

**CERTIFICATE OF ANALYSIS**

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**Product Description:** Kidney Injury Panel 3 (human) Kit  
**Kit Catalog Numbers:** K15189D-Series  
**Kit Lot Number:** K0040388  
**Expiration Date:** 30 Jun 2019

**Acceptance Data/ Percent Recovery Specifications:**

Spot	Name	Calibrator		Kidney Injury Control 1		Kidney Injury 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
		Kidney Injury Control 1	8690	pg/mL
		Kidney Injury Control 2	463	pg/mL
2	Calbindin	20X Calibrator	498000	pg/mL
		Kidney Injury Control 1	93700	pg/mL
		Kidney Injury Control 2	5810	pg/mL
3	Clusterin	20X Calibrator	4040000	pg/mL
		Kidney Injury Control 1	696000	pg/mL
		Kidney Injury Control 2	45200	pg/mL
4	KIM-1	20X Calibrator	394000	pg/mL
		Kidney Injury Control 1	73200	pg/mL
		Kidney Injury Control 2	4570	pg/mL
5	Osteoactivin	20X Calibrator	768000	pg/mL
		Kidney Injury Control 1	142000	pg/mL
		Kidney Injury Control 2	9810	pg/mL
6	TFF3	20X Calibrator	36000	pg/mL
		Kidney Injury Control 1	6250	pg/mL
		Kidney Injury Control 2	464	pg/mL
7	VEGF	20X Calibrator	47800	pg/mL
		Kidney Injury Control 1	8690	pg/mL
		Kidney Injury 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	43,200	9.9	24900	845,000	2.9	202000	525,000	5.3
475	8,960	14.0	6230	168,000	2.7	50500	155,000	3.7
119	1,950	12.0	1560	23,300	4.5	12600	36,000	4.5
29.7	548	4.8	389	4,100	5.0	3160	9,450	4.6
7.42	251	11.0	97.3	1,150	3.2	789	2,670	2.9
1.86	178	12.0	24.3	528	5.5	197	1,130	3.0
0.464	160	13.0	6.08	384	4.8	49.3	657	4.2
0.00	160	29.0	0.00	330	7.5	0.00	595	7.7

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KIM-1 - Spot 4		
Conc. pg/mL	ECL Signal	%CV
19700	620,000	3.4
4930	209,000	3.2
1230	50,100	3.8
308	11,800	2.8
77.0	3,030	2.3
19.2	873	3.1
4.81	335	4.2
0.00	168	13.0

Osteoactivin - Spot 5		
Conc. pg/mL	ECL Signal	%CV
38400	159,000	3.1
9600	50,400	3.4
2400	13,900	4.9
600	3,770	2.7
150	1,420	3.7
37.5	814	4.0
9.38	650	4.3
0.00	599	4.1

TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV
1800	144,000	5.4
450	28,900	4.1
113	6,250	4.4
28.1	1,590	6.8
7.03	584	6.8
1.76	327	12.0
0.439	302	14.0
0.00	304	14.0

VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2390	399,000	11.0
598	66,700	7.1
149	11,300	8.7
37.3	2,260	13.0
9.34	666	13.0
2.33	254	14.0
0.583	160	8.6
0.00	129	16.0

**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	A0040188	≤ -70°C	31 Aug 2019
Blocker A Solution	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	Calibrator CV	High Intraplate %CV 29.9% and High Interplate %CV 28.1%
2	αGST	1	Control Conc.	High Control-1 recovery 127.8% and High Control-2 recovery 125.9%

**Statement:**

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
<b>Review/Approval</b>	Dawn Stollar	Quality Assurance	<i>Dawn Stollar</i>	23 JUN 2017