

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040397
Expiration Date: 30 Jun 2019

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	38000	pg/mL
		KIP-3 Control 1	8690	pg/mL
		KIP-3 Control 2	463	pg/mL
2	Calbindin	20X Calibrator	498000	pg/mL
		KIP-3 Control 1	93700	pg/mL
		KIP-3 Control 2	5810	pg/mL
3	Clusterin	20X Calibrator	4040000	pg/mL
		KIP-3 Control 1	696000	pg/mL
		KIP-3 Control 2	45200	pg/mL
4	KIM-1	20X Calibrator	394000	pg/mL
		KIP-3 Control 1	73200	pg/mL
		KIP-3 Control 2	4570	pg/mL
5	Osteoactivin	20X Calibrator	768000	pg/mL
		KIP-3 Control 1	142000	pg/mL
		KIP-3 Control 2	9810	pg/mL
6	TFF3	20X Calibrator	36000	pg/mL
		KIP-3 Control 1	6250	pg/mL
		KIP-3 Control 2	464	pg/mL
7	VEGF	20X Calibrator	47800	pg/mL
		KIP-3 Control 1	8690	pg/mL
		KIP-3 Control 2	599	pg/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:

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
1900	73,700	13.0	24900	1,200,000	4.9	202000	705,000	4.3
475	14,200	7.8	6230	220,000	4.1	50500	208,000	3.3
119	3,190	6.6	1560	34,900	4.2	12600	47,000	3.9
29.7	809	9.9	389	6,310	5.0	3160	12,600	5.7
7.42	281	7.7	97.3	1,620	4.0	789	3,170	4.7
1.86	165	6.6	24.3	646	2.8	197	1,150	3.2
0.464	135	8.9	6.08	401	4.1	49.3	536	5.3
0.00	116	8.1	0.00	318	3.9	0.00	413	7.7

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KIM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
19700	789,000	2.8
4930	276,000	2.5
1230	67,500	2.0
308	15,500	2.7
77.0	3,720	2.6
19.2	1,070	3.0
4.81	384	4.0
0.00	163	7.3

Osteoactivin - Spot 5		
Conc. pg/mL	ECL Signal	%CV
38400	212,000	5.2
9600	65,500	3.6
2400	18,900	4.9
600	5,090	4.5
150	1,810	3.9
37.5	947	3.5
9.38	753	4.1
0.00	705	12.0

TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
1800	184,000	7.6
450	36,400	5.5
113	7,850	7.1
28.1	1,930	6.7
7.03	768	23.0
1.76	364	20.0
0.439	244	9.1
0.00	210	21.0

VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2390	788,000	2.6
598	127,000	2.2
149	22,900	3.8
37.3	4,880	2.6
9.34	1,350	1.6
2.33	501	3.4
0.583	289	3.8
0.00	224	7.1

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0055975	2-8°C	30 Nov 2019
Anti-hu αGST Antibody	D0040705	2-8°C	31 Jan 2020
Anti-hu Calbindin Antibody	D0040706	2-8°C	30 Nov 2019
Anti-hu Clusterin Antibody	D0040707	2-8°C	30 Nov 2019
Anti-hu KIM-1 Antibody	D0040708	2-8°C	30 Nov 2019
Anti-hu Osteoactivin Antibody	D0040709	2-8°C	30 Nov 2019
Anti-hu TFF3 Antibody	D0040710	2-8°C	30 Nov 2019
Anti-hu VEGF Antibody	D0040711	2-8°C	31 Dec 2019
Kidney Injury Panel 3 (human) Calibrator Blend	A0040188	≤ -70°C	31 Aug 2019
Blocker A Kit	Not Kit Specific	Not Kit Specific	N/A
Diluent 37	M0370019	≤ -10°C	30 Jun 2019
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	Control Conc.	High control-1 recovery at 128% and high control-2 recovery at 196.4% (Specifications 75-125%)
2	αGST	1	Control CV	High CV for Control-2 at 23.7% (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	Dawn Stollar	Quality Assurance	<i>Dawn Stollar</i>	09 JAN 2018