



CERTIFICATE OF ANALYSIS

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COA-04938

Product Description: Cardiac Injury Panel 2 (rat) Kit
Kit Catalog Numbers: K15155C-1, K15155C-2 , K15155C-4
Kit Lot Number: K0040274
Expiration Date: 28 FEB 2015

Acceptance Data:

Metric		Specifications	Assay	
			cTnI	cTnT
% Recovery Concentration	Calibrators	80% - 120%	Pass	Pass
	Controls	80% - 120%	Pass	Pass
	ULOQ	80% - 120%	Pass	Pass
	LLOQ	80% - 120%	Pass	Pass
% Recovery CV	Calibrators	<20%	Pass	Pass
	Controls	<20%	Pass	Pass
	ULOQ	<20%	Pass	Pass
	LLOQ	<20%	Pass	Pass

Metric		Specifications	FABP3
% Recovery Concentration	Calibrators	80% - 120%	Pass
	Controls	80% - 120%	Pass
	ULOQ	75% - 125%	Pass
	LLOQ	75% - 125%	Pass
% Recovery CV	Calibrators	<20%	Pass
	Controls	<20%	Pass
	ULOQ	<20%	Pass
	LLOQ	<20%	Pass

Non-specific Binding Specifications			
Spot name			
	cTnI	cTnT	FABP3
cTnI		<5.0%	<0.5%
cTnT	<0.5%		<0.5%
FABP3	<0.5%	<5.0%	
	Pass	Pass	Pass



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Concentration of Materials Tested:

Units = ng/mL	Assay		
	cTnI	cTnT	FABP3
20X Calibrator	512	908	1662
Control 1	116	326	158
Control 2	33.0	94.0	53.0
Control 3	4.00	21.0	21.0
ULOQ	20.0	35.5	25.0
LLOQ	0.098	0.490	0.390

Standard Curve Data from Kit QC:

cTnI		
Conc., (ng/mL)	Average Signal	%CV
25.6	234 679	2.0
6.40	52 563	1.5
1.60	12 115	1.5
0.400	3017	1.6
0.100	805	3.2
0.0250	250	3.5
0.00625	103	6.7
0	52	11.0

cTnT		
Conc., (ng/mL)	Average Signal	%CV
45.4	574 475	2.7
11.4	88 294	2.4
2.84	8687	2.8
0.709	1051	5.6
0.177	289	11.8
0.0443	167	25.4
0.0111	142	26.5
0	121	26.3

FABP3		
Conc., (ng/mL)	Average Signal	%CV
83.1	73 676	3.1
20.8	49 273	3.4
5.19	17 483	2.7
1.30	3354	3.2
0.325	1327	3.8
0.0812	983	2.0
0.0203	906	2.5
0	862	3.1




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Cardiac Injury Panel 2 (rat) Kit Components			
Description	Lot Number	Storage Temperature	Expiration Date
Cardiac Injury Panel 3 (rat) Plate	Z0054706	2-8°C	31 JAN 2016
Anti-rat cTnI Antibody	D0040386	2-8°C	31 MAR 2016
Anti-rat cTnT Antibody	D0040384	2-8°C	31 MAR 2016
Anti-rat FABP3 Antibody	D0040383	2-8°C	31 MAR 2016
Cardiac Injury Panel 3 (rat) Calibrator Blend	A0040063	≤ -70°C	31 OCT 2014
EDTA pH 8.0	R0010427	Room Temperature	31 JAN 2016
DTT	R0010426	≤ -10°C	31 JAN 2016
Diluent 7	M0070042	≤ -10°C	31 MAY 2016
Diluent 30	M0300012	≤ -10°C	29 FEB 2016
MSD Read Buffer T (4X)	Non Kit Specific	Room Temperature	N/A

Statement: The above kit lot was tested using MSD procedures and it conforms to MSD's specifications. The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Dana Short	Quality Control		12 NOV 2014




Meso Scale Diagnostics, L.L.C.

Memo: Cardiac Injury Panel 3 (rat) Calibrator Blend, Lot A0040063

October 24, 2014

Based on a real-time stability study, the date of expiration for this calibrator is extended to 30 months. The expiration date of Lot A0040063 has been extended to February 28, 2015.

Function	Name	Signature	Date
Quality Assurance	Michael Grossman		24 Oct 2014

This memo supersedes all other statements of date of expiration for this calibrator, Lot A0040063.