

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 5 (human) Kit
Kit Catalog Numbers: K15188D-Series
Kit Lot Number: K0040393
Expiration Date: 28 Feb 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	< 1.0%*
7	UMOD	< 1.0%	NA

* See Additional Comments.

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Albumin	20X Calibrator	4580000	pg/ml
		Control 1	20606	pg/ml
		Control 2	3717	pg/ml
		Control 3	776	pg/ml
2	B2M	20X Calibrator	426000	pg/ml
		Control 1	2260	pg/ml
		Control 2	443	pg/ml
		Control 3	91.9	pg/ml
3	Cystatin C	20X Calibrator	792000	pg/ml
		Control 1	3562	pg/ml
		Control 2	660	pg/ml
		Control 3	156	pg/ml
4	EGF	20X Calibrator	9300	pg/ml
		Control 1	40.8	pg/ml
		Control 2	7.43	pg/ml
		Control 3	1.65	pg/ml
5	NGAL	20X Calibrator	304000	pg/ml
		Control 1	1468	pg/ml
		Control 2	277	pg/ml
		Control 3	59.6	pg/ml
6	OPN	20X Calibrator	1898000	pg/ml
		Control 1	9288	pg/ml
		Control 2	1805	pg/ml
		Control 3	390	pg/ml
7	UMOD	20X Calibrator	2360000	pg/ml
		Control 1	11457	pg/ml
		Control 2	2234	pg/ml
		Control 3	468	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
229000	218,000	12.0
57300	72,800	12.0
14300	17,600	11.0
3580	4,610	9.7
895	1,510	9.8
224	756	9.6
55.9	611	7.2
0.00	568	9.4

B2M - Spot 2		
Conc. pg/ml	ECL Signal	%CV
21300	54,300	17.0
5330	22,200	9.0
1330	6,470	8.4
333	1,730	12.0
83.2	593	9.3
20.8	268	6.9
5.20	214	5.5
0.00	182	4.3

Cystatin C - Spot 3		
Conc. pg/ml	ECL Signal	%CV
39600	368,000	4.8
9900	146,000	2.4
2480	23,000	4.7
619	3,730	4.0
155	996	3.7
38.7	441	3.2
9.67	322	3.6
0.00	286	2.4

EGF - Spot 4		
Conc. pg/ml	ECL Signal	%CV
465	596,000	4.4
116	150,000	5.6
29.1	28,800	7.7
7.27	5,450	4.6
1.82	1,350	5.3
0.454	377	7.2
0.114	156	5.2
0.00	81	5.3

NGAL - Spot 5		
Conc. pg/ml	ECL Signal	%CV
15200	351,000	9.6
3800	107,000	6.7
950	26,100	6.3
238	6,890	5.8
59.4	1,970	9.4
14.8	589	3.9
3.71	309	5.7
0.00	194	9.8

OPN - Spot 6		
Conc. pg/ml	ECL Signal	%CV
94900	482,000	4.2
23700	175,000	8.2
5930	39,300	8.8
1480	5,870	3.3
371	1,020	4.6
92.7	297	9.8
23.2	188	9.9
0.00	143	15.0

UMOD - Spot 7		
Conc. pg/ml	ECL Signal	%CV
118000	662,000	3.7
29500	148,000	2.5
7380	35,600	2.5
1840	8,650	3.3
461	2,730	1.9
115	1,150	1.9
28.8	836	2.6
0.00	675	5.3

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Components:


Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 5 (human) Plate	Z0055976	2-8°C	30 Nov 2019
Anti-hu Albumin Antibody	D0040696	2-8°C	31 Oct 2019
Anti-hu B2M Antibody	D0040697	2-8°C	31 Oct 2019
Anti-hu Cystatin C Antibody	D0040698	2-8°C	31 Oct 2019
Anti-hu EGF Antibody	D0040699	2-8°C	30 Nov 2019
Anti-hu NGAL Antibody	D0040700	2-8°C	31 Oct 2019
Anti-hu OPN Antibody	D0040701	2-8°C	31 Oct 2019
Anti-hu UMOD Antibody	D0040702	2-8°C	30 Nov 2019
Kidney Injury Panel 5 (human) Calibrator Blend	A0040176	≤ -70°C	28 Feb 2019
MSD Blocker A Solution	Not Kit Specific	Not Kit Specific	N/A
Diluent 37	M0370020	≤ -10°C	31 Oct 2019
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Comments:

Assay	Spot	Specification	Comment
1 UMOD	7	NSB	The actual measured NSB of UMOD on the OPN spot was 1.61%

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		27 JUL 2017