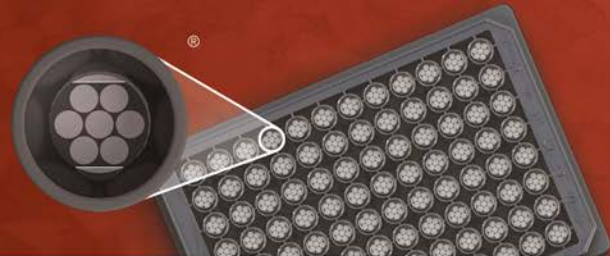


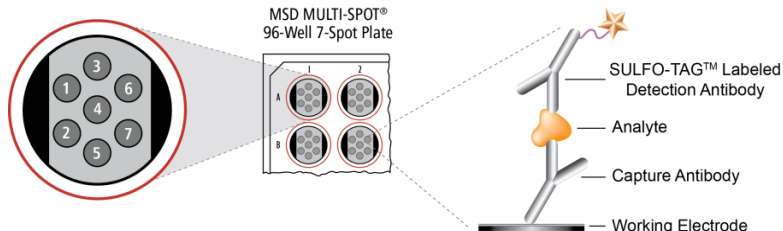
MSD® Kidney Injury Panel 5 (human) Kit

For quantitative determination in human urine



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

1. Albumin
2. B2M
3. Cystatin C
4. EGF
5. NGAL
6. OPN
7. UMOD



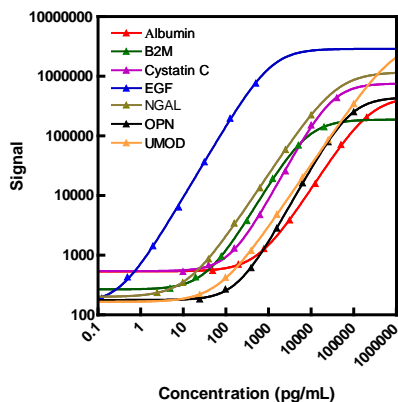
Monitoring protein markers as indicators of drug-induced kidney toxicity shows promise in improving drug safety and accelerating development timelines. MSD produces a series of high performance, multiplex panels to measure biomarkers of kidney injury. Multiple exploratory biomarkers of kidney toxicity are grouped by their relative abundance in urine and their correlation with the severity and location of renal damage. The Kidney Injury Panel 5 (human) Kit measures levels of albumin, B2M, cystatin C, EGF, NGAL, OPN, and UMOD 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 (C of A) supplied with the kit. Visit www.mesoscale.com for a complete listing of our products.

Catalog Numbers

Kidney Injury Panel 5 (human) Kit	
Kit size	
1 plate	K15188D-1
5 plates	K15188D-2
25 plates	K15188D-4

Assay Sensitivity

The following standard curves illustrate the dynamic range of the assays in the Kidney Injury Panel 5 (human) Kit.



	Albumin	B2M	Cystatin C	EGF
Average LLOD (pg/mL)	141	6.1	27	0.13
	NGAL	OPN	UMOD	
Average LLOD (pg/mL)	2.9	90	26	

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 36 runs.

Ordering information

MSD Customer Service
Phone: 1-301-947-2085
Fax: 1-301-990-2776
Email: CustomerService@mesoscale.com

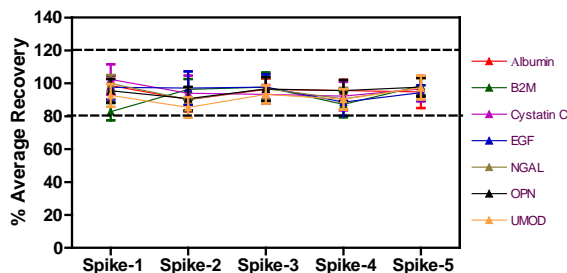
Company Address

MESO SCALE DISCOVERY®
division of
Meso Scale Diagnostics, LLC.
9238 Gaither Road
Gaithersburg, MD 20877 USA

www.mesoscale.com®

Spike Recovery

Eight human urine samples were diluted 500-fold then spiked with calibrators at multiple levels throughout the range of the assay.
% Recovery = measured/expected * 100



