

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 3 (mouse) Kit

Kit Catalog Numbers: K15186C-Series

Kit Lot Number: K0040460

Expiration Date: 30 Nov 2019

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	0.0160	75% - 125%	< 25%	20.0	80% - 120%	< 20%
3	FABP3	0.535	80% - 120%	< 20%	26.8	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	480	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	1966	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	1300	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	3860	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

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
24.0	449,000	2.8	98.3	22,700	4.4	65.0	103,000	9.4
6.00	94,700	3.9	24.6	15,800	5.7	16.3	27,000	4.9
1.50	19,100	6.8	6.14	5,180	5.2	4.06	6,120	7.1
0.375	4,300	3.6	1.54	1,010	5.0	1.02	1,540	6.7
0.0938	1,160	6.6	0.384	447	5.4	0.254	594	3.4
0.0234	423	5.0	0.0960	413	6.0	0.0635	358	3.8
0.00586	238	5.2	0.0240	364	5.5	0.0159	297	3.1
0.00	185	9.0	0.00	413	7.0	0.00	280	3.1

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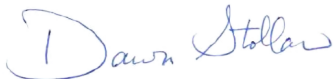
sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV
193	658,000	3.8
48.3	180,000	2.5
12.1	41,800	3.4
3.02	10,000	3.7
0.754	2,790	6.0
0.188	952	3.9
0.0471	484	3.4
0.00	321	3.7

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 3 (Mouse) Plate	Z0055960	2-8°C	30 Nov 2019
Anti-ms cTnI Antibody	D0040712	2-8°C	30 Nov 2019
Anti-ms FABP3 Antibody	D0040713	2-8°C	30 Nov 2019
Anti-ms MyI3 Antibody	D0040714	2-8°C	31 Jan 2020
Anti-ms sTnI Antibody	D0040715	2-8°C	30 Nov 2019
Muscle Injury Panel 3 Calibrator Blend	A0040196	≤ -70°C	30 Nov 2019
Diluent 33	M0330010	≤ -10°C	31 Dec 2019
Diluent 30	M0300021	≤ -10°C	30 Jun 2020
DTT	R0010598	≤ -10°C	31 Dec 2019
EDTA pH 8.0	R00X1122	Room Temperature	31 Mar 2020
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		15 MAR 2019