

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040465
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	αGST	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	αGST	< 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%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	αGST	20X Calibrator	328000	pg/mL
		KIP-3 Control 1	16300	pg/mL
		KIP-3 Control 2	3523	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

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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:

αGST - 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
16400	96,600	8.1	32200	1,260,000	4.6	248000	413,000	4.4
4100	19,900	8.2	8050	256,000	4.9	62000	120,000	5.5
1030	4,160	5.0	2010	40,700	4.2	15500	29,900	6.4
256	987	7.8	503	7,290	4.5	3880	8,110	4.9
64.1	326	6.6	126	1,770	4.8	969	2,290	4.6
16.0	160	4.3	31.4	611	3.9	242	974	3.5
4.00	118	6.7	7.86	338	3.8	60.5	616	3.2
0.00	102	8.7	0.00	246	5.8	0.00	515	4.3

KIM-1 - Spot 4			Osteoactivin - Spot 5			TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
26500	639,000	3.0	47800	152,000	4.8	2400	162,000	7.4
6630	217,000	1.9	12000	46,700	5.2	600	30,600	5.9
1660	48,100	4.1	2990	13,200	5.2	150	6,770	8.3
414	10,700	3.4	747	3,780	4.9	37.5	1,740	3.5
104	2,540	3.0	187	1,350	3.5	9.38	617	17.0
25.9	701	3.4	46.7	787	12.0	2.34	273	4.1
6.47	261	3.3	11.7	615	2.3	0.586	204	8.4
0.00	109	5.9	0.00	551	2.0	0.00	159	10.0

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VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2830	688,000	3.7
708	120,000	1.6
177	23,100	2.9
44.2	5,040	3.4
11.1	1,370	3.4
2.76	490	3.9
0.691	280	3.4
0.00	211	4.5

Components:


Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056330	2-8°C	31 Jan 2021
Anti-hu αGST Antibody	D0040793	2-8°C	31 Jan 2022
Anti-hu Calbindin Antibody	D0040836	2-8°C	31 Jan 2023
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

Additional Comments:

Assay	Spot	Specification	Comment
1 αGST	1	Control Conc.	Low Control-2 recovery 14.8% (specs 75-125%)
2 αGST	1	Control CV	High control-2 CV 20.1 % (specs NMT 20%)

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		13 JAN 2020