



**RFE MEMO**

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**Product Description(s):** Cardiac Injury Panel 3 (rat) Kit  
**Catalog Number(s) / Size(s):** K15161C-Series  
**Lot Number:** K0040385

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0040385 has been extended to 31 MAY 2019.

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

Description	Lot Number	Original Expiration Date	New Expiration Date
Diluent 30	M0300019	30 SEP 2018	31 MAY 2019
EDTA pH 8.0	R0010562	31 MAY 2018	31 MAY 2019
Diluent 7	M0070051	31 MAR 2019	31 MAY 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar		16 APR 2019

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

## CERTIFICATE OF ANALYSIS

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**Product Description:** Cardiac Injury Panel 3 (rat)  
**Kit Catalog Numbers:** K15161C-Series  
**Kit Lot Number:** K0040385  
**Expiration Date:** 31 May 2018

**Acceptance Data/ Percent Recovery Specifications:**

Spot	Name	Calibrator		Muscle/Cardiac Panel Control 1(20X)		Muscle/Cardiac Panel Control 2(20X)		Muscle/Cardiac Panel Control 3(20X)	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	cTnI	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
2	cTnT	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
3	FABP3	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	MyI3	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	cTnI	0.100	80% - 120%	< 20%	20.0	80% - 120%	< 20%
2	cTnT	0.490	80% - 120%	< 20%	35.0	80% - 120%	< 20%
3	FABP3	0.390	75% - 125%	< 20%	25.0	75% - 125%	< 20%
4	MyI3	0.0500	80% - 120%	< 20%	44.0	80% - 120%	< 20%

**Acceptance Data/ Non Specific Binding Specifications:**

Spot	Name	NSB Spec
1	cTnI	< 1.0%
2	cTnT	< 5.0%
3	FABP3	< 1.0%
4	MyL3	< 1.0%

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### Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	cTnI	20X Calibrator	883	ng/mL
		Muscle/Cardiac Panel Control 1(20X)	106	ng/mL
		Muscle/Cardiac Panel Control 2(20X)	31	ng/mL
		Muscle/Cardiac Panel Control 3(20X)	4	ng/mL
2	cTnT	20X Calibrator	1539	ng/mL
		Muscle/Cardiac Panel Control 1(20X)	285	ng/mL
		Muscle/Cardiac Panel Control 2(20X)	91	ng/mL
		Muscle/Cardiac Panel Control 3(20X)	22	ng/mL
3	FABP3	20X Calibrator	1649	ng/mL
		Muscle/Cardiac Panel Control 1(20X)	165	ng/mL
		Muscle/Cardiac Panel Control 2(20X)	60	ng/mL
		Muscle/Cardiac Panel Control 3(20X)	23	ng/mL
4	MyI3	20X Calibrator	1200	ng/mL
		Muscle/Cardiac Panel Control 1(20X)	530	ng/mL
		Muscle/Cardiac Panel Control 2(20X)	93	ng/mL
		Muscle/Cardiac Panel Control 3(20X)	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

### Standard Curve Data:

cTnI - Spot 1			cTnT - Spot 2			FABP3 - Spot 3		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
44.1	199,000	3.9	77.0	421,000	5.4	82.5	72,500	5.1
11.0	45,800	3.6	19.2	72,700	3.4	20.6	45,800	2.2
2.76	10,800	3.3	4.81	7,450	3.7	5.15	12,800	2.7
0.690	2,730	2.6	1.20	779	4.0	1.29	2,400	2.7
0.172	699	3.5	0.301	206	8.9	0.322	1,060	3.6
0.0431	228	3.3	0.0751	135	13.0	0.0805	823	3.6
0.0108	103	6.2	0.0188	132	15.0	0.0201	779	5.4
0.00	66	8.4	0.00	122	14.0	0.00	755	3.4

**CERTIFICATE OF ANALYSIS**

Myl3 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
60.0	233,000	3.7
15.0	58,900	3.8
3.75	13,400	4.1
0.938	3,210	4.6
0.234	862	3.7
0.0586	296	3.6
0.0146	157	8.7
0.00	112	17.0

**Components:**


Description	Lot Number	Storage Temperature	Expiration Date
Cardiac Injury Panel 3 (rat) Plate	Z0055826	2-8°C	31 Jul 2019
Anti-rcTnI Antibody	D0040675	2-8°C	31 Jul 2019
Anti-rat cTnT Antibody	D0040673	2-8°C	31 Aug 2019
Anti-rat FABP3 Antibody	D0040672	2-8°C	31 Oct 2019
Anti-rat Myl3 Antibody	D0040674	2-8°C	31 Jul 2019
Cardiac Injury Panel 3 (rat) Calibrator Blend	A0040202	≤ -70°C	31 Jul 2019
Diluent 7	M0070051	≤ -10°C	31 Mar 2019
Diluent 30	M0300019	≤ -10°C	30 Sep 2018
DTT	R0010583	≤ -10°C	31 Jul 2019
EDTA pH 8.0	R0010562	Room Temperature	31 May 2018
MSD Read Buffer T	Not Kit Specific	Not Kit Specific	N/A

**Additional Comments:**

	Assay	Spot	Specification	Comment
1	cTnI	1	Calibrator CV	Avg signal ratio = 49.0%
2	cTnT	2	Calibrator CV	Avg signal ratio = 39.0%

**Statement:**

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

	Name	Function	Signature	Date
<b>Review/Approval</b>	Dawn Stollar	Quality Assurance		16 APR 2019