

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040438
Expiration Date: 31 Jan 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		KIP-3 Control 1		KIP-3 Control 2	
		Recovery	CV	Recovery	CV	Recovery	CV
1	alpha GST	80% - 120%	< 20%	75% - 125%*	< 20%*	75% - 125%*	< 20%*
2	Calbindin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	Clusterin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	KIM-1	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
5	Osteoactivin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
6	TFF3	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
7	VEGF	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

* See Additional Comments.

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	alpha GST	< 1.0%
2	Calbindin	< 1.0%
3	Clusterin	< 1.0%
4	KIM-1	< 1.0%
5	Osteoactivin	< 1.0%
6	TFF3	< 1.0%
7	VEGF	< 1.0%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	alpha GST	20X Calibrator	40000	pg/mL
		KIP-3 Control 1	8690	pg/mL
		KIP-3 Control 2	463	pg/mL
2	Calbindin	20X Calibrator	644000	pg/mL
		KIP-3 Control 1	93700	pg/mL
		KIP-3 Control 2	5810	pg/mL
3	Clusterin	20X Calibrator	4960000	pg/mL
		KIP-3 Control 1	696000	pg/mL
		KIP-3 Control 2	45200	pg/mL
4	KIM-1	20X Calibrator	530000	pg/mL
		KIP-3 Control 1	73200	pg/mL
		KIP-3 Control 2	4570	pg/mL
5	Osteoactivin	20X Calibrator	956000	pg/mL
		KIP-3 Control 1	142000	pg/mL
		KIP-3 Control 2	9810	pg/mL
6	TFF3	20X Calibrator	48000	pg/mL
		KIP-3 Control 1	6250	pg/mL
		KIP-3 Control 2	464	pg/mL
7	VEGF	20X Calibrator	56600	pg/mL
		KIP-3 Control 1	8690	pg/mL
		KIP-3 Control 2	599	pg/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:

alpha GST - Spot 1			Calbindin - Spot 2			Clusterin - Spot 3		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
2000	83,700	6.9	32200	989,000	2.9	248000	367,000	2.1
500	18,800	6.8	8050	206,000	5.9	62000	112,000	3.3
125	4,060	6.8	2010	31,400	5.1	15500	27,700	6.4
31.3	1,070	6.2	503	5,760	5.6	3880	7,830	3.0
7.81	389	6.1	126	1,510	5.1	969	2,640	3.5
1.95	240	5.1	31.4	587	2.5	242	1,520	3.1
0.488	207	7.5	7.86	367	3.1	60.5	1,180	1.3
0.00	188	6.4	0.00	297	4.9	0.00	1,100	1.8

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KIM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
26500	526,000	4.2
6630	185,000	3.3
1660	41,300	3.9
414	9,270	3.4
104	2,230	3.4
25.9	639	4.8
6.47	247	5.1
0.00	120	8.0

Osteoactivin - Spot 5		
Conc. pg/mL	ECL Signal	%CV
47800	132,000	3.9
12000	42,000	3.7
2990	11,900	4.5
747	3,360	4.0
187	1,270	4.2
46.7	727	3.5
11.7	616	2.7
0.00	551	2.5

TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
2400	134,000	5.3
600	27,500	2.9
150	5,830	3.5
37.5	1,480	5.8
9.38	503	8.6
2.34	255	5.5
0.586	199	8.1
0.00	199	14.0

VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2830	629,000	1.7
708	121,000	2.6
177	22,600	2.6
44.2	5,030	3.7
11.1	1,390	1.8
2.76	490	2.6
0.691	298	3.7
0.00	228	10.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056330	2-8°C	31 Jan 2021
Anti-hu alphaGST Antibody	D0040793	2-8°C	31 Jan 2022
Anti-hu Calbindin Antibody	D0040794	2-8°C	31 Mar 2022
Anti-hu Clusterin Antibody	D0040795	2-8°C	31 Jan 2022
Anti-hu KIM-1 Antibody	D0040796	2-8°C	31 Jan 2022
Anti-hu Osteoactivin Antibody	D0040797	2-8°C	28 Feb 2022
Anti-hu TFF3 Antibody	D0040798	2-8°C	31 Jan 2022
Anti-hu VEGF Antibody	D0040799	2-8°C	31 Jan 2022
Kidney Injury Panel 3 (human) Calibrator Blend	A0040212	≤ -70°C	31 Jan 2021
Blocker A	Not Kit Specific	Not Kit Specific	N/A
Diluent 37	M0370021	≤ -10°C	28 Feb 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

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Additional Comments:

	Assay	Spot	Specification	Comment
1	alpha GST	1	Control Conc.	Control-1 recovery: 12.2%; Control-2 recovery: 7.2%
2	alpha GST	1	Control CV	Control-2 CV: 32.8%

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	<i>Dawn Stollar</i>	13 NOV 2018