

## CERTIFICATE OF ANALYSIS

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**Product Description:** Muscle Injury Panel 3 (mouse) Kit  
**Kit Catalog Numbers:** K15186C-Series  
**Kit Lot Number:** K0040475  
**Expiration Date:** 31 Aug 2021

**Acceptance Data/ Percent Recovery Specifications:**

Spot	Name	Calibrator		Muscle injury Panel 3 (mouse) Control 1		Muscle Injury Panel 3 (mouse) Control 2		Muscle injury Panel 3 (mouse) 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	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	0.0700	75% - 125%	< 25%	20.0	80% - 120%	< 20%
3	FABP3	0.535	80% - 120%	< 20%	20.0	80% - 120%	< 20%
5	MyI3	0.135	80% - 120%	< 20%	41.4	80% - 120%	< 20%
6	sTnI	0.505	80% - 120%	< 20%	155	80% - 120%	< 20%

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

Spot	Name	NSB Spec
1	cTnI	< 1.0%
3	FABP3	< 1.0%
5	MyI3	< 1.0%
6	sTnI	< 1.0%

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### Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	cTnI	20X Calibrator	618	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	43.2	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	5.88	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	1.6	ng/mL
3	FABP3	20X Calibrator	1550	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	48.6	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	12.2	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	4.64	ng/mL
5	MyI3	20X Calibrator	866	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	105	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	26.6	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	1.8	ng/mL
6	sTnI	20X Calibrator	4680	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	195	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	31.6	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	5.04	ng/mL

Controls 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			FABP3 - Spot 3			MyI3 - Spot 5		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
30.9	594,000	5.9	77.5	152,000	4.9	43.3	169,000	5.8
7.72	128,000	6.1	19.4	108,000	6.8	10.8	41,900	5.0
1.93	24,300	8.4	4.84	42,600	4.7	2.71	9,690	6.8
0.483	5,110	8.6	1.21	7,750	4.5	0.677	2,390	7.2
0.121	1,340	8.1	0.303	1,870	6.0	0.169	740	5.2
0.0302	494	15.0	0.0757	978	11.0	0.0423	298	7.2
0.00754	250	21.0	0.0189	812	14.0	0.0106	199	8.8
0.00	170	25.0	0.00	728	12.0	0.00	175	10.0

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sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV
234	640,000	6.2
58.5	157,000	4.5
14.6	31,900	4.5
3.66	6,840	11.0
0.914	1,890	9.6
0.229	695	13.0
0.0571	325	13.0
0.00	223	20.0

**Components:**

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 3 (Mouse) Plate	Z0056537	2-8°C	30 Nov 2021
Anti-ms cTnI Antibody	D0040870	2-8°C	30 Nov 2022
Anti-ms FABP3 Antibody	D0040871	2-8°C	31 Dec 2022
Anti-ms MyI3 Antibody	D0040872	2-8°C	31 Jan 2023
Anti-ms sTnI Antibody	D0040873	2-8°C	30 Nov 2022
Muscle Injury Panel 3 (mouse) Calibrator Blend	A0040244	≤ -70°C	30 Jun 2022
Diluent 33	M0330011	≤ -10°C	31 Aug 2021
Diluent 30	M0300026	≤ -10°C	31 Oct 2021
DTT	Not Kit Specific	Not Kit Specific	N/A
EDTA pH 8.0	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
<b>Review/Approval</b>	Karen Hamilla	Quality		30 JAN 2020