



RFE MEMO

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

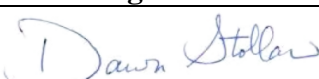
Catalog Number(s) / Size(s): K15180C-Series

Lot Number: K0040449

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040449 has been extended to 31 MAR 2020.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 11	M0110030	31 MAR 2019	31 MAR 2020

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar		05 APR 2019

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

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Product Description: Muscle Injury Panel 2 (rat) Kit

Kit Catalog Numbers: K15180C-Series

Kit Lot Number: K0040449

Expiration Date: 31 Mar 2019

Acceptance Data/ Percent Recovery Specifications:

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

Acceptance Data/ Non Specific Binding Specifications:

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

Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
2	rt TIMP-1	20X Calibrator	782	ng/mL
		Muscle Injury Panel 2 Control 1	203	ng/mL
		Muscle Injury Panel 2 Control 2	8.37	ng/mL
3	rt CK	20X Calibrator	4600	ng/mL
		Muscle Injury Panel 2 Control 1	915	ng/mL
		Muscle Injury Panel 2 Control 2	154	ng/mL
		Muscle Injury Panel 2 Control 3	53.3	ng/mL

Control data was generated utilizing internal reference controls.

Concentrations provided in this table refer to the stock concentration of the calibrators. For top of the standard curve concentrations, please refer to the Standard Curve Data

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Standard Curve Data:


rt TIMP-1 - Spot 2			rt CK - Spot 3		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
39.1	1,480,000	0.9	230	224,000	5.6
9.78	965,000	6.5	57.5	31,000	7.7
2.44	193,000	4.0	14.4	5,590	5.1
0.611	23,900	6.8	3.59	1,360	3.5
0.153	3,400	4.6	0.898	566	3.6
0.0382	901	5.1	0.225	344	6.1
0.00955	487	5.8	0.0562	297	5.0
0.00	357	13.0	0.00	256	11.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 2 (rat) Plate	Z0056373	2-8°C	31 Mar 2021
Anti-rat TIMP-1 Antibody	D0040810	2-8°C	31 Jul 2022
Anti-rat CK Antibody	D0040809	2-8°C	31 May 2022
Muscle Injury Panel 2 (rat) Calibrator Blend	A0040211	≤ -70°C	31 Dec 2020
Blocker A Solution	Not Kit Specific	Not Kit Specific	N/A
Diluent 11	M0110030	≤ -10°C	31 Mar 2019
Diluent 5	M0050063	≤ -10°C	30 Nov 2020
Blocker D-R	R0010641	≤ -10°C	28 Feb 2021
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

Statement:

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

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance		05 APR 2019