	Spike Concentration (pg/mL)				
	Spike 1	Spike 2	Spike 3	Spike 4	Spike 5
Albumin	160 000	40 000	10 000	2500	625
B2M	16 000	4000	1000	250	63
Cystatin C	32 000	8000	2000	500	125
EGF	400	100	25	6.3	1.6
NGAL	8000	2000	500	125	31
OPN	80 000	20 000	5000	1250	313
UMOD	80 000	20 000	5000	1250	313

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

MSD Toxicology Assays

Precision

Control samples with high, medium, and low levels of each analyte were measured using a minimum of 2 replicates on 11 runs over 5 days. Average intra-run %CV is the average %CV of the control replicates within an individual run. Inter-run %CV is the variability of controls across 11 runs.

	Control	Runs	Average Conc. (pg/mL)	Average Intra-run %CV	Inter-run %CV
Albumin	High	11	82 714	7.0	10.4
	Mid	11	15 052	6.8	13.9
	Low	11	2688	3.4	9.5
B2M	High	11	3728	6.5	13.8
	Mid	11	563	3.4	8.6
	Low	11	119	4.7	10.1
Cystatin C	High	11	32 816	6.2	23.6
	Mid	11	4364	4.3	13.9
	Low	11	823	4.1	14.7
EGF	High	11	134	8.2	14.1
	Mid	11	40	7.3	14.5
	Low	11	2.4	6.1	12.2
NGAL	High	11	3105	5.2	9.7
	Mid	11	2328	3.4	10.9
	Low	11	41	6.2	16.6
OPN	High	11	9380	6.5	18.4
	Mid	11	3157	7.6	16.0
	Low	11	349	7.1	19.9
UMOD	High	11	28 985	4.9	14.3
	Mid	11	5660	4.1	13.4
	Low	11	1254	3.1	10.5

Tested Samples

Normal and disease samples (both urine and serum), were diluted 500-fold and tested with the Kidney Injury Panel 5 (human). Median and range of concentrations for each sample set are displayed below. Concentrations are corrected for sample dilution.

Sample	Statistic	Albumin	B2M	Cystatin C	EGF	NGAL	OPN	UMOD
Normal Urine*	Median (ng/mL)	2002	106	38	6.5	18	1031	1350
	Range (ng/mL)	<LLOD–48 757	37–1130	<LLOD–370	0.43–51	4.2–225	<LLOD–8146	347–7846
	Number of Samples	35	35	35	35	35	35	35
	Samples above LLOD	33	35	30	35	35	30	35
Kidney Disease Urine*	Median (ng/mL)	17 822	398	79	1.50	93	214	2897
	Range (ng/mL)	597–150 866	59–4557	<LLOD–5410	0.38–9.3	8.2–1148	<LLOD–2265	876–12 062
	Number of Samples	15	15	15	15	15	15	15
	Samples above LLOD	15	15	14	15	15	13	15
Normal Serum*	Median (ng/mL)	**	1632	1169	0.085	63	67	74
	Range (ng/mL)	**	673–2637	423–2071	<LLOD–0.28	28–175	<LLOD–150	14–158
	Number of Samples	-	15	15	15	15	15	15
	Samples above LLOD	-	15	15	9	15	12	15
Kidney Disease Serum*	Median (ng/mL)	**	4315	3449	0.35	411	158	58
	Range (ng/mL)	**	1728–6400	1071–7927	0.13–4.0	63–1149	56–986	26–4229
	Number of Samples	-	15	15	15	15	15	15
	Samples above LLOD	-	15	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 500-fold dilution signal. Albumin testing in human serum requires >500-fold dilution.

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