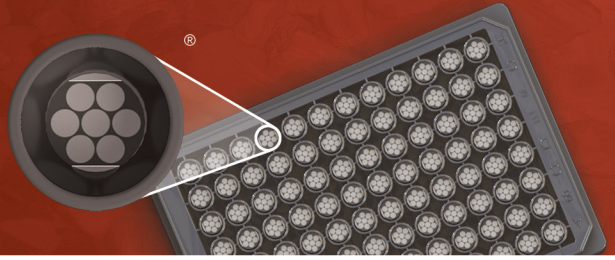
MSD® Muscle Injury Panel 3 (mouse) Kit



For quantitative determination in mouse serum and plasma

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

Catalog Numbers

Muscle Injury Panel 3 (mouse) Kit	
Kit size	
1 plate	K15186C-1
5 plates	K15186C-2
25 plates	K15186C-4

Ordering information

MSD Customer Service
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Company Address

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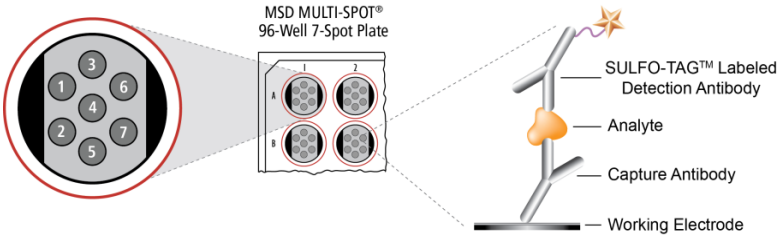
www.mesoscale.com®

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

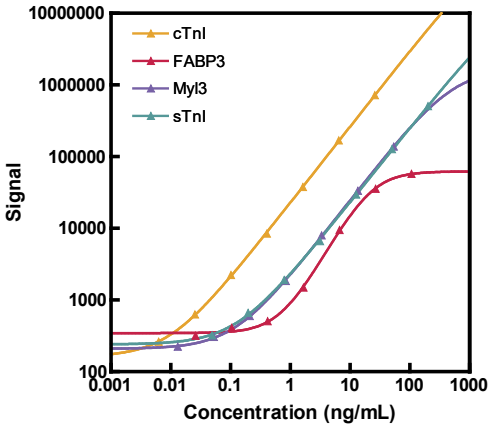
1. cTnI
2. *BSA Blocked*
3. FABP3
4. *BSA Blocked*
5. Myl3
6. sTnI
7. *BSA Blocked*



The incidence of skeletal muscle injury is increasingly more prevalent in preclinical evaluation of new therapeutic targets. Traditional serological biomarkers, including creatine kinase (CK), aldolase, and aspartate aminotransferase (AST), lack sensitivity and specificity, particularly in rodent studies, which limits their utility as accurate biomarkers of skeletal muscle toxicity. The Muscle Injury Panel 3 (mouse) is designed to distinguish myocardial damage from damage to skeletal muscle and other tissues. This panel can also discriminate between slow-twitch (Type I) and fast-twitch (Type II) muscle fiber toxicity. We developed biomarker assays for FABP3, Myl3, and cardiac and skeletal troponin I (cTnI and sTnI) under a design control process that follows "fit-for-purpose" principles. Each assay is validated for sensitivity, specificity, spike recovery, dilution linearity, precision, accuracy, robustness, and sample handling using mouse serum and plasma. The panel is available on 96-well 7-spot plates. Representative data from the kit validation process is presented below. 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 Muscle Injury Panel 3 (mouse).



	cTnI	FABP3	Myl3	sTnI
Average LLOD (ng/mL)	0.00880	0.300	0.0479	0.0846
LLOQ (ng/mL)	0.070	1.000	0.300	0.505
ULOQ (ng/mL)	20.0	26.8	41.4	155

The lower limit of detection (LLOD) is a calculated concentration based on a signal 2.5 standard deviations above the background (zero calibrator blank).
A multi-plate, multi-day study was performed to measure the reproducibility of the assay. The lower limit of quantification (LLOQ) and upper limit of quantification (ULOQ) were established from the multiple plate run.
The LLOQ for for all analytes is the lowest concentration where the %CV of the calculated concentration is less than 25% and the percent recovery of the standard is between 75% and 125%.
The ULOQ for all analytes is the highest concentration where the %CV of the calculated concentration is less than 20% and the percent recovery of the standard is between 80% and 120%.

