

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15181C-Series
Kit Lot Number: K0040431
Expiration Date: 31 Dec 2019

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	263,000	5.8	50.5	315,000	5.9	95.8	75,400	3.8
8.70	79,100	5.6	16.8	75,500	9.9	31.9	61,000	4.3
2.90	24,000	9.3	5.61	12,700	15.0	10.6	36,300	3.6
0.967	7,460	4.8	1.87	1,980	7.5	3.55	14,300	6.5
0.322	2,570	5.1	0.623	526	6.4	1.18	4,280	5.4
0.107	930	5.2	0.208	237	6.4	0.394	2,010	5.2
0.0358	380	4.2	0.0693	174	6.2	0.131	1,300	5.9
0.00	109	6.1	0.00	149	14.0	0.00	1,200	3.2

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MyI3 - Spot 5			sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
49.5	260,000	5.0	195	298,000	3.1
16.5	88,000	6.9	65.0	83,900	5.0
5.50	25,400	8.6	21.7	22,400	7.0
1.83	7,480	10.0	7.22	6,270	14.0
0.611	2,550	4.4	2.41	2,380	11.0
0.204	946	6.8	0.802	927	5.1
0.0679	422	9.5	0.267	445	6.2
0.00	176	8.3	0.00	190	8.5

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056290	2-8°C	30 Nov 2020
Anti-rcTnI Antibody	D0040773	2-8°C	30 Nov 2021
Anti-rat cTnT Antibody	D0040774	2-8°C	30 Nov 2021
Anti-rat FABP3 Antibody	D0040775	2-8°C	30 Nov 2021
Anti-rat MyI3 Antibody	D0040776	2-8°C	30 Nov 2021
Anti-rat sTnI Antibody	D0040777	2-8°C	31 Jul 2022
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040216	≤ -70°C	31 Mar 2021
Diluent 7	M0070055	≤ -10°C	31 Dec 2020
Diluent 30	M0300023	≤ -10°C	31 Dec 2020
DTT	R0010635	≤ -10°C	31 Dec 2020
EDTA pH 8.0	R0010599	Room Temperature	31 Dec 2019
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		21 MAR 2019