

**CERTIFICATE OF ANALYSIS**

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**Product Description:** Kidney Injury Panel 1 (rat) Kit  
**Kit Catalog Numbers:** K15162C-Series  
**Kit Lot Number:** K0040452  
**Expiration Date:** 30 Apr 2021

**Acceptance Data/ Percent Recovery Specifications:**

Spot	Name	Calibrator		Kidney Injury Panel 1 (rat) Control 1		Kidney Injury Panel 1 (rat) Control 2		Kidney Injury Panel 1 (rat) 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%

**Acceptance Data/ Non Specific Binding Specifications:**

Spot	Name	Lipocalin	Osteopontin	Albumin	TIMP-1
1	Lipocalin	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	TIMP-1	< 1.0%	< 1.0%	< 1.0%	NA

**Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
1	Lipocalin-2	20X Calibrator	4600	ng/mL
		Kidney Injury Panel 1 (rat) Control 1	1580	ng/mL
		Kidney Injury Panel 1 (rat) Control 2	674	ng/mL
		Kidney Injury Panel 1 (rat) Control 3	217	ng/mL
2	Osteopontin	20X Calibrator	1036	ng/mL
		Kidney Injury Panel 1 (rat) Control 1	442	ng/mL
		Kidney Injury Panel 1 (rat) Control 2	86.6	ng/mL
		Kidney Injury Panel 1 (rat) Control 3	16	ng/mL
3	Albumin	20X Calibrator	980000	ng/mL
		Kidney Injury Panel 1 (rat) Control 1	152300	ng/mL
		Kidney Injury Panel 1 (rat) Control 2	77500	ng/mL
		Kidney Injury Panel 1 (rat) Control 3	22500	ng/mL
4	TIM-1	20X Calibrator	197	ng/mL
		Kidney Injury Panel 1 (rat) Control 1	19.9	ng/mL
		Kidney Injury Panel 1 (rat) Control 2	3.3	ng/mL
		Kidney Injury Panel 1 (rat) Control 3	0.97	ng/mL

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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
230	16,600	3.9	51.8	127,000	2.4	49000	485	4.5
76.7	8,630	2.6	17.3	33,400	3.9	16300	1,040	4.1
25.6	4,290	1.9	5.76	6,870	11.0	5440	2,580	2.9
8.52	2,210	1.8	1.92	1,430	3.0	1810	5,910	1.3
2.84	1,320	1.1	0.640	440	3.6	605	11,100	1.7
0.947	1,070	1.1	0.213	190	4.5	202	16,500	1.9
0.316	957	1.4	0.0711	119	9.8	67.2	19,800	1.9
0.00	925	0.9	0.00	79	11.0	0.00	22,100	2.1


TIM-1 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
9.86	254,000	2.3
3.29	96,900	1.3
1.10	33,200	1.5
0.365	10,800	3.2
0.122	3,730	1.9
0.0406	1,300	1.4
0.0135	500	1.8
0.00	99	6.8

**Components:**

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 1 (rat) Plate	Z0056546	2-8°C	31 Dec 2021
Anti-rat Lipocalin-2 Antibody	D0040814	2-8°C	31 Mar 2022
Anti-rat Osteopontin Antibody	D0040815	2-8°C	30 Jun 2022
Albumin Tracer	D0040813	2-8°C	31 Mar 2022
Anti-rat TIM-1/KIM-1/HAVCR Antibody	D0040816	2-8°C	31 Jul 2022
Kidney Injury Panel 1 (rat) Calibrator Blend	A0040225	≤ -70°C	30 Apr 2021
Blocker A	Not Kit Specific	Not Kit Specific	N/A
Diluent 29	M0290025	≤ -10°C	31 Dec 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

**Statement:**

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
<b>Review/Approval</b>	Karen Hamilla	Quality		20 AUG 2019