

CERTIFICATE OF ANALYSIS

Page 1 of 3

Product Description: Kidney Injury Panel 1 (rat) Kit

Kit Catalog Numbers: K15162C-Series

Kit Lot Number: K0040390

Expiration Date: 28 Feb 2019

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-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

CERTIFICATE OF ANALYSIS

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Lipocalin-2	20X Calibrator	4270	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	1007	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	1283000	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	50.2	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	0.972	ng/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:

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
214	12,800	5.3	50.4	134,000	3.6	64200	385	3.4
71.2	6,390	2.9	16.8	35,400	2.2	21400	986	2.7
23.7	3,160	2.5	5.59	7,330	2.3	7130	2,480	2.5
7.91	1,780	2.4	1.86	1,770	1.5	2380	5,760	2.2
2.64	1,160	3.7	0.622	568	4.8	792	11,700	2.7
0.879	953	6.4	0.207	294	13.0	264	18,800	2.7
0.293	839	7.8	0.0691	197	18.0	88.0	24,000	2.7
0.00	855	8.1	0.00	158	26.0	0.00	27,900	4.7

CERTIFICATE OF ANALYSIS


TIM-1 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
2.51	86,000	2.2
0.837	28,700	2.1
0.279	9,870	3.2
0.0930	3,330	2.8
0.0310	1,210	2.3
0.0103	497	4.1
0.00344	260	8.5
0.00	157	17.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 1 (rat) Plate	Z0055969	2-8°C	30 Nov 2019
Anti-rat Lipocalin-2 Antibody	D0040686	2-8°C	31 Aug 2019
Anti-rat Osteopontin Antibody	D0040687	2-8°C	31 Aug 2019
Albumin Tracer	D0040685	2-8°C	31 Aug 2019
Anti-rat TIM-1/KIM-1/HAVCR Antibody	D0040688	2-8°C	31 Aug 2019
Kidney Injury Panel 1 (rat) Calibrator Blend	A0040174	≤ -70°C	28 Feb 2019
Blocker A Kit	Not Kit Specific	Not Kit Specific	N/A
Diluent 29	M0290023	≤ -10°C	31 Oct 2019
Read Buffer T (4X)	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
Review/Approval	Dawn Stollar	Quality Assurance		27 FEB 2018