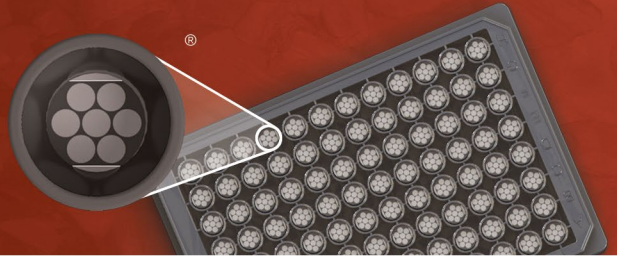
MSD® Kidney Injury Panel 3 (human) Kit



For quantitative determination in human serum and urine

www.mesoscale.com®

Catalog Numbers

Kidney Injury Panel 3 (human) Kit	
Kit size	
1 plate	K15189D-1
5 plates	K15189D-2
25 plates	K15189D-4

Ordering Information

MSD Customer Service
Phone: 1-240-314-2795
Fax: 1-301-990-2776
Email: CustomerService@mesoscale.com
www.mesoscale.com/support

Scientific Support

Phone: 1-301-947-2025
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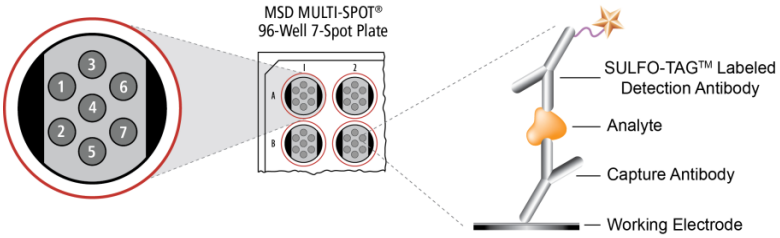
www.mesoscale.com/support

Company Address

MESO SCALE DISCOVERY®
A division of
Meso Scale Diagnostics, LLC.
1601 Research Boulevard
Rockville, MD 20850-3173
USA

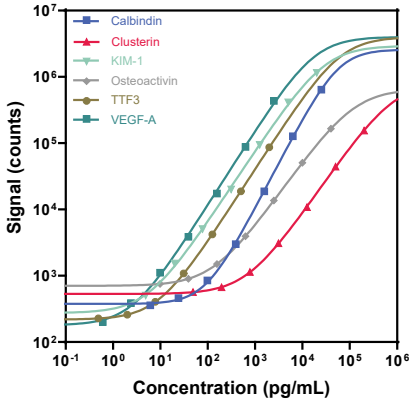
1. –
2. Calbindin
3. Clusterin
4. HAVCR1/KIM-1
5. Osteoactivin
6. TFF3
7. VEGF-A



Measurement of protein biomarkers as indicators of drug-induced kidney toxicity shows promise for improving drug safety and accelerating development timelines. MSD produces high-performance, multiplex panels to measure biomarkers of kidney injury. Multiple exploratory biomarkers of kidney toxicity are measured to determine their relative abundance in urine and their correlation with the severity and location of renal damage. MSD offers the Kidney Injury Panel 3 (human) Kit for monitoring levels of Calbindin, Clusterin, HAVCR1/KIM-1, Osteoactivin, TFF3, and VEGF-A (formerly named VEGF) in human urine. The kit is tested for sensitivity, specificity, spike recovery, dilution linearity, precision, accuracy, robustness, and sample handling. The assay is available on 96-well, 7-spot plates. Representative data from assay development are presented below. Lot-specific standard curves can be found in the certificate of analysis (COA) supplied with the kit. Visit www.mesoscale.com for a complete listing of our products.

Assay Sensitivity

The following standard curves illustrate the dynamic range of the assays in the Kidney Injury Panel 3 (human) Kit.

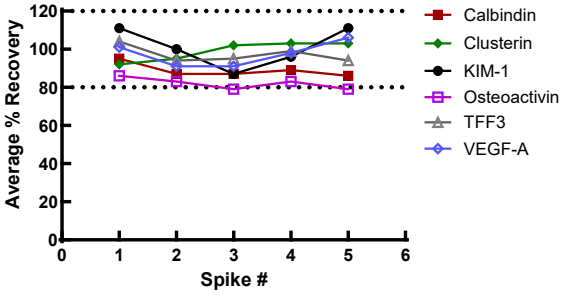


	Calbindin	Clusterin	HAVCR1/KIM-1
Median LLOD (pg/mL)	7.9	32	1.6
	Osteoactivin	TFF3	VEGF-A
Median LLOD (pg/mL)	12	2.9	0.17

The lower limit of detection (LLOD) is a calculated concentration based on a signal 2.5 standard deviations above the background (zero calibrator blank). The LLOD shown above was calculated from nine kit lots.

