

CERTIFICATE OF ANALYSIS

Product Description: Kidney Injury Panel 5 (human) Kit
Kit Catalog Numbers: K15188D-Series
Kit Lot Number: K0040454
Expiration Date: 31 Aug 2020

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	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	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	39500	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	143,000	12.0
49500	54,000	9.7
12400	14,500	8.2
3090	3,540	5.2
773	1,390	5.1
193	875	9.4
48.3	729	9.9
0.00	674	14.0

B2M - Spot 2		
Conc. pg/mL	ECL Signal	%CV
20800	101,000	15.0
5200	46,500	12.0
1300	15,400	17.0
325	3,810	11.0
81.3	1,070	11.0
20.3	389	5.9
5.08	227	4.7
0.00	184	5.4

Cystatin C - Spot 3		
Conc. pg/mL	ECL Signal	%CV
40600	592,000	4.3
10200	293,000	7.3
2540	67,400	4.5
634	12,400	7.2
159	2,330	3.1
39.6	832	2.5
9.91	477	3.0
0.00	397	2.1

EGF - Spot 4		
Conc. pg/mL	ECL Signal	%CV
517	1,040,000	3.1
129	346,000	4.3
32.3	77,500	4.8
8.08	16,900	6.0
2.02	3,950	4.2
0.505	1,030	4.0
0.126	326	5.7
0.00	94	7.5

NGAL - Spot 5		
Conc. pg/mL	ECL Signal	%CV
10900	469,000	7.5
2730	142,000	4.3
681	36,300	4.8
170	8,220	8.1
42.6	2,200	4.8
10.6	681	5.2
2.66	301	7.1
0.00	174	3.3

OPN - Spot 6		
Conc. pg/mL	ECL Signal	%CV
96400	702,000	7.1
24100	313,000	5.3
6030	82,100	6.8
1510	12,800	8.3
377	2,170	8.9
94.1	660	5.7
23.5	392	4.3
0.00	326	5.4

UMOD - Spot 7		
Conc. pg/mL	ECL Signal	%CV
106000	1,680,000	1.7
26500	670,000	1.1
6630	174,000	2.3
1660	42,600	3.6
414	11,200	3.1
104	3,270	2.6
25.9	1,370	3.9
0.00	743	4.6

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Components:

Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 5 (human) Plate	Z0056310	2-8°C	31 Dec 2020
Anti-hu Albumin Antibody	D0040785	2-8°C	31 Dec 2021
Anti-hu B2M Antibody	D0040786	2-8°C	31 Jan 2022
Anti-hu Cystatin C	D0040787	2-8°C	28 Feb 2022
Anti-hu EGF Antibody	D0040788	2-8°C	31 Dec 2021
Anti-hu NGAL Antibody	D0040789	2-8°C	31 Dec 2021
Anti-hu OPN Antibody	D0040790	2-8°C	31 Dec 2021
Anti-hu UMOD Antibody	D0040791	2-8°C	31 Dec 2021
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	M0370022	≤ -10°C	31 Mar 2021
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		18 DEC 2018