

CERTIFICATE OF ANALYSIS

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Product Description: Kidney Injury Panel 5 (human) Kit
Kit Catalog Numbers: K15188D-series
Kit Lot Number: K0040423
Expiration Date: 30 Jun 2019

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		KIP-5 Control 1		KIP-5 Control 2		KIP-5 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	NSB Spec
1	Albumin	< 1.0%
2	B2M	< 1.0%
3	Cystatin C	< 1.0%
4	EGF	< 1.0%
5	NGAL	< 1.0%
6	OPN	< 3.0%
7	UMOD	< 1.0%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	Albumin	20X Calibrator	3960000	pg/mL
		KIP-5 Control 1	540000	pg/mL
		KIP-5 Control 2	132000	pg/mL
		KIP-5 Control 3	37000	pg/mL
2	B2M	20X Calibrator	416000	pg/mL
		KIP-5 Control 1	76300	pg/mL
		KIP-5 Control 2	22300	pg/mL
		KIP-5 Control 3	4790	pg/mL
3	Cystatin C	20X Calibrator	812000	pg/mL
		KIP-5 Control 1	196000	pg/mL
		KIP-5 Control 2	41600	pg/mL
		KIP-5 Control 3	11000	pg/mL
4	EGF	20X Calibrator	10340	pg/mL
		KIP-5 Control 1	3120	pg/mL
		KIP-5 Control 2	704	pg/mL
		KIP-5 Control 3	202	pg/mL
5	NGAL	20X Calibrator	218000	pg/mL
		KIP-5 Control 1	38500	pg/mL
		KIP-5 Control 2	9920	pg/mL
		KIP-5 Control 3	2460	pg/mL
6	OPN	20X Calibrator	1928000	pg/mL
		KIP-5 Control 1	326000	pg/mL
		KIP-5 Control 2	85300	pg/mL
		KIP-5 Control 3	21600	pg/mL
7	UMOD	20X Calibrator	2120000	pg/mL
		KIP-5 Control 1	392000	pg/mL
		KIP-5 Control 2	104000	pg/mL
		KIP-5 Control 3	27000	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:

Albumin - Spot 1		
Conc. pg/mL	ECL Signal	%CV
198000	195,000	9.6
49500	62,000	8.8
12400	14,000	6.6
3090	3,330	8.6
773	1,200	8.1
193	668	9.7
48.3	584	5.8
0.00	550	7.4

B2M - Spot 2		
Conc. pg/mL	ECL Signal	%CV
20800	92,700	14.0
5200	41,100	11.0
1300	11,800	5.9
325	2,760	6.0
81.3	839	8.4
20.3	318	4.6
5.08	206	5.3
0.00	165	8.5

Cystatin C - Spot 3		
Conc. pg/mL	ECL Signal	%CV
40600	511,000	3.3
10200	221,000	4.6
2540	35,800	3.5
634	5,650	4.0
159	1,270	3.3
39.6	511	2.9
9.91	340	5.3
0.00	278	7.2

EGF - Spot 4		
Conc. pg/mL	ECL Signal	%CV
517	633,000	3.7
129	156,000	6.3
32.3	29,200	6.5
8.08	5,490	6.9
2.02	1,380	6.2
0.505	388	5.7
0.126	165	5.5
0.00	84	8.3

NGAL - Spot 5		
Conc. pg/mL	ECL Signal	%CV
10900	308,000	4.0
2730	81,400	3.7
681	20,800	6.2
170	4,800	5.6
42.6	1,430	7.6
10.6	476	5.7
2.66	266	3.8
0.00	192	6.9

OPN - Spot 6		
Conc. pg/mL	ECL Signal	%CV
96400	365,000	5.5
24100	119,000	6.2
6030	24,500	10.0
1510	3,590	6.0
377	763	3.9
94.1	306	6.0
23.5	237	4.5
0.00	206	11.0

UMOD - Spot 7		
Conc. pg/mL	ECL Signal	%CV
106000	663,000	1.5
26500	160,000	2.4
6630	40,800	2.4
1660	10,600	2.6
414	3,240	2.2
104	1,300	2.3
25.9	821	5.5
0.00	626	5.3

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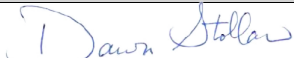
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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 5 (human) Plate	Z0056187	2-8°C	31 Aug 2020
Anti-hu Albumin Antibody	D0040665	2-8°C	30 Jun 2019
Anti-hu B2M Antibody	D0040666	2-8°C	31 Jul 2019
Anti-hu Cystatin C Antibody	D0040667	2-8°C	30 Jun 2019
Anti-hu EGF Antibody	D0040668	2-8°C	30 Jun 2019
Anti-hu NGAL Antibody	D0040669	2-8°C	30 Jun 2019
Anti-hu OPN Antibody	D0040670	2-8°C	30 Jun 2019
Anti-hu UMOD Antibody	D0040671	2-8°C	30 Jun 2019
Kidney Injury Panel 5 (human) Calibrator Blend	A0040210	≤ -70°C	31 Aug 2020
Blocker A Kit	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

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		06 MAR 2019