

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15162C-Series
Kit Lot Number: K0040481
Expiration Date: 28 Feb 2022

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Kidney Injury Panel 1 Control 1		Kidney Injury Panel 1 Control 2		Kidney Injury Panel 1 Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Lipocalin-2	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	Osteopontin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	Albumin	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	TIM-1	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	Lipocalin-2	1.56	70% - 130%*	< 20%*	150	80% - 120%*	< 20%
2	Osteopontin	0.390	80% - 120%	< 20%	37.5	80% - 120%	< 20%
3	Albumin	781	80% - 120%	< 20%	33200	80% - 120%	< 20%
4	TIM-1	0.0200	80% - 120%	< 20%	1.88	80% - 120%	< 20%

* See Additional Comments.

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	Lipocalin-2	Osteopontin	Albumin	TIM-1
1	Lipocalin-2	NA	< 1.0%	< 1.0%	< 1.0%
2	Osteopontin	< 5.0%	NA	< 1.0%	< 1.0%
3	Albumin	< 1.0%	< 1.0%	NA	< 1.0%
4	TIM-1	< 1.0%	< 1.0%	< 1.0%	NA

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Lipocalin-2	20X Calibrator	4180	ng/mL
		Kidney Injury Panel 1 Control 1	879	ng/mL
		Kidney Injury Panel 1 Control 2	338	ng/mL
		Kidney Injury Panel 1 Control 3	119	ng/mL
2	Osteopontin	20X Calibrator	928	ng/mL
		Kidney Injury Panel 1 Control 1	209	ng/mL
		Kidney Injury Panel 1 Control 2	68.9	ng/mL
		Kidney Injury Panel 1 Control 3	27	ng/mL
3	Albumin	20X Calibrator	890000	ng/mL
		Kidney Injury Panel 1 Control 1	182000	ng/mL
		Kidney Injury Panel 1 Control 2	96200	ng/mL
		Kidney Injury Panel 1 Control 3	55500	ng/mL
4	TIM-1	20X Calibrator	179	ng/mL
		Kidney Injury Panel 1 Control 1	9.38	ng/mL
		Kidney Injury Panel 1 Control 2	3.1	ng/mL
		Kidney Injury Panel 1 Control 3	1.16	ng/mL

Control data was generated utilizing internal reference controls.

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:

Lipocalin-2 - Spot 1			Osteopontin - Spot 2			Albumin - Spot 3		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
209	14,200	2.8	46.4	81,700	3.2	44500	517	3.4
69.7	7,610	1.4	15.5	21,100	4.5	14800	1,230	2.2
23.2	4,000	3.8	5.16	4,240	5.0	4940	3,060	1.9
7.74	2,180	3.1	1.72	1,010	6.6	1650	6,810	1.6
2.58	1,350	4.3	0.573	315	5.8	549	13,200	1.7
0.860	1,060	4.8	0.191	143	7.2	183	19,500	1.5
0.287	946	7.1	0.0636	93	15.0	61.0	23,700	1.4
0.00	812	8.3	0.00	58	14.0	0.00	26,400	1.4

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TIM-1 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
8.97	218,000	1.4
2.99	85,500	1.6
0.997	30,900	2.7
0.332	10,600	2.5
0.111	3,670	3.8
0.0369	1,310	1.9
0.0123	487	2.1
0.00	82	4.8

Components:


Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 1 (rat) Plate	Z0056586	2-8°C	28 Feb 2022
Anti-rat Lipocalin-2 Antibody	D0040878	2-8°C	30 Apr 2023
Anti-rat Osteopontin Antibody	D0040879	2-8°C	28 Feb 2023
Rat Albumin Tracer	D0040877	2-8°C	28 Feb 2023
Anti-rat TIM-1/KIM-1/HAVCR Antibody	D0040880	2-8°C	30 Apr 2023
Kidney Injury Panel 1 (rat) Calibrator Blend	A0040240	≤ -70°C	30 Apr 2022
Blocker A Solution	Not Kit Specific	Not Kit Specific	N/A
Diluent 29	M0290026	≤ -10°C	31 May 2022
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Comments:

	Assay	Spot	Specification	Comment
1	Lipocalin-2	1	LLOQ Conc.	LLOQ % Recovery = 30.9%
2	Lipocalin-2	1	LLOQ CV	Interplate CV = 45.5% Intraplate CV = 38.0%
3	Lipocalin-2	1	ULOQ Conc.	ULOQ % Recovery = 127.2%

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		20 APR 2020