



RFE MEMO

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Product Description(s): Muscle Injury Panel 2 (rat) Kit


Catalog Number(s) / Size(s): K15180C-Series

Lot Number: K0040500

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040500 has been extended to 30 SEP 2022.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Blocker D-R	R0010656	30 SEP 2021	30 SEP 2022
Diluent 11	M0110044	30 Jun 2022	30 SEP 2022
Diluent 5	M0050069	31 May 2022	30 SEP 2022

Function	Name	Signature	Date
Quality	Karen Hamilla		29 SEP 2021

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 2 (rat) Kit
Kit Lot Number: K0040500
Expiration Date: 30 Sep 2021
Kit Catalog Numbers: K15180C-Series

Precision and Accuracy Specifications:

		Calibrator		Muscle Injury Panel 2 Control 1		Muscle Injury Panel 2 Control 2	
Spot	Name	Recovery	CV	Recovery	CV	Recovery	CV
2	TIMP-1	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
3	CK	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%

Non-Specific Binding Specifications:

Spot	Name	NSB Spec
2	TIMP-1	< 1.0%
3	CK	< 1.0%

Stock Concentration of Calibrator:


Spot	Name	Conc.	Units
2	TIMP-1	882	ng/mL
3	CK	3820	ng/mL

Lot-Specific Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 2 (rat) Plate	Z0056741	2-8°C	31 Dec 2022
Anti-rat TIMP-1 Antibody	D0040924	2-8°C	31 Mar 2024
Anti-rat CK Antibody	D0040923	2-8°C	30 Jun 2024
Muscle Injury Panel 2 (rat) Calibrator Blend	A0040252	≤ -70°C	31 Jan 2023
Blocker D-R	R0010656	≤ -10°C	30 Sep 2021
Diluent 11	M0110044	≤ -10°C	30 Jun 2022
Diluent 5	M0050069	≤ -10°C	31 May 2022

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		09 MAR 2021

QA-FM-309-A

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