



**RFE MEMO**

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**Product Description(s):** Muscle Injury Panel 3 (mouse) Kit

**Catalog Number(s) / Size(s):** K15186C - Series

**Lot Number:** K0040520

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040520 has been extended to 30 SEP 2023.

The expiration date for the following kit component has been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Muscle Injury Panel 3 (mouse) Calibrator Blend	A0040249	30 SEP 2022	30 SEP 2023

Function	Name	Signature	Date
Quality	Karen Hamilla		12 AUG 2022

This memo supersedes all other statements regarding date of expiration for this product.

## CERTIFICATE OF ANALYSIS

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**Product Description:** Muscle Injury Panel 3 (mouse) Kit  
**Kit Lot Number:** K0040520  
**Expiration Date:** 30 Sep 2022  
**Kit Catalog Numbers:** K15186C-Series

**Precision and Accuracy Specifications:**

Spot	Name	Calibrator		Muscle Injury Panel 3 Control 1		Muscle Injury Panel 3 Control 2		Muscle Injury Panel 3 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%

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	0.505	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	662	ng/mL
3	FABP3	1706	ng/mL
5	Myl3	956	ng/mL
6	sTnI	4820	ng/mL


**CERTIFICATE OF ANALYSIS**

**Lot-Specific Components:**

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 3 (mouse) Plate	Z0056976	2-8°C	30 Nov 2023
Anti-ms cTnI Antibody	D0040961	2-8°C	31 Dec 2024
Anti-ms FABP3 Antibody	D0040962	2-8°C	30 Apr 2025
Anti-ms Myl3 Antibody	D0040963	2-8°C	31 May 2025
Anti-ms sTnI Antibody	D0040964	2-8°C	31 Dec 2024
Muscle Injury Panel 3 (mouse) Calibrator Blend	A0040249	≤ -70°C	30 Sep 2022
Diluent 33	M0330015	≤ -10°C	30 Jun 2024
Diluent 30	M0300034	≤ -10°C	31 May 2024

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

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Karen Hamilla	Quality		03 MAY 2022