RAMP® Cardiac Controls 1

CAT. NO.: C5003-1
QUANTITY: 6 X 3 ML

INTENDED USE

FOR IN VITRO DIAGNOSTIC USE

The RAMP® 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® Platform. RAMP® Cardiac Controls are not intended for use as a standard.

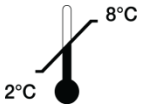
SUMMARY

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

PRODUCT DESCRIPTION

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

STORAGE AND STABILITY



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

PROCEDURE

The RAMP® Cardiac Controls should be treated the same as patient specimens and run in accordance with the instructions accompanying the RAMP® 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® Cardiac Controls should not be used past the expiration date on the vial label.
The RAMP® Cardiac Controls are a stabilized liquid product. To obtain consistent assay values, the RAMP® 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 even 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 for lot specific value assignment. To request a faxed or emailed copy of the value assignment, contact your local distributor or techsupport@responsebio.com.

RESPONSE BIOMEDICAL CORP.
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RAMP® CARDIAC CONTROLS

Lot No.: XXXXXX **Use By:** YYYY.MM **CAT. NO.:** C5003-1 **SIZE:** 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

www.responsebio.com/cardiaccontrols

GLOSSARY OF SYMBOLS

REF Catalogue Number	LOT Lot Number	Use-by Date	CONTROL Control	8°C 2°C Temperature Limit	IVD *in vitro* Diagnostic Device	Manufacturer
EC REP European Representative	CE CE Mark	Σ Contains sufficient for <n> tests	Biohazard	Consult Instructions for Use		

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