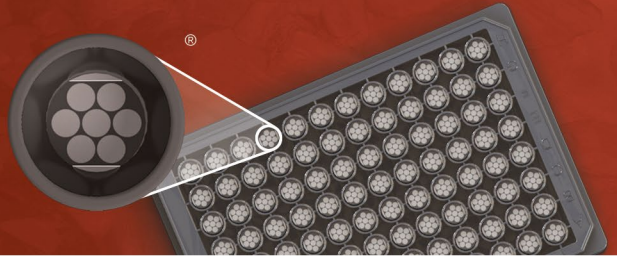
Kidney Injury Panel 3 (human) Kit



For quantitative determination in human serum and urine

Alzheimer's Disease
BioProcess
Cardiac
Cell Signaling
Clinical Immunology
Cytokines
Growth Factors
Hypoxia
Immunogenicity
Inflammation
Metabolic
Oncology
Toxicology
Vascular

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

Scientific Support

Phone: 1-240-314-2798
Email: ScientificSupport@mesoscale.com

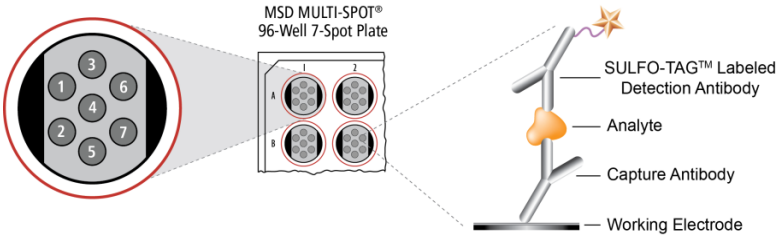
Company Address

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

www.mesoscale.com®

For Research Use Only. Not for use in diagnostic procedures.

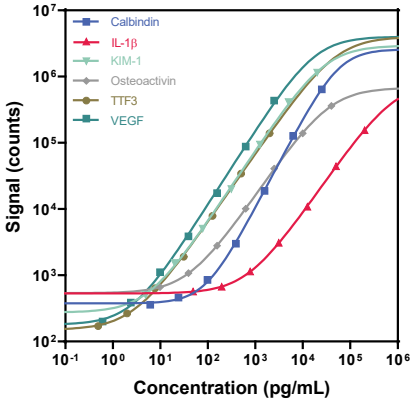
1. –
2. Calbindin
3. Clusterin
4. KIM-1
5. Osteoactivin
6. TFF3
7. VEGF



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, KIM-1, Osteoactivin, TFF3, and 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.

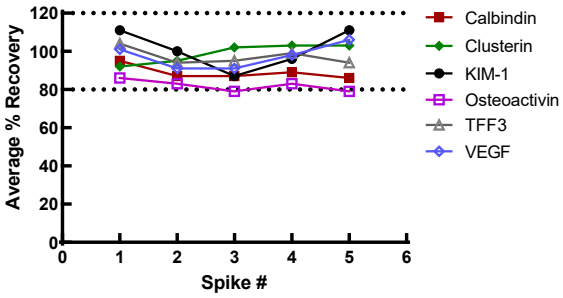


	Calbindin	Clusterin	KIM-1
Average LLOD (pg/mL)	15	133	0.89
	Osteoactivin	TFF3	VEGF
Average LLOD (pg/mL)	5.0	1.6	0.67

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 based on 30 runs.

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	1250	5000	20 000
Clusterin	625	2500	10 000	40 000	160 000
KIM-1	31	125	500	2000	8000
Osteoactivi	78	313	1250	5000	20 000
TFF3	6.3	25	100	400	1600
VEGF	7.8	31	125	500	2000

Spot the Difference®

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	10 302	4.9	4.5
	Mid	6	1394	4.5	4.5
	Low	6	172	3.5	3.2
Clusterin	High	6	28 946	5.4	5.2
	Mid	6	5782	12.4	11.4
	Low	6	771	8.7	16.2
KIM-1	High	6	16 656	8.0	7.9
	Mid	6	2360	3.6	3.3
	Low	6	107	2.5	3.9
Osteoactivin	High	6	46191	10.3	9.2
	Mid	6	2687	5.6	6.0
	Low	6	230	5.0	5.6
TFF3	High	6	1019	6.7	6.6
	Mid	6	173	5.2	5.6
	Low	6	29	4.1	4.2
VEGF	High	6	1045	3.5	4.2
	Mid	6	119	3.6	5.0
	Low	6	10	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	KIM-1	Osteoactivin	TFF3	VEGF
Normal Urine*	Median (ng/mL)	4.5	24	0.31	0.24	<LLOD	0.45
	Range (ng/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 (ng/mL)	2.6	58	1.4	0.37	0.043	0.40
	Range (ng/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 (ng/mL)	4.9	**	0.17	7.9	0.31	0.16
	Range (ng/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 (ng/mL)	4.1	**	0.29	11	0.69	0.67
	Range (ng/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 standard curve at 10-fold dilution. Clusterin testing in human serum requires >10-fold dilution.*