

## CERTIFICATE OF ANALYSIS

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**Product Description:** Muscle Injury Panel 3 (mouse) Kit  
**Kit Lot Number:** K0040502  
**Expiration Date:** 31 Dec 2022  
**Kit Catalog Numbers:** K15186C-Series

**Precision and Accuracy Specifications:**

Spot	Name	Calibrator		Muscle Injury Panel 3 (mouse) Control 1		Muscle Injury Panel 3 (mouse) Control 2		Muscle Injury Panel 3 (mouse) Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	cTnI	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	FABP3	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
5	Myl3	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
6	sTnI	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

\* See Additional Comments.

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	cTnI	0.0700	75% - 125%	< 25%	20.0	80% - 120%*	< 20%
3	FABP3	1.00	75% - 125%	< 25%	26.8	80% - 120%*	< 20%*
5	Myl3	0.300	75% - 125%	< 25%	41.4	80% - 120%	< 20%
6	sTnI	0.51	75% - 125%	< 25%*	155	80% - 120%	< 20%

**Non-Specific Binding Specifications:**

Spot	Name	NSB Spec
1	cTnI	< 1.0%
3	FABP3	< 1.0%
5	Myl3	< 1.0%
6	sTnI	< 1.0%

**Stock Concentration of Calibrator:**

Spot	Name	Conc.	Units
1	cTnI	928	ng/mL
3	FABP3	1776	ng/mL
5	Myl3	928	ng/mL
6	sTnI	5720	ng/mL

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### Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 3 (mouse) Plate	Z0056767	2-8°C	31 Jan 2023
Anti-ms cTnI Antibody	D0040929	2-8°C	30 Apr 2024
Anti-ms FABP3 Antibody	D0040930	2-8°C	31 Jan 2024
Anti-ms Myl3 Antibody	D0040931	2-8°C	31 Mar 2024
Anti-ms sTnI Antibody	D0040932	2-8°C	31 Mar 2024
Muscle Injury Panel 3 (mouse) Calibrator Blend	A0040254	≤ -70°C	28 Feb 2023
Diluent 33	M0330014	≤ -10°C	31 May 2023
Diluent 30	M0300031	≤ -10°C	31 Dec 2022

Additional components may be provided to execute the assay. Additional components are not lot-specific.

### Additional Comments:

Spot	Assay	Specification	Comment
1	cTnI	80-120%	ULOQ Conc. = 137.1%
3	FABP3	80-120%	ULOQ Conc. = 135.7%
3	FABP3	< 20%	ULOQ CV = 29.8%
6	sTnI	< 25%	LLOQ CV = 37.5%

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		05 May 2021