-Series

Kit Lot Number: K0081435

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%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	SAA	20X Calibrator	4940000	pg/mL
		Vascular Injury Control 1	48500	pg/mL
		Vascular Injury Control 2	4720	pg/mL
		Vascular Injury Control 3	607	pg/mL
2	CRP	20X Calibrator	3760000	pg/mL
		Vascular Injury Control 1	24600	pg/mL
		Vascular Injury Control 2	4800	pg/mL
		Vascular Injury Control 3	610	pg/mL
3	VCAM-1	20X Calibrator	994000	pg/mL
		Vascular Injury Control 1	16600	pg/mL
		Vascular Injury Control 2	1600	pg/mL
		Vascular Injury Control 3	200	pg/mL
4	ICAM-1	20X Calibrator	998000	pg/mL
		Vascular Injury Control 1	13000	pg/mL
		Vascular Injury Control 2	1350	pg/mL
		Vascular Injury Control 3	166	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:

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
247000	876,000	2.7	188000	1,000,000	3.1	49700	546,000	1.8
49400	187,000	3.6	37600	359,000	3.5	9940	139,000	3.1
9880	33,200	4.0	7520	78,000	4.0	1990	23,900	3.8
1980	6,400	2.5	1500	15,900	4.8	398	3,830	3.4
395	1,340	3.3	301	3,300	4.2	79.5	783	2.0
79.0	323	3.5	60.2	798	6.7	15.9	203	2.9
15.8	118	6.2	12.0	266	12.0	3.18	93	3.5
0.00	69	7.5	0.00	150	20.0	0.00	66	7.1

ICAM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
49900	743,000	5.6
9980	160,000	4.8
2000	32,600	5.1
399	6,390	5.1
79.8	1,340	4.4
16.0	303	4.4
3.19	103	7.8
0.00	60	15.0

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Panel 2 (human) Plate	Z0056665	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	A0080249	≤ -70°C	30 Nov 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), 100 mL	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		17 SEP 2020