

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040440
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%

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	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

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Standard Curve Data:

αGST - Spot 1		
Conc. pg/mL	ECL Signal	%CV
2000	108,000	15.0
500	26,600	8.0
125	6,190	11.0
31.3	1,530	9.9
7.81	501	5.7
1.95	250	7.4
0.488	190	4.7
0.00	168	5.7

Calbindin - Spot 2		
Conc. pg/mL	ECL Signal	%CV
32200	1,120,000	3.1
8050	243,000	5.1
2010	35,100	3.9
503	5,630	7.2
126	1,570	3.9
31.4	761	3.3
7.86	578	3.3
0.00	485	6.5

Clusterin - Spot 3		
Conc. pg/mL	ECL Signal	%CV
248000	769,000	6.5
62000	253,000	4.3
15500	61,200	4.8
3880	16,000	5.1
969	4,460	3.0
242	1,840	5.4
60.5	1,110	5.0
0.00	930	7.2

KIM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
26500	868,000	3.7
6630	337,000	3.0
1660	83,000	3.3
414	19,100	3.0
104	4,960	4.7
25.9	1,580	3.9
6.47	743	4.1
0.00	474	3.6

Osteoactivin - Spot 5		
Conc. pg/mL	ECL Signal	%CV
47800	259,000	4.2
12000	91,600	5.6
2990	26,100	5.4
747	7,050	2.7
187	2,640	2.1
46.7	1,520	3.8
11.7	1,230	3.3
0.00	1,160	3.4

TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
2400	247,000	4.1
600	56,600	4.0
150	12,200	4.3
37.5	3,110	5.0
9.38	1,030	4.6
2.34	522	7.3
0.586	381	6.4
0.00	330	7.4


VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2830	526,000	8.2
708	93,600	6.7
177	16,300	9.4
44.2	3,280	9.8
11.1	1,010	8.7
2.76	409	9.3
0.691	284	9.5
0.00	229	11.0

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0055948	2-8°C	30 Nov 2019
Anti-hu αGST Antibody	D0040677	2-8°C	31 Jul 2019
Anti-hu Calbindin Antibody	D0040678	2-8°C	31 Jul 2019
Anti-hu Clusterin Antibody	D0040679	2-8°C	31 Jul 2019
Anti-hu KIM-1 Antibody	D0040680	2-8°C	31 Aug 2019
Anti-hu Osteoactivin Antibody	D0040681	2-8°C	31 Jul 2019
Anti-hu TFF3 Antibody	D0040682	2-8°C	30 Sep 2019
Anti-hu VEGF Antibody	D0040683	2-8°C	31 Jul 2019
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	M0370019	≤ -10°C	30 Jun 2019
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Statement:

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance		18 SEP 2018