Spike Recovery

Eight normal human urine samples were diluted 20-fold and then spiked with calibrators at multiple levels throughout the range of the assay. % Recovery = measured/expected × 100



	Spike Concentration (pg/mL)				
	Spike 1	Spike	Spike 3	Spike 4	Spike 5
Calbindin	78	313	1,250	5,000	20,000
Clusterin	625	2,500	10,000	40,000	160,000
HAVCR1/KI	31	125	500	2,000	8,000
Osteoactivi	78	313	1,250	5,000	20,000
TFF3	6.3	25	100	400	1,600
VEGF-A	7.8	31	125	500	2,000

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Precision

Control samples with high, medium, and low levels of each analyte were measured using a minimum of 2 replicates on 6 runs over 2 days. Average intra-run %CV is the average %CV of the control replicates on an individual run. Inter-run %CV is the variability of controls across 6 runs.

	Control	Runs	Average Conc. (pg/mL)	Average Intra-run %CV	Inter-run %CV
Calbindin	High	6	10,300	4.9	4.5
	Mid	6	1,390	4.5	4.5
	Low	6	172	3.5	3.2
Clusterin	High	6	28,900	5.4	5.2
	Mid	6	5,780	12.4	11.4
	Low	6	771	8.7	16.2
HAVCR1/KIM-1	High	6	16,700	8.0	7.9
	Mid	6	2,360	3.6	3.3
	Low	6	107	2.5	3.9
Osteoactivin	High	6	2,690	10.3	9.2
	Mid	6	230	5.6	6.0
	Low	6	1,020	5.0	5.6
TFF3	High	6	173	6.7	6.6
	Mid	6	29	5.2	5.6
	Low	6	1,050	4.1	4.2
VEGF-A	High	6	119	3.5	4.2
	Mid	6	10	3.6	5.0
	Low	6	10,300	6.0	5.6

Tested Samples

Normal and disease samples (both urine and serum) were diluted 10-fold and tested with the Kidney Injury Panel 3 (human). Median and range of concentrations for each sample set are displayed below. Concentrations are corrected for sample dilution.

Sample*	Statistic	Calbindin	Clusterin	HAVCR1/KIM-1	Osteoactivin	TFF3	VEGF-A
Normal Urine	Median (pg/mL)	4.5	24	0.31	0.24	<LLOD	0.45
	Range (pg/mL)	<LLOD–13	<LLOD–200	<LLOD–2.2	<LLOD–0.60	<LLOD–0.53	<LLOD–1.4
	Number of samples	35	35	35	35	35	35
	Samples above LLOD	34	33	34	34	15	34
Kidney Disease Urine	Median (pg/mL)	2.6	58	1.4	0.37	0.043	0.40
	Range (pg/mL)	0.61–15	2.3–253	0.083–3.7	0.18–1.1	<LLOD–2.6	0.19–0.83
	Number of samples	15	15	15	15	15	15
	Samples above LLOD	15	15	15	15	9	15
Normal Serum	Median (pg/mL)	4.9	**	0.17	7.9	0.31	0.16
	Range (pg/mL)	2.0–8.0	**	0.11–0.26	5.6–18	0.17–0.51	0.098–0.21
	Number of samples	15	–	15	15	15	15
	Samples above LLOD	15	–	15	15	15	15
Kidney Disease Serum	Median (pg/mL)	4.1	**	0.29	11	0.69	0.67
	Range (pg/mL)	2.9–6.4	**	0.19–0.83	7.6–17	0.41–2.3	0.15–4.0
	Number of samples	15	–	15	15	15	15
	Samples above LLOD	15	–	15	15	15	15

**Clinical information associated with normal and kidney disease samples was not available.*

***Sample signal exceeds the top of the standard curve at 10-fold dilution. Clusterin testing in human serum requires >10-fold dilution.*

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