

## LIQUID CARDIAC CONTROL - LEVEL I (CRD LIQ CONTROL I)

**CAT. NO.** CQ505I      **LOT NO.** 4198CK  
**SIZE:** 3 x 3 ml      **EXPIRY:** 2019-09-28

**GTIN:** 05055273207446

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of Cardiac Markers on clinical chemistry and Immunoassay systems.

### DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the table below.

### SAFETY PRECAUTIONS AND WARNINGS

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

This Cardiac Control 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 NON-REACTIVE. 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.

Health and Safety Data Sheets are available on request.

### STORAGE AND STABILITY

**UNOPENED:** Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

**OPENED:** Store refrigerated (+2°C to +8°C). Liquid 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.

### PREPARATION FOR USE

The Liquid Cardiac Controls are supplied ready to use.

### MATERIALS PROVIDED

Liquid Cardiac Control - Level I    3 x 3 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

### ASSIGNED VALUES

Values are assigned from a consensus of results obtained from external laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

07 Nov 17 bfm

## CARDIAC CONTROL LEVEL 1 (CRD LIQ CONTROL 1)

Lot No. 4198CK Cat. No. CQ5051

Size. 3 x 3 ml Expiry. 2019-09-28

Range

| Analyte    | unit         | Target | low   | high  | methods   |
|------------|--------------|--------|-------|-------|---|
| Troponin I | ng/ml = µg/l | 0.022  | 0.018 | 0.026 | Siemens Dimension Vista high sensitivity Troponin I |
|            | ng/l = pg/ml | 22.0   | 17.6  | 26.4  |   |
|            | ng/ml = µg/l | 0.018  | 0.014 | 0.022 | Siemens Dimension EXL high sensitivity Troponin I   |
|            | ng/l = pg/ml | 18.0   | 14.4  | 21.6  |   |