

CERTIFICATE OF ANALYSIS

Page 1 of 3

Product Description: Kidney Injury Panel 3 (human) Kit
Kit Catalog Numbers: K15189D-Series
Kit Lot Number: K0040476
Expiration Date: 30 Nov 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		KIP-3 Control 1		KIP-3 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%

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	αGST	20X Calibrator	534000	pg/mL
		KIP-3 Control 1	16300	pg/mL
		KIP-3 Control 2	3523	pg/mL
2	Calbindin	20X Calibrator	428000	pg/mL
		KIP-3 Control 1	93700	pg/mL
		KIP-3 Control 2	5810	pg/mL
3	Clusterin	20X Calibrator	4000000	pg/mL
		KIP-3 Control 1	696000	pg/mL
		KIP-3 Control 2	45200	pg/mL

CERTIFICATE OF ANALYSIS

4	KIM-1	20X Calibrator	510000	pg/mL
		KIP-3 Control 1	73200	pg/mL
		KIP-3 Control 2	4570	pg/mL
5	Osteoactivin	20X Calibrator	736000	pg/mL
		KIP-3 Control 1	142000	pg/mL
		KIP-3 Control 2	9810	pg/mL
6	TFF3	20X Calibrator	48000	pg/mL
		KIP-3 Control 1	6250	pg/mL
		KIP-3 Control 2	464	pg/mL
7	VEGF	20X Calibrator	47600	pg/mL
		KIP-3 Control 1	8690	pg/mL
		KIP-3 Control 2	599	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

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
26700	107,000	6.9	21400	679,000	8.0	200000	254,000	3.8
6680	24,100	6.0	5350	112,000	6.5	50000	71,800	9.5
1670	5,710	3.5	1340	18,500	6.8	12500	20,600	5.9
417	1,600	6.2	334	4,070	6.5	3130	7,260	3.0
104	631	7.1	83.6	1,540	3.8	781	3,910	2.1
26.1	395	6.8	20.9	933	4.0	195	3,180	3.6
6.52	336	3.2	5.22	805	3.4	48.8	3,030	3.7
0.00	313	5.0	0.00	740	2.5	0.00	2,890	1.0

KIM-1 - Spot 4			Osteoactivin - Spot 5			TFF3 - Spot 6		
Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV	Conc. pg/mL	ECL Signal	%CV
25500	627,000	2.7	36800	164,000	6.1	2400	170,000	4.3
6380	205,000	3.2	9200	51,800	2.7	600	32,300	5.2
1590	48,500	3.1	2300	15,000	5.3	150	7,250	5.1
398	11,800	4.8	575	5,380	3.6	37.5	1,900	5.1
99.6	2,960	1.8	144	3,090	2.7	9.38	707	6.0
24.9	873	2.6	35.9	2,420	3.0	2.34	372	6.6
6.23	351	6.6	8.98	2,230	4.1	0.586	290	9.9
0.00	160	7.0	0.00	2,160	2.4	0.00	259	9.1

CERTIFICATE OF ANALYSIS

VEGF - Spot 7		
Conc. pg/mL	ECL Signal	%CV
2380	651,000	3.4
595	163,000	3.2
149	40,000	3.0
37.2	10,400	2.3
9.30	3,210	2.0
2.32	1,390	2.7
0.581	900	3.4
0.00	717	2.2

Components:


Description	Lot Number	Storage Temperature	Expiration Date
Kidney Injury Panel 3 (human) Plate	Z0056538	2-8°C	30 Nov 2021
Anti-hu αGST Antibody	D0040863	2-8°C	28 Feb 2023
Anti-hu Calbindin Antibody	D0040864	2-8°C	31 May 2023
Anti-hu Clusterin Antibody	D0040865	2-8°C	31 Jan 2023
Anti-hu KIM-1 Antibody	D0040866	2-8°C	30 Nov 2022
Anti-hu Osteoactivin Antibody	D0040867	2-8°C	30 Nov 2022
Anti-hu TFF3 Antibody	D0040868	2-8°C	30 Nov 2022
Anti-hu VEGF Antibody	D0040869	2-8°C	31 May 2023
Kidney Injury Panel 3 (human) Calibrator Blend	A0040239	≤ -70°C	31 Jul 2022
Blocker A	Not Kit Specific	Not Kit Specific	N/A
Diluent 37	Not Kit Specific	Not Kit Specific	N/A
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Additional Comments:

Assay	Spot	Specification	Comment
1 αGST	1	Control Conc.	Control-1 recovery 67.4% and Control-2 recovery 11.2% (specifications 75-125%)
2 αGST	1	Control CV	Control-2 CV 28.0% (Specifications NMT 20%)

Statement:

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

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		25 FEB 2020