

RAMP® Cardiac Controls

CAT. No.: C2003-2 Size: 3 x 3 ML

2

INTENDED USE

The RAMP® Cardiac Controls are intended for *in vitro* diagnostic use in the quality control of cardiac markers on the RAMP® Platform.

DESCRIPTION

The RAMP® Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the following RAMP® analytes: CK-MB, D-dimer, Myoglobin, NT-proBNP, and Troponin I.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

These Cardiac Controls contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NONREACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

STORAGE AND STABILITY

OPENED: Store refrigerated at +2°C to +8°C. RAMP® Cardiac Controls are stable for 30 days at +2°C to

+8°C if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE

RETURNED to the original vial.

UNOPENED: The product is stable to the expiration date printed on the individual vials, when stored at

+2°C to +8°C.

PREPARATION FOR USE

The RAMP® Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED

Liquid Cardiac Control – Level 2 3 x 3 ml



MATERIALS REQUIRED BUT NOT PROVIDED

RAMP® test kit RAMP® instrument

ASSIGNED VALUES

Values are assigned from internal testing conducted at Response Biomedical Corp. The expected range of the mean is provided to aid laboratory until it has established its own mean and SD for its methods; please visit www.responsebio.com/cardiaccontrols to view and download suggested ranges for use with specific lots in your laboratory.

RAMP® CARDIAC CONTROLS										
Lot No.: XXXXXX	Use	By: YYYY.M	M CAT. NO	o.: C2003-2	SIZE: 3 X 3 ML					
Range										
analyte	level	unit	target	low	high					
CK-MB	2	ng/mL	Target 2	Low 2	High 2					
D-dimer	2	ng/mL FEU	Target 2	Low 2	High 2					
Myoglobin	2	ng/mL	Target 2	Low 2	High 2					
NT-proBNP	2	ng/L	Target 2	Low 2	High 2					
Troponin I	2	ng/mL	Target 2	Low 2	High 2					
Digoxin	2	ng/mL	N/A	N/A	N/A					
Homocysteine	2	μmol/L	N/A	N/A	N/A					
hsCRP	2	Mg/L	N/A	N/A	N/A					
Troponin T	2	μg/L	N/A	N/A	N/A					

ASSISTANCE

If a method is unavailable or if you have any questions regarding the use of this product, contact: Response Biomedical - Technical Support, Canada

TF +1.888.525.7267 (North America)

T +1.604.219.6119 (Rest of World)

E techsupport@responsebio.com



www.responsebio.com/cardiaccontrols

GLOSSARY OF SYMBOLS

REF	LOT	\sum	CONTROL	1	IVD	3					
Reference Number	Lot Number	Use By Date	Control	Temperature Limitations	<i>in vitro</i> Diagnostic Device	Manufacturer					
EC REP	CE	$\sum_{}$		×							
European Representative	CE Mark	Contains sufficient for <n> tests</n>	Biohazard	Harmful							



Response Biomedical Corp. 1781 – 75th Avenue W., Vancouver, BC, V6P 6P2, Canada EMERGO EUROPE, Prinsessegracht 20 2514 AP, The Hague, The Netherlands

