

## CERTIFICATE OF ANALYSIS

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**Product Description:** Kidney Injury Panel 5 (human) Kit  
**Kit Catalog Numbers:** K15188D-series  
**Kit Lot Number:** K0040404  
**Expiration Date:** 31 Oct 2019

### Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Control 1		Control 2		Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	Albumin	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	B2M	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	Cystatin C	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
4	EGF	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
5	NGAL	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
6	OPN	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
7	UMOD	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

### Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	Albumin	B2M	Cystatin C	EGF	NGAL
1	Albumin	NA	< 1.0%	< 1.0%	< 1.0%	< 1.0%
2	B2M	< 1.0%	NA	< 1.0%	< 1.0%	< 1.0%
3	Cystatin C	< 1.0%	< 1.0%	NA	< 1.0%	< 1.0%
4	EGF	< 1.0%	< 1.0%	< 1.0%	NA	< 1.0%
5	NGAL	< 1.0%	< 1.0%	< 1.0%	< 1.0%	NA
6	OPN	< 1.0%	< 1.0%	< 1.0%	< 1.0%	< 1.0%
7	UMOD	< 1.0%	< 1.0%	< 1.0%	< 1.0%	< 1.0%

Spot	Name	OPN	UMOD
1	Albumin	< 1.0%	< 1.0%
2	B2M	< 1.0%	< 1.0%
3	Cystatin C	< 1.0%	< 1.0%
4	EGF	< 1.0%	< 1.0%
5	NGAL	< 1.0%	< 1.0%
6	OPN	NA	< 3.0%
7	UMOD	< 1.0%	NA

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**Stock Concentration of Material Tested :**

Spot	Name	Item	Conc	Units
1	Albumin	20X Calibrator	4020000	pg/mL
		Control 1	533500	pg/mL
		Control 2	131500	pg/mL
		Control 3	35950	pg/mL
2	B2M	20X Calibrator	436000	pg/mL
		Control 1	77250	pg/mL
		Control 2	21550	pg/mL
		Control 3	4525	pg/mL
3	Cystatin C	20X Calibrator	838000	pg/mL
		Control 1	186500	pg/mL
		Control 2	40500	pg/mL
		Control 3	10550	pg/mL
4	EGF	20X Calibrator	10040	pg/mL
		Control 1	2995	pg/mL
		Control 2	674	pg/mL
		Control 3	201	pg/mL
5	NGAL	20X Calibrator	220000	pg/mL
		Control 1	38900	pg/mL
		Control 2	9610	pg/mL
		Control 3	2390	pg/mL
6	OPN	20X Calibrator	1930000	pg/mL
		Control 1	312000	pg/mL
		Control 2	83100	pg/mL
		Control 3	21300	pg/mL
7	UMOD	20X Calibrator	2200000	pg/mL
		Control 1	383500	pg/mL
		Control 2	101550	pg/mL
		Control 3	25400	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

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## Standard Curve Data:

Albumin - Spot 1		
Conc. pg/mL	ECL Signal	%CV
201000	177,000	6.9
50300	49,700	7.6
12600	10,800	7.6
3140	2,700	6.3
785	1,020	7.3
196	638	8.2
49.1	547	8.9
0.00	515	11.0

B2M - Spot 2		
Conc. pg/mL	ECL Signal	%CV
21800	76,500	7.2
5450	31,000	8.7
1360	8,100	9.4
341	1,950	10.0
85.2	642	5.7
21.3	311	3.9
5.32	238	3.7
0.00	220	8.4

Cystatin C - Spot 3		
Conc. pg/mL	ECL Signal	%CV
41900	486,000	3.0
10500	206,000	6.5
2620	32,600	5.8
655	5,300	3.8
164	1,210	3.4
40.9	528	4.2
10.2	333	5.4
0.00	332	13.0

EGF - Spot 4		
Conc. pg/mL	ECL Signal	%CV
502	635,000	4.7
126	155,000	7.0
31.4	29,600	7.5
7.84	5,750	7.2
1.96	1,400	6.1
0.490	407	7.8
0.123	170	5.1
0.00	93	7.0

NGAL - Spot 5		
Conc. pg/mL	ECL Signal	%CV
11000	266,000	4.0
2750	64,500	4.2
688	15,500	5.0
172	3,640	4.8
43.0	1,020	4.5
10.7	389	3.6
2.69	250	5.3
0.00	206	7.9

OPN - Spot 6		
Conc. pg/mL	ECL Signal	%CV
96500	481,000	6.4
24100	145,000	6.6
6030	24,200	7.9
1510	3,310	5.8
377	658	7.9
94.2	329	16.0
23.6	241	16.0
0.00	241	14.0

UMOD - Spot 7		
Conc. pg/mL	ECL Signal	%CV
110000	482,000	1.7
27500	111,000	2.1
6880	27,500	1.8
1720	7,080	2.7
430	2,230	2.5
107	1,040	3.9
26.9	750	4.0
0.00	659	7.6

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### Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 5 (human) Plate	Z0056045	2-8°C	28 Feb 2020
Anti-hu Albumin Antibody	D0040720	2-8°C	31 Dec 2019
Anti-hu B2M Antibody	D0040721	2-8°C	31 Dec 2019
Anti-hu Cystatin C Antibody	D0040722	2-8°C	31 Dec 2019
Anti-hu EGF Antibody	D0040723	2-8°C	31 Dec 2019
Anti-hu NGAL Antibody	D0040724	2-8°C	31 Dec 2019
Anti-hu OPN Antibody	D0040725	2-8°C	31 Dec 2019
Anti-hu UMOD Antibody	D0040726	2-8°C	31 Jan 2020
Kidney Injury Panel 5 (human) Calibrator Blend	A0040200	≤ -70°C	31 Mar 2020
Blocker A Kit	Not Kit Specific	Not Kit Specific	N/A
Diluent 37	M0370020	≤ -10°C	31 Oct 2019
Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

### 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		16 FEB 2018