

RAMP[®] Cardiac Controls

2

CAT. NO.: C2003-2

SIZE: 3 x 3 ML

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.

RAMP® CARDIAC CONTROLS
Lot No.: 110215 Use By: 2016.10 CAT. No.: C2003-2 SIZE: 3 x 3 ML

Range					
analyte	level	unit	target	low	high
CK-MB	2	ng/mL	41.38	30.00	57.06
D-dimer	2	ng/mL FEU	207	<100	673
Myoglobin	2	ng/mL	189.6	138.3	259.9
NT-proBNP	2	ng/L	1680	1060	2662
Troponin I	2	ng/mL	4.33	3.17	5.90
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
GLOSSARY OF SYMBOLS

 Reference Number	 Lot Number	 Use By Date	 Control	 Temperature Limitations	 <i>in vitro</i> Diagnostic Device	 Manufacturer
 European Representative	 CE Mark	 Contains sufficient for <n> tests	 Biohazard	 Harmful		

 EMERGO EUROPE, Molenstraat 15
 2513 BH, The Hague, The Netherlands