MSD Advantage

- **Multiplexing:** Multiple analytes can be measured in one well using typical sample volumes of 25 µL or less without compromising speed or performance
- **Large dynamic range**: Linear range of up to five logs enables the measurement of native levels of biomarkers in normal and diseased samples without multiple dilutions
- **Minimal background:** The stimulation mechanism (electricity) is decoupled from the signal (light)
- **Simple protocols:** Only labels near the electrode surface are detected, enabling assays with fewer washes
- **Flexibility:** Labels are stable, non-radioactive, and conveniently conjugated to biological molecules
- **High sensitivity and precision:** Multiple excitation cycles of each label enhance light levels and improve sensitivity

Spike Recovery

Normal mouse serum, EDTA plasma, and heparin plasma samples were diluted 4-fold and spiked with calibrators at multiple levels throughout the range of the assay. The average percent recovery shown below was calculated from samples within the quantitative range of the assay. % Recovery=measured/expected*100

	cTnI			FABP3			Myl3			sTnI		
Sample Type	Spike Conc. (ng/mL)	Average % Recovery	% Range	Spike Conc. (ng/mL)	Average % Recovery	% Range	Spike Conc. (ng/mL)	Average % Recovery	% Range	Spike Conc. (ng/mL)	Average % Recovery	% Range
Serum (N=6)	0.144–0.163	112	104–126	0.591–0.669	106	101–110	0.336–0.346	121	104–137	1.08–1.26	103	90–110
	0.578–0.650	114	105–123	2.37–2.68	115	106–120	1.35–1.38	136	127–157	4.33–5.05	102	91–109
	2.31–2.60	114	103–125	9.46–10.7	114	101–128	5.38–5.53	140	126–163	17.3–20.2	97	89–102
EDTA Plasma (N=7)	0.144–0.163	117	101–138	0.591–0.669	99	88–109	0.336–0.346	129	113–140	1.08–1.26	101	88–110
	0.578–0.650	118	99–132	2.37–2.68	103	91–116	1.35–1.38	135	112–157	4.33–5.05	99	86–107
	2.31–2.60	115	101–125	9.46–10.7	105	74–133	5.38–5.53	132	124–140	17.3–20.2	92	81–101
Heparin Plasma (N=7)	0.144–0.163	106	103–110	0.591–0.669	105	100–110	0.336–0.346	129	124–142	1.08–1.26	103	92–113
	0.578–0.650	108	101–113	2.37–2.68	104	93–112	1.35–1.38	142	132–150	4.33–5.05	97	85–106
	2.31–2.60	107	97–112	9.46–10.7	102	82–111	5.38–5.53	138	121–154	17.3–20.2	89	76–96

Tested Samples

Serum, EDTA plasma, and heparin plasma samples were collected from normal CD-1 mice, diluted 4-fold, and tested with the Muscle Injury Panel 3 (mouse). Median and range of concentrations for each sample set are displayed below. Concentrations are corrected for sample dilution.

Sample Type	Statistic	cTnI	FABP3	Myl3	sTnI
Serum	Median (ng/mL)	0.771	22.7	1.80	<LLOQ
	Range (ng/mL)	<LLOQ–5.68	<LLOQ–>ULOQ	<LLOQ–24.6	<LLOQ–11.1
	Number of Samples	28	28	28	28
	Samples in Quantitative Range	23	26	21	8
EDTA Plasma	Median (ng/mL)	1.11	69.3	1.83	<LLOQ
	Range (ng/mL)	0.183–2.23	21.8–>ULOQ	0.652–20.3	<LLOQ–21.5
	Number of Samples	16	16	16	16
	Samples in Quantitative Range	16	11	16	3
Heparin Plasma	Median (ng/mL)	3.04	98.1	2.04	<LLOQ
	Range (ng/mL)	0.855–5.32	42.3–>ULOQ	0.792–5.08	<LLOQ–4.06
	Number of Samples	16	16	16	16
	Samples in Quantitative Range	16	9	16	5

Precision

Controls were made by spiking calibrator into mouse serum at levels throughout the range of the assay. Analyte levels were measured using a minimum of 3 replicates on 41 runs over 14 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 41 runs. Inter-lot %CV is the variability of controls across 2 kit lots.

	Control	Runs	Average Conc.(ng/mL)	Average Intra-run %CV	Inter-run %CV	Inter-lot %CV
cTnI	High	41	11.0	6.1	8.4	4.8
	Mid	41	1.58	4.7	8.6	5.6
	Low	41	0.430	4.2	9.3	6.7
FABP3	High	41	12.6	6.8	10.9	10.0
	Mid	41	3.25	6.0	9.3	7.9
	Low	41	1.25	6.2	12.9	12.5
Myl3	High	41	26.9	5.1	8.0	3.7
	Mid	41	6.98	5.3	7.1	1.8
	Low	41	0.489	5.2	10.0	7.9
sTnI	High	41	49.9	6.3	10.2	4.7
	Mid	41	8.25	4.6	10.0	4.0
	Low	41	1.34	4.9	11.0	7.9

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