

**CERTIFICATE OF ANALYSIS**

**Product Description:** Muscle Injury Panel 1 (rat) Kit  
**Kit Catalog Numbers:** K15181C-Series  
**Kit Lot Number:** K0040506  
**Expiration Date:** 31 Mar 2021

**Acceptance Data/ Percent Recovery Specifications:**

Spot	Name	Calibrator		Muscle Injury Panel 1 Control 1		Muscle Injury Panel 1 Control 2		Muscle Injury Panel 1 Control 3	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	cTnI	80% - 120%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%	75% - 125%	< 20%
2	cTnT	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	MyI3	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	0.0977	80% - 120%	< 20%	20.0	80% - 120%	< 20%
2	cTnT	0.488	80% - 120%	< 20%	35.0	80% - 120%	< 20%
3	FABP3	0.391	75% - 125%	< 25%	15.0	75% - 125%	< 25%
5	MyI3	0.170	75% - 125%	< 25%	44.0	80% - 120%	< 20%
6	sTnI	0.781	80% - 120%	< 20%	160	80% - 120%	< 20%

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

Spot	Name	cTnI	cTnT	FABP3	MyI3
1	cTnI	NA	< 1.0%	< 1.0%	< 1.0%
2	cTnT	< 1.0%	NA	< 1.0%	< 1.0%
3	FABP3	< 1.0%	< 1.0%	NA	< 1.0%
5	MyI3	< 1.0%	< 1.0%	< 1.0%	NA
6	sTnI	< 1.0%	< 1.0%	< 1.0%	< 1.0%

Spot	Name	sTnI
1	cTnI	< 65.0%
2	cTnT	< 15.0%
3	FABP3	< 1.0%
5	MyI3	< 1.0%
6	sTnI	NA

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### Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	cTnI	20X Calibrator	522	ng/mL
		Muscle Injury Panel 1 Control 1	116	ng/mL
		Muscle Injury Panel 1 Control 2	28.1	ng/mL
		Muscle Injury Panel 1 Control 3	7.05	ng/mL
2	cTnT	20X Calibrator	1010	ng/mL
		Muscle Injury Panel 1 Control 1	265	ng/mL
		Muscle Injury Panel 1 Control 2	88.4	ng/mL
		Muscle Injury Panel 1 Control 3	27.9	ng/mL
3	FABP3	20X Calibrator	1916	ng/mL
		Muscle Injury Panel 1 Control 1	89.1	ng/mL
		Muscle Injury Panel 1 Control 2	47.3	ng/mL
		Muscle Injury Panel 1 Control 3	29.2	ng/mL
5	MyI3	20X Calibrator	990	ng/mL
		Muscle Injury Panel 1 Control 1	208	ng/mL
		Muscle Injury Panel 1 Control 2	31.7	ng/mL
		Muscle Injury Panel 1 Control 3	4.85	ng/mL
6	sTnI	20X Calibrator	3900	ng/mL
		Muscle Injury Panel 1 Control 1	825	ng/mL
		Muscle Injury Panel 1 Control 2	198	ng/mL
		Muscle Injury Panel 1 Control 3	50.1	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
26.1	195,000	8.0	50.5	343,000	5.6	95.8	87,100	6.2
8.70	57,600	8.1	16.8	77,600	11.0	31.9	72,200	5.6
2.90	17,200	4.3	5.61	12,200	7.8	10.6	43,700	7.5
0.967	5,580	4.7	1.87	1,940	11.0	3.55	16,600	4.8
0.322	1,890	11.0	0.623	530	6.9	1.18	4,870	5.4
0.107	653	11.0	0.208	216	9.8	0.394	2,190	4.4
0.0358	302	7.0	0.0693	144	7.4	0.131	1,500	5.5
0.00	99	7.3	0.00	112	8.4	0.00	1,220	7.1

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MyI3 - Spot 5			sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
49.5	395,000	3.1	195	251,000	4.3
16.5	144,000	3.9	65.0	73,000	5.6
5.50	43,200	3.3	21.7	21,200	5.1
1.83	12,700	4.1	7.22	6,550	5.3
0.611	4,180	6.2	2.41	2,420	3.9
0.204	1,490	6.7	0.802	937	5.2
0.0679	578	5.6	0.267	436	7.6
0.00	152	13.0	0.00	185	16.0

### Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056661	2-8°C	30 Jun 2022
Anti-rcTnI Antibody	D0040897	2-8°C	30 Jun 2023
Anti-rat cTnT Antibody	D0040898	2-8°C	30 Sep 2023
Anti-rat FABP3 Antibody	D0040845	2-8°C	31 Mar 2023
Anti-rat MyI3 Antibody	D0040900	2-8°C	30 Jun 2023
Anti-rat sTnI Antibody	D0040901	2-8°C	30 Jun 2023
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040216	≤ -70°C	31 Mar 2021
Diluent 7	M0070062	≤ -10°C	31 May 2022
Diluent 30	M0300028	≤ -10°C	31 Aug 2022
DTT	Not Kit Specific	Not Kit Specific	N/A
EDTA	Not Kit Specific	Not Kit Specific	N/A
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	Karen Hamilla	Quality		08 SEP 2020