

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15181C-Series
Kit Lot Number: K0040499
Expiration Date: 31 Oct 2021

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Muscle Injury Panel 1 Control 1		Muscle Injury Panel 1 Control 2		Muscle Injury Panel 1 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%	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	0.0977	80% - 120%	< 20%	17.0	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	386	ng/mL
		Muscle Injury Panel 1 Control 1	116	ng/mL
		Muscle Injury Panel 1 Control 2	28.1	ng/mL
		Muscle Injury Panel 1 Control 3	7.05	ng/mL
2	cTnT	20X Calibrator	1118	ng/mL
		Muscle Injury Panel 1 Control 1	265	ng/mL
		Muscle Injury Panel 1 Control 2	88.4	ng/mL
		Muscle Injury Panel 1 Control 3	27.9	ng/mL
3	FABP3	20X Calibrator	1830	ng/mL
		Muscle Injury Panel 1 Control 1	89.1	ng/mL
		Muscle Injury Panel 1 Control 2	47.3	ng/mL
		Muscle Injury Panel 1 Control 3	29.2	ng/mL
5	MyI3	20X Calibrator	1070	ng/mL
		Muscle Injury Panel 1 Control 1	208	ng/mL
		Muscle Injury Panel 1 Control 2	31.7	ng/mL
		Muscle Injury Panel 1 Control 3	4.85	ng/mL
6	sTnI	20X Calibrator	3820	ng/mL
		Muscle Injury Panel 1 Control 1	825	ng/mL
		Muscle Injury Panel 1 Control 2	198	ng/mL
		Muscle Injury Panel 1 Control 3	50.1	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
19.3	121,000	9.3	55.9	413,000	3.7	91.5	97,900	6.9
6.43	35,400	7.2	18.6	94,700	10.0	30.5	82,000	4.9
2.14	11,100	3.6	6.21	15,800	2.8	10.2	52,600	7.3
0.715	3,450	7.1	2.07	2,680	3.7	3.39	23,100	4.9
0.238	1,200	9.3	0.690	743	5.6	1.13	8,580	6.3
0.0794	435	8.9	0.230	273	4.3	0.377	4,680	4.5
0.0265	209	7.1	0.0767	162	6.9	0.126	3,570	3.7
0.00	92	7.2	0.00	111	8.2	0.00	3,070	5.5

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MyI3 - Spot 5			sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
53.5	335,000	2.7	191	199,000	3.8
17.8	117,000	4.0	63.7	57,200	4.8
5.94	34,900	4.6	21.2	17,400	3.3
1.98	10,200	3.5	7.07	5,560	4.0
0.660	3,300	3.8	2.36	1,990	3.0
0.220	1,120	4.6	0.786	764	4.8
0.0734	468	6.6	0.262	362	6.0
0.00	142	8.8	0.00	180	21.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056739	2-8°C	31 Dec 2022
Anti-rcTnI Antibody	D0040848	2-8°C	31 Jan 2023
Anti-rat cTnT Antibody	D0040921	2-8°C	31 Dec 2023
Anti-rat FABP3 Antibody	D0040899	2-8°C	31 Oct 2023
Anti-rat MyI3 Antibody	D0040759	2-8°C	31 Oct 2021
Anti-rat sTnI Antibody	D0040922	2-8°C	31 Dec 2023
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040253	≤ -70°C	30 Apr 2022
Diluent 7	M0070064	≤ -10°C	30 Nov 2022
Diluent 30	M0300031	≤ -10°C	31 Dec 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		06 OCT 2020