

# RAMP<sup>®</sup> Cardiac Controls

# 2

CAT. NO.: C5003-2

QUANTITY: 6 X 3 ML

## INTENDED USE

### FOR IN VITRO DIAGNOSTIC USE

The RAMP<sup>®</sup> Cardiac Controls are intended for use as an assayed quality control material for CK-MB, D-Dimer, Myoglobin, Troponin I and NT-proBNP on the RAMP<sup>®</sup> Platform. RAMP<sup>®</sup> CardiacControls are not intended for use as a standard.

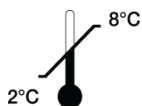
## SUMMARY

In clinical laboratories the use of quality control materials to objectively monitor the accuracy and precision of procedures is well established. The RAMP<sup>®</sup> CardiacControls are provided at 2 levels to assist in the monitoring of analytical systems within the clinical range.

## PRODUCT DESCRIPTION

The RAMP<sup>®</sup> CardiacControls are prepared from human plasma, human serum and human proteins. Preservatives and stabilizers have been added to maintain product integrity. The RAMP<sup>®</sup> CardiacControls are ready-to-use liquid control requiring no reconstitution or frozen storage.

## STORAGE AND STABILITY



RAMP<sup>®</sup> CardiacControls are stable until the expiration date on the vial when stored unopened at 2-8°C. Once opened, RAMP<sup>®</sup> CardiacControls are stable for 30 days when stored tightly capped at 2-8°C.

## PROCEDURE

The RAMP<sup>®</sup> CardiacControls should be treated the same as patient specimens and run in accordance with the instructions accompanying the RAMP<sup>®</sup> test kit being used. Gently mix the contents of each vial before sampling to ensure homogeneity. Replace the cap immediately and store at 2-8°C.

QC materials should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

## LIMITATIONS OF PROCEDURE

The RAMP<sup>®</sup> CardiacControls should not be used past the expiration date on the vial label.

The RAMP<sup>®</sup> CardiacControls are a stabilized liquid product. To obtain consistent assay values, the RAMP<sup>®</sup> Multi-Analyte Controls require storage and handling as detailed in STORAGE and STABILITY.

Accurate and reproducible results are dependent upon properly functioning instruments and reagents. The published assay values were obtained using reagents and procedures available at the time of assay. In the event reagents or procedures are altered by the manufacturer, different assay values may be obtained.

## ASSIGNMENT VALUES

The assigned mean values were derived from analyses of vials representative of the entire lot.

Analyte values were obtained from internal testing at Response Biomedical Corp.

The Expected Range of the mean is provided to assist the laboratory until it has established its own mean and standard deviation. It is considered good laboratory practice for each laboratory to establish its own mean and standard deviation for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method.

The values are usually method dependent. The variations which can occur over time and between laboratories may be attributed to differences in laboratory technique, instrumentation, reagent lot, method modifications, and other systematic errors including random errors.

Refer to [www.responsebio.com/cardiaccontrols](http://www.responsebio.com/cardiaccontrols) for lot specific value assignment. To request a faxed or emailed copy of the value assignment, contact your local distributor or [techsupport@responsebio.com](mailto:techsupport@responsebio.com).

<b>RAMP<sup>®</sup> CARDIAC CONTROLS</b>							
<b>Lot No.:</b>	XXXXXX	<b>Use By:</b>	YYYY.MM	<b>CAT. NO.:</b>	C5003-2	<b>SIZE:</b>	6 x 3 ML
Range							
analyte	level	unit	target	low	high		
CK-MB	1	ng/mL	Target 1	Low 1	High 1		
D-dimer	1	ng/mL FEU	Target 1	Low 1	High 1		
Myoglobin	1	ng/mL	Target 1	Low 1	High 1		
NT-proBNP	1	ng/L	Target 1	Low 1	High 1		
Troponin I	1	ng/mL	Target 1	Low 1	High 1		
hsCRP	1	mg/L	N/A	N/A	N/A		

**WARNINGS AND PRECAUTIONS**

Wash hands thoroughly after handling. Do not eat, drink, or smoke while using this product. Wear protective gloves/clothing. Avoid breathing mist/vapours/spray. Use only in a well-ventilated area.  
 IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician. Rinse mouth.  
 IF ON SKIN: Wash with plenty of soap and water. CALL a POISON CENTRE or doctor/physician if you feel unwell. Remove/take off immediately all contaminated clothing. Wash contaminated clothing before reuse. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 Store locked up. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container in accordance with local/regional/national/international regulation.



**Human source material. Treat as potentially infectious.**

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag. While these methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

**ASSISTANCE**

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](mailto:techsupport@responsebio.com)



[www.responsebio.com/cardiaccontrols](http://www.responsebio.com/cardiaccontrols)

**GLOSSARY OF SYMBOLS**

<b>REF</b> Catalogue Number	<b>LOT</b> Lot Number	 Use-by Date	<b>CONTROL</b> Control	 Temperature Limit	<b>IVD</b> <i>in vitro</i> Diagnostic Device	 Manufacturer
<b>EC REP</b> European Representative	<b>CE</b> CE Mark	 Contains sufficient for <n> tests	 Biohazard	 Consult Instructions for Use	 <b>JANT PHARMACAL CORPORATION</b> Laboratory & Point of Care Diagnostics 16530 Ventura Blvd., Suite 512 Encino, CA 91436 Tel: 818-986-8530 Toll Free: 800-676-5565 info@jantdx.com jantdx.com	



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