

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15181C-series
Kit Lot Number: K0040417
Expiration Date: 31 Jul 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	Myl3	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%	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	Myl3	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	Myl3
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	Myl3	< 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	Myl3	< 1.0%
6	sTnI	NA

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	cTnI	20X Calibrator	608	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	1328	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	1698	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	992	ng/mL
		Muscle/Cardiac Panel Control 1	518	ng/mL
		Muscle/Cardiac Panel Control 2	84.1	ng/mL
		Muscle/Cardiac Panel Control 3	2.33	ng/mL
6	sTnI	20X Calibrator	4120	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

Controls tested may not be the same lot as shipped.

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
30.4	262,000	7.9	66.4	322,000	8.0	84.9	48,200	5.7
10.1	75,300	7.1	22.1	81,600	9.2	28.3	37,200	4.7
3.38	23,100	6.3	7.38	14,400	8.5	9.43	22,100	4.9
1.13	7,070	7.0	2.46	2,300	9.8	3.14	8,380	5.5
0.375	2,380	6.0	0.820	573	7.7	1.05	2,700	5.7
0.125	865	6.2	0.273	226	4.4	0.349	1,390	4.5
0.0417	361	5.7	0.0911	148	7.0	0.116	980	5.2
0.00	107	8.4	0.00	115	8.5	0.00	958	5.7

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Myl3 - Spot 5		
Conc. ng/mL	ECL Signal	%CV
49.6	250,000	5.9
16.5	87,400	4.4
5.51	26,200	6.8
1.84	7,570	7.5
0.612	2,510	5.3
0.204	879	5.1
0.0680	384	6.8
0.00	144	7.7

sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV
206	353,000	9.2
68.7	108,000	4.3
22.9	31,600	4.0
7.63	9,560	3.7
2.54	3,680	6.6
0.848	1,460	5.6
0.283	731	13.0
0.00	440	20.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056127	2-8°C	31 May 2020
Anti-rcTnI Antibody	D0040746	2-8°C	31 Jul 2020
Anti-rat cTnT Antibody	D0040747	2-8°C	31 Jul 2020
Anti-rat FABP3 Antibody	D0040748	2-8°C	31 May 2020
Anti-rat Myl3 Antibody	D0040749	2-8°C	31 Oct 2021
Anti-rat sTnI Antibody	D0040750	2-8°C	31 May 2020
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040206	≤ -70°C	31 Oct 2020
Diluent 7	M0070052	≤ -10°C	31 Jul 2019
Diluent 30	M0300021	≤ -10°C	30 Jun 2020
DTT	R0010598	≤ -10°C	31 Dec 2019
EDTA pH 8.0	R00X1135	Room Temperature	30 Jun 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	<i>Dawn Stollar</i>	22 JUN 2018