

CERTIFICATE OF ANALYSIS

Page 1 of 4

Product Description: Muscle Injury Panel 1 (rat) Kit

Kit Catalog Numbers: K15181C-Series

Kit Lot Number: K0040421

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

CERTIFICATE OF ANALYSIS

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

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
30.4	295,000	8.6	66.4	359,000	4.5	84.9	69,900	6.9
10.1	80,500	7.8	22.1	88,400	13.0	28.3	55,700	5.1
3.38	22,700	5.0	7.38	14,800	13.0	9.43	30,200	6.8
1.13	7,290	5.0	2.46	2,270	9.2	3.14	10,900	5.2
0.375	2,570	6.9	0.820	568	6.9	1.05	3,120	5.9
0.125	999	5.8	0.273	240	8.4	0.349	1,560	5.3
0.0417	503	4.3	0.0911	169	5.9	0.116	1,060	3.6
0.00	247	13.0	0.00	138	10.0	0.00	991	9.6

CERTIFICATE OF ANALYSIS

Myl3 - Spot 5			sTnI - Spot 6		
Conc. ng/ml	ECL Signal	%CV	Conc. ng/ml	ECL Signal	%CV
49.6	302,000	6.5	206	305,000	12.0
16.5	98,100	15.0	68.7	88,700	4.3
5.51	28,900	13.0	22.9	23,100	3.8
1.84	9,090	6.8	7.63	6,930	3.3
0.612	2,900	7.1	2.54	2,500	5.5
0.204	1,070	7.7	0.848	1,010	4.0
0.0680	477	4.7	0.283	492	3.8
0.00	180	11.0	0.00	231	12.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056166	2-8°C	31 Jul 2020
Anti-rcTnI Antibody	D0040756	2-8°C	31 Aug 2021
Anti-rat cTnT Antibody	D0040757	2-8°C	31 Jul 2020
Anti-rat FABP3 Antibody	D0040758	2-8°C	30 Nov 2021
Anti-rat Myl3 Antibody	D0040749	2-8°C	31 Oct 2021
Anti-rat sTnI Antibody	D0040760	2-8°C	31 Jul 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 2021
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

Additional Comments:


Assay	Spot	Specification	Comment
1 cTnI	1	Calibrator CV	Avg Signal Ratio = 40.3%
2 cTnT	2	Calibrator CV	Avg Signal Ratio = 46.7%

CERTIFICATE OF ANALYSIS

Page 4 of 4

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		06 MAR 2019