

CERTIFICATE OF ANALYSIS

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Product Description: Cardiac Injury Panel 3 (rat) Kit

Kit Catalog Numbers: K15161C-Series

Kit Lot Number: K0040434

Expiration Date: 31 Dec 2020

Acceptance Data/ Percent Recovery Specifications:

Spot	Name	Calibrator		Muscle/Cardiac Panel Control 1 (20X)		Muscle/Cardiac Panel Control 2 (20X)		Muscle/Cardiac Panel Control 3 (20X)	
		Recovery	CV	Recovery	CV	Recovery	CV	Recovery	CV
1	cTnI	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
2	cTnT	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
3	FABP3	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%
4	MyI3	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%	80% - 120%	< 20%

Spot	Name	LLOQ			ULOQ		
		Value	Recovery	CV	Value	Recovery	CV
1	cTnI	0.0980	80% - 120%	< 20%	20.0	80% - 120%	< 20%
2	cTnT	0.490	80% - 120%	< 20%	35.0	80% - 120%	< 20%
3	FABP3	0.390	75% - 125%	< 20%	25.0	75% - 125%	< 20%
4	MyI3	0.0540	80% - 120%	< 20%	44.0	80% - 120%	< 20%

Acceptance Data/ Non Specific Binding Specifications:

Spot	Name	NSB Spec
1	cTnI	< 1.0%
2	cTnT	< 5.0%
3	FABP3	< 1.0%
4	MyI3	< 1.0%

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Stock Concentration of Material Tested :

Spot	Name	Item	Conc	Units
1	cTnI	20X Calibrator	722	ng/mL
		Muscle/Cardiac Panel Control 1 (20X)	106	ng/mL
		Muscle/Cardiac Panel Control 2 (20X)	31	ng/mL
		Muscle/Cardiac Panel Control 3 (20X)	4	ng/mL
2	cTnT	20X Calibrator	1210	ng/mL
		Muscle/Cardiac Panel Control 1 (20X)	285	ng/mL
		Muscle/Cardiac Panel Control 2 (20X)	91	ng/mL
		Muscle/Cardiac Panel Control 3 (20X)	22	ng/mL
3	FABP3	20X Calibrator	1696	ng/mL
		Muscle/Cardiac Panel Control 1 (20X)	165	ng/mL
		Muscle/Cardiac Panel Control 2 (20X)	60	ng/mL
		Muscle/Cardiac Panel Control 3 (20X)	23	ng/mL
4	MyI3	20X Calibrator	1154	ng/mL
		Muscle/Cardiac Panel Control 1 (20X)	530	ng/mL
		Muscle/Cardiac Panel Control 2 (20X)	93	ng/mL
		Muscle/Cardiac Panel Control 3 (20X)	3	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
36.1	109,000	3.3	60.5	448,000	6.6	84.8	63,000	3.2
9.03	24,500	3.4	15.1	66,000	4.0	21.2	43,500	2.4
2.26	5,740	3.3	3.78	6,160	3.4	5.30	15,800	3.1
0.564	1,440	3.4	0.945	700	9.7	1.32	3,030	2.9
0.141	399	1.7	0.236	193	5.1	0.331	1,250	3.8
0.0353	144	4.3	0.0591	108	4.9	0.0828	927	3.0
0.00881	78	6.5	0.0148	90	8.8	0.0207	878	3.0
0.00	58	7.9	0.00	87	14.0	0.00	829	3.0

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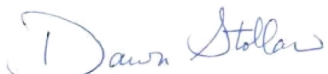
MyI3 - Spot 4		
Conc. ng/mL	ECL Signal	%CV
57.7	271,000	7.0
14.4	65,500	4.4
3.61	14,100	4.6
0.902	3,150	5.1
0.225	864	3.2
0.0563	293	4.2
0.0141	176	6.8
0.00	137	13.0

Components:

Description	Lot Number	Storage Temperature	Expiration Date
Cardiac Injury panel 3 (rat) Plate	Z0056309	2-8°C	31 Dec 2020
Anti-rcTnI Antibody	D0040784	2-8°C	31 Jan 2022
Anti-rat cTnT Antibody	D0040782	2-8°C	31 May 2022
Anti-rat FABP3 Antibody	D0040781	2-8°C	31 Dec 2021
Anti-rat MyI3 Antibody	D0040783	2-8°C	31 Jan 2022
Cardiac Injury Panel 3 (rat) Calibrator Blend	A0040218	≤ -70°C	31 Mar 2021
Diluent 7	M0070056	≤ -10°C	31 Jan 2021
Diluent 30	M0300024	≤ -10°C	31 Jan 2021
DTT	R0010643	≤ -10°C	31 Jan 2021
EDTA pH 8.0	R0010636	Room Temperature	31 Dec 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		28 MAR 2019