

CERTIFICATE OF ANALYSIS

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Product Description: Muscle Injury Panel 1 (rat) Kit
Kit Catalog Numbers: K15181C-Series; K15161C-Series; K15155C-Series
Kit Lot Number: K0040489
Expiration Date: 31 Dec 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%	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	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	310	ng/mL
		Muscle/Cardiac Panel Control 1	116	ng/mL
		Muscle/Cardiac Panel Control 2	28.1	ng/mL
		Muscle/Cardiac Panel Control 3	7.05	ng/mL
2	cTnT	20X Calibrator	920	ng/mL
		Muscle/Cardiac Panel Control 1	265	ng/mL
		Muscle/Cardiac Panel Control 2	88.4	ng/mL
		Muscle/Cardiac Panel Control 3	27.9	ng/mL
3	FABP3	20X Calibrator	2140	ng/mL
		Muscle/Cardiac Panel Control 1	89.1	ng/mL
		Muscle/Cardiac Panel Control 2	47.3	ng/mL
		Muscle/Cardiac Panel Control 3	29.2	ng/mL
5	MyI3	20X Calibrator	1526	ng/mL
		Muscle/Cardiac Panel Control 1	208	ng/mL
		Muscle/Cardiac Panel Control 2	31.7	ng/mL
		Muscle/Cardiac Panel Control 3	4.85	ng/mL
6	sTnI	20X Calibrator	3920	ng/mL
		Muscle/Cardiac Panel Control 1	825	ng/mL
		Muscle/Cardiac Panel Control 2	198	ng/mL
		Muscle/Cardiac Panel 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
15.5	86,300	13.0	46.0	173,000	9.0	107	78,300	5.8
5.17	25,400	8.8	15.3	32,400	12.0	35.7	60,700	4.8
1.72	7,960	7.6	5.11	5,480	8.9	11.9	36,700	7.9
0.574	2,680	7.1	1.70	1,100	8.5	3.96	13,900	5.2
0.191	1,010	8.7	0.568	375	9.7	1.32	4,110	4.9
0.0638	418	12.0	0.189	184	10.0	0.440	1,720	8.2
0.0213	206	9.3	0.0631	136	14.0	0.147	1,190	6.3
0.00	161	24.0	0.00	121	15.0	0.00	987	6.4

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MyI3 - Spot 5			sTnI - Spot 6		
Conc. ng/mL	ECL Signal	%CV	Conc. ng/mL	ECL Signal	%CV
76.3	473,000	3.5	196	230,000	5.5
25.4	171,000	5.9	65.3	57,500	5.5
8.48	53,100	5.4	21.8	14,400	6.0
2.83	16,000	5.5	7.26	4,300	7.9
0.942	5,280	5.9	2.42	1,550	5.9
0.314	1,710	3.8	0.807	580	5.2
0.105	659	5.7	0.269	311	13.0
0.00	123	7.8	0.00	149	16.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Muscle Injury Panel 1 (rat) Plate	Z0056661	2-8°C	30 Jun 2022
Anti-rat cTnI Antibody	D0040897	2-8°C	30 Jun 2023
Anti-rat cTnT Antibody	D0040898	2-8°C	30 Sep 2023
Anti-rat FABP3 Antibody	D0040845	2-8°C	31 Mar 2023
Anti-rat MyI3 Antibody	D0040900	2-8°C	30 Jun 2023
Anti-rat sTnI Antibody	D0040901	2-8°C	30 Jun 2023
Muscle Injury Panel 1 (rat) Calibrator Blend	A0040247	≤ -70°C	31 Dec 2021
Diluent 7	M0070062	≤ -10°C	31 May 2022
Diluent 30	M0300028	≤ -10°C	31 Aug 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		29 JUN 2020