

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040483
Expiration Date: 31 Mar 2022

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%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	αGST	20X Calibrator	534000	pg/mL
		KIP-3 Control 1	12900	pg/mL
		KIP-3 Control 2	602	pg/mL
2	Calbindin	20X Calibrator	428000	pg/mL
		KIP-3 Control 1	105000	pg/mL
		KIP-3 Control 2	6580	pg/mL
3	Clusterin	20X Calibrator	4000000	pg/mL
		KIP-3 Control 1	719000	pg/mL
		KIP-3 Control 2	51000	pg/mL
4	KIM-1	20X Calibrator	510000	pg/mL
		KIP-3 Control 1	79000	pg/mL
		KIP-3 Control 2	5050	pg/mL
5	Osteoactivin	20X Calibrator	736000	pg/mL
		KIP-3 Control 1	151000	pg/mL
		KIP-3 Control 2	10700	pg/mL
6	TFF3	20X Calibrator	48000	pg/mL
		KIP-3 Control 1	6480	pg/mL
		KIP-3 Control 2	438	pg/mL
7	VEGF	20X Calibrator	47600	pg/mL
		KIP-3 Control 1	9070	pg/mL
		KIP-3 Control 2	623	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
26700	156,000	7.5	21400	829,000	4.6	200000	411,000	2.8
6680	36,700	11.0	5350	148,000	6.4	50000	118,000	5.5
1670	8,060	7.5	1340	22,400	3.3	12500	30,600	2.0
417	2,120	9.6	334	4,280	4.9	3130	9,330	3.1
104	751	14.0	83.6	1,200	6.1	781	4,100	4.3
26.1	410	8.9	20.9	499	5.5	195	2,990	5.3
6.52	337	8.0	5.22	330	5.8	48.8	2,640	5.2
0.00	312	11.0	0.00	275	4.5	0.00	2,550	9.2

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KIM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
25500	639,000	3.7
6380	217,000	2.5
1590	48,100	3.6
398	10,900	4.2
99.6	2,690	3.2
24.9	755	4.5
6.23	276	4.0
0.00	116	5.9

Osteoactivin - Spot 5		
Conc. pg/mL	ECL Signal	%CV
36800	192,000	4.6
9200	58,900	5.1
2300	16,600	3.2
575	4,680	4.9
144	1,840	3.6
35.9	1,090	4.4
8.98	917	4.8
0.00	840	4.1

TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
2400	130,000	6.3
600	26,400	7.8
150	5,720	8.4
37.5	1,530	6.0
9.38	545	6.1
2.34	296	5.2
0.586	241	7.0
0.00	234	14.0

VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2380	645,000	3.5
595	152,000	3.8
149	35,900	4.1
37.2	8,840	3.8
9.30	2,430	4.5
2.32	831	4.1
0.581	427	3.3
0.00	286	5.9

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056611	2-8°C	31 Mar 2022
Anti-hu αGST Antibody	D0040882	2-8°C	31 Mar 2023
Anti-hu Calbindin Antibody	D0040883	2-8°C	30 Jun 2023
Anti-hu Clusterin Antibody	D0040884	2-8°C	31 May 2023
Anti-hu KIM-1 Antibody	D0040885	2-8°C	31 Mar 2023
Anti-hu Osteoactivin Antibody	D0040886	2-8°C	31 Mar 2023
Anti-hu TFF3 Antibody	D0040887	2-8°C	31 Mar 2023
Anti-hu VEGF Antibody	D0040888	2-8°C	31 May 2023
Kidney Injury Panel 3 (human) Calibrator Blend	A0040239	≤ -70°C	31 Jul 2022
Diluent 37	M0370029	≤ -10°C	31 Jul 2022
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

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Additional Comments:

	Assay	Spot	Specification	Comment
1	αGST	1	Calibrator CV	Calibrator-5 CV 21.4% (Specifications NMT 20%)
2	αGST	1	Control Conc.	Control-1 recovery 234.3% and Control-2 recovery 138.6% (Specifications 75-125%)
3	αGST	1	Control CV	Control-1 CV 44.0% and Control-2 CV 27.9% (Specifications 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		01 APR 2020