

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 3 (mouse) Kit
Kit Catalog Numbers: K15186C - Series
Kit Lot Number: K0040492
Expiration Date: 31 May 2022

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	1.00	75% - 125%	< 25%	26.8	80% - 120%	< 20%
5	MyI3	0.300	75% - 125%	< 25%	41.4	80% - 120%	< 20%
6	sTnI	0.505	75% - 125%	< 25%	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	662	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	37.1	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	5.3	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	1.49	ng/mL
3	FABP3	20X Calibrator	1706	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	47.8	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	11.3	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	4.02	ng/mL
5	MyI3	20X Calibrator	956	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	91.8	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	23.5	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	1.57	ng/mL
6	sTnI	20X Calibrator	4820	ng/mL
		Muscle injury Panel 3 (mouse) Control 1	203	ng/mL
		Muscle Injury Panel 3 (mouse) Control 2	32	ng/mL
		Muscle injury Panel 3 (mouse) Control 3	5.13	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			FABP3 - Spot 3			MyI3 - Spot 5		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
33.1	518,000	7.6	85.3	121,000	8.5	47.8	239,000	3.5
8.28	118,000	9.9	21.3	90,400	3.6	11.9	56,200	5.2
2.07	23,600	8.1	5.33	37,400	6.6	2.99	13,400	4.7
0.517	5,380	7.8	1.33	7,020	7.5	0.747	3,220	5.7
0.129	1,400	7.5	0.333	1,620	8.0	0.187	909	4.2
0.0323	466	10.0	0.0833	844	12.0	0.0467	337	5.0
0.00808	230	18.0	0.0208	766	16.0	0.0117	205	7.8
0.00	146	10.0	0.00	790	29.0	0.00	161	5.5

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sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV
241	534,000	4.4
60.3	135,000	5.7
15.1	29,700	6.2
3.77	6,840	6.1
0.941	2,040	6.2
0.235	727	15.0
0.0588	370	28.0
0.00	291	33.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 3 (mouse) Plate	Z0056676	2-8°C	31 Jul 2022
Anti-ms cTnI Antibody	D0040907	2-8°C	31 Aug 2023
Anti-ms FABP3 Antibody	D0040908	2-8°C	30 Sep 2023
Anti-ms Myl3 Antibody	D0040909	2-8°C	31 Aug 2023
Anti-ms sTnI Antibody	D0040910	2-8°C	31 Aug 2023
Muscle Injury Panel 3 (mouse) Calibrator Blend	A0040249	≤ -70°C	30 Sep 2022
Diluent 33	M0330013	≤ -10°C	31 May 2022
Diluent 30	M0300030	≤ -10°C	31 Oct 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		16 JUL 2020