

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15181C-Series
Kit Lot Number: K0040468
Expiration Date: 31 Mar 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Muscle/Cardiac Panel Control 1		Muscle/Cardiac Panel Control 2		Muscle/Cardiac Panel 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%	N/A	N/A
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/Cardiac Panel Control 1	114	ng/mL
		Muscle/Cardiac Panel Control 2	31.6	ng/mL
		Muscle/Cardiac Panel Control 3	3.93	ng/mL
2	cTnT	20X Calibrator	1010	ng/mL
		Muscle/Cardiac Panel Control 1	353	ng/mL
		Muscle/Cardiac Panel Control 2	88	ng/mL
		Muscle/Cardiac Panel Control 3	19.4	ng/mL
3	FABP3	20X Calibrator	1916	ng/mL
		Muscle/Cardiac Panel Control 1	164	ng/mL
		Muscle/Cardiac Panel Control 2	58.6	ng/mL
		Muscle/Cardiac Panel Control 3	23.2	ng/mL
5	MyI3	20X Calibrator	990	ng/mL
		Muscle/Cardiac Panel Control 1	518	ng/mL
		Muscle/Cardiac Panel Control 2	84.1	ng/mL
6	sTnI	20X Calibrator	3900	ng/mL
		Muscle/Cardiac Panel Control 1	1960	ng/mL
		Muscle/Cardiac Panel Control 2	321	ng/mL
		Muscle/Cardiac Panel Control 3	34.5	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	205,000	6.9	50.5	400,000	4.6	95.8	60,600	2.9
8.70	60,100	6.2	16.8	92,700	8.8	31.9	49,000	4.5
2.90	17,900	5.3	5.61	17,100	8.2	10.6	29,300	5.0
0.967	6,050	7.5	1.87	3,430	10.0	3.55	11,200	6.1
0.322	2,010	6.2	0.623	1,020	6.6	1.18	3,280	7.1
0.107	881	6.0	0.208	408	5.4	0.394	1,480	3.4
0.0358	375	13.0	0.0693	346	23.0	0.131	970	6.1
0.00	222	28.0	0.00	185	15.0	0.00	843	3.3

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MyI3 - Spot 5			sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
49.5	240,000	5.9	195	247,000	6.0
16.5	82,100	5.1	65.0	73,400	6.5
5.50	23,800	10.0	21.7	20,600	3.9
1.83	7,460	6.9	7.22	6,570	5.4
0.611	2,630	5.1	2.41	2,390	4.0
0.204	990	6.5	0.802	908	3.3
0.0679	512	6.6	0.267	424	3.9
0.00	241	5.0	0.00	187	5.7

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056508	2-8°C	30 Sep 2021
Anti-rc TnI Antibody	D0040840	2-8°C	30 Sep 2022
Anti-rat cTnT Antibody	D0040841	2-8°C	30 Nov 2022
Anti-rat FABP3 Antibody	D0040842	2-8°C	30 Sep 2022
Anti-rat MyI3 Antibody	D0040843	2-8°C	30 Sep 2022
Anti-rat sTnI Antibody	D0040844	2-8°C	30 Sep 2022
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040216	≤ -70°C	31 Mar 2021
Diluent 7	M0070060	≤ -10°C	31 Oct 2021
Diluent 30	M0300025	≤ -10°C	31 Jul 2021
DTT	R0010649	≤ -10°C	31 May 2021
EDTA	R0010662	Room Temperature	30 Nov 2021
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		15 AUG 2019