

# RAMP® Cardiac Controls

CAT. No.: C2003-3 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 3 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 | O CAT. NO | .: C2003-3 | SIZE: 3 X 3 ML |  |  |  |  |  |
| Range                  |       |             |           |            |                |  |  |  |  |  |
| analyte                | level | unit        | target    | low        | high           |  |  |  |  |  |
| CK-MB                  | 3     | ng/mL       | N/A       | N/A        | N/A            |  |  |  |  |  |
| D-dimer                | 3     | ng/mL FEU   | 1325      | 791        | 2218           |  |  |  |  |  |
| Myoglobin              | 3     | ng/mL       | N/A       | N/A        | N/A            |  |  |  |  |  |
| NT-proBNP              | 3     | ng/L        | 16742     | 12966      | 21618          |  |  |  |  |  |
| Troponin I             | 3     | ng/mL       | N/A       | N/A        | N/A            |  |  |  |  |  |
| Digoxin                | 3     | ng/mL       | N/A       | N/A        | N/A            |  |  |  |  |  |
| Homocysteine           | 3     | μmol/L      | N/A       | N/A        | N/A            |  |  |  |  |  |
| hsCRP                  | 3     | Mg/L        | N/A       | N/A        | N/A            |  |  |  |  |  |
| Troponin T             | 3     | 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**

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

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