

## TRI-LEVEL CARDIAC CONTROL (CRD CONTROL 1, 2, 3)

**CAT NO.** CQ3100      **LOT NO.** 4671CK, 4672CK, 4673CK  
**SIZE** 3 x 1 ml      **EXPIRY:** 2025-12-28  
**GTIN:** 05055273201840

### 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 following analytes at level 1: CK Total, CK-MB Mass, Homocysteine, Myoglobin, Troponin I and Troponin T. Target values and ranges are supplied for the following analytes at levels 2 & 3: CK Total, CK-MB (Activity and Mass) Homocysteine, Myoglobin, Troponin I and Troponin T.

### SAFETY PRECAUTIONS AND WARNINGS

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

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

**OPENED:** Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 5 days at +2°C to +8°C, and 4 weeks at -20°C if kept capped in original container and free from contamination. Troponin I is stable for 2 weeks at -20°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:** Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

### PREPARATION FOR USE

The Tri-Level Cardiac Control is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 1 ml of redistilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

### MATERIALS PROVIDED

|                           |         |          |
|---------------------------|---------|----------|
| Tri-Level Cardiac Control | Level 1 | 1 x 1 ml |
|                           | Level 2 | 1 x 1 ml |
|                           | Level 3 | 1 x 1 ml |

### MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

### ASSIGNED VALUES

Each batch of Cardiac Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these 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).



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

Cat. No. CQ3100 Lot. No. 4671CK Size 1 x 1ml Expiry 2025-12-28

| Range        |              |        |       |       |  |
|--------------|--------------|--------|-------|-------|--|
| Analyte      | unit         | Target | low   | high  | methods                                    |
| CK Total     | U/l          | 107    | 88    | 126   | Vitros 37°C                                |
|              | U/l          | 82     | 67    | 97    | CK-NAC (IFCC) 37°C                         |
|              | U/l          | 51     | 42    | 60    | CK-NAC (IFCC) 30°C                         |
|              | U/l          | 35     | 28    | 42    | CK-NAC (IFCC) 25°C                         |
| CK-MB Mass   | ng/ml = µg/l | 4.69   | 3.28  | 6.10  | Roche Elecsys Modular E170 Cobas 6000/e411 |
|              | ng/ml = µg/l | 4.02   | 2.81  | 5.23  | Abbott Architect / Alinity                 |
| Homocysteine | µmol/l       | 12.4   | 9.92  | 14.9  | Abbott Architect                           |
|              | µmol/l       | 17.2   | 13.8  | 20.6  | Roche Cobas 6000/8000                      |
|              | µmol/l       | 16.2   | 13.0  | 19.4  | Enzymatic                                  |
| Myoglobin    | ng/ml = µg/l | 48.1   | 33.7  | 62.5  | Abbott Architect                           |
| Troponin I   | ng/ml = µg/l | 0.272  | 0.218 | 0.326 | Ortho Vitros ECi                           |
|              | ng/l = pg/ml | 272    | 218   | 326   |  |
|              | ng/ml = µg/l | 0.281  | 0.225 | 0.337 | Abbott Architect                           |
|              | ng/l = pg/ml | 281    | 225   | 337   |  |
|              | ng/ml = µg/l | 0.304  | 0.243 | 0.365 | Abbott i STAT                              |
|              | ng/l = pg/ml | 304    | 243   | 365   |  |
|              | ng/ml = µg/l | 0.102  | 0.082 | 0.122 | Roche Elecsys/E170/c6000/e411              |
|              | ng/l = pg/ml | 102    | 82.0  | 122   |  |
|              | ng/ml = µg/l | 0.277  | 0.222 | 0.332 | Abbott Architect STAT hs                   |
|              | ng/l = pg/ml | 277    | 222   | 332   |  |
|              | ng/ml = µg/l | 0.212  | 0.170 | 0.254 | bioMerieux VIDAS hs Troponin I             |
|              | ng/l = pg/ml | 212    | 170   | 254   |  |
|              | ng/ml = µg/l | 0.237  | 0.190 | 0.284 | Siemens Centaur CP/XP/XPT TNIH             |
|              | ng/l = pg/ml | 237    | 190   | 284   |  |
| Troponin T   | ng/ml = µg/l | 0.016  | 0.011 | 0.021 | Roche Cobas Troponin T HS                  |
|              | ng/l = pg/ml | 16.0   | 11.0  | 21.0  |  |
|              | ng/ml = µg/l | 0.016  | 0.011 | 0.021 | Roche Cobas Troponin T hs STAT             |
|              | ng/l = pg/ml | 16.0   | 11.0  | 21.0  |  |
|              | ng/ml = µg/l | 0.016  | 0.011 | 0.021 | Roche Cobas e801 TnT hs                    |
|              | ng/l = pg/ml | 16.0   | 11.0  | 21.0  |  |

## CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot. No. 4672CK Size 1 x 1ml Expiry 2025-12-28

| Analyte        | unit         | Target | Range |       | methods                                    |
|----------------|--------------|--------|-------|-------|--|
|                |              |        | low   | high  |  |
| CK Total       | U/l          | 306    | 251   | 361   | Vitros 37°C                                |
|                | U/l          | 224    | 184   | 264   | CK-NAC (IFCC) 37°C                         |
|                | U/l          | 140    | 115   | 165   | CK-NAC (IFCC) 30°C                         |
|                | U/l          | 95     | 78    | 112   | CK-NAC (IFCC) 25°C                         |
| CK-MB Activity | U/l          | 19.3   | 15.4  | 23.2  | Immunoinhibition substrate start 37°C      |
|                | U/l          | 11.2   | 8.95  | 13.5  | Immunoinhibition substrate start 30°C      |
|                | U/l          | 6.85   | 5.47  | 8.23  | Immunoinhibition substrate start 25°C      |
|                | U/l          | 16.7   | 13.4  | 20.0  | Immunoinhibition serum start 37°C          |
|                | U/l          | 9.71   | 7.79  | 11.6  | Immunoinhibition serum start 30°C          |
|                | U/l          | 5.93   | 4.76  | 7.10  | Immunoinhibition serum start 25°C          |
|                | U/l          | 20.0   | 16.0  | 24.0  | Immunoinhibition (IFCC) 37°C               |
|                | U/l          | 11.6   | 9.30  | 13.9  | Immunoinhibition (IFCC) 30°C               |
| CK-MB Mass     | ng/ml = µg/l | 16.1   | 11.3  | 20.9  | Roche Elecsys Modular E170 Cobas 6000/e411 |
|                | ng/ml = µg/l | 15.8   | 11.1  | 20.5  | Abbott Architect / Alinity                 |
| Homocysteine   | µmol/l       | 19.6   | 15.7  | 23.5  | Abbott Architect                           |
|                | µmol/l       | 31.9   | 25.5  | 38.3  | Roche Cobas 6000/8000                      |
|                | µmol/l       | 22.9   | 18.3  | 27.5  | Enzymatic                                  |
| Myoglobin      | ng/ml = µg/l | 155    | 109   | 202   | Abbott Architect                           |
| Troponin I     | ng/ml = µg/l | 13.0   | 10.4  | 15.6  | Ortho Vitros ECi                           |
|                | ng/l = pg/ml | 13000  | 10400 | 15600 |  |
|                | ng/ml = µg/l | 2.55   | 2.04  | 3.06  | Abbott Architect                           |
|                | ng/l = pg/ml | 2550   | 2040  | 3060  |  |
|                | ng/ml = µg/l | 10.2   | 8.16  | 12.2  | Abbott i STAT                              |
|                | ng/l = pg/ml | 10200  | 8160  | 12200 |  |
|                | ng/ml = µg/l | 1.16   | 0.928 | 1.39  | Roche Elecsys/E170/c6000/e411              |
|                | ng/l = pg/ml | 1160   | 928   | 1392  |  |
|                | ng/ml = µg/l | 2.45   | 1.96  | 2.94  | Abbott Architect STAT hs                   |
|                | ng/l = pg/ml | 2450   | 1960  | 2940  |  |
|                | ng/ml = µg/l | 11.7   | 9.36  | 14.0  | bioMerieux VIDAS hs Troponin I             |
|                | ng/l = pg/ml | 11700  | 9360  | 14000 |  |
|                | ng/ml = µg/l | 6.89   | 5.51  | 8.27  | Siemens Centaur CP/XP/XPT TNIH             |
|                | ng/l = pg/ml | 6890   | 5510  | 8270  |  |
| Troponin T     | ng/ml = µg/l | 0.244  | 0.171 | 0.317 | Roche Cobas h232                           |
|                | ng/l = pg/ml | 244    | 171   | 317   |  |
| Troponin T     | ng/ml = µg/l | 0.331  | 0.232 | 0.430 | Roche Cobas Troponin T hs STAT             |
|                | ng/l = pg/ml | 331    | 232   | 430   |  |
|                | ng/ml = µg/l | 0.411  | 0.288 | 0.534 | Roche Cobas e801 TnT hs                    |
|                | ng/l = pg/ml | 411    | 288   | 534   |  |

## CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot. No. 4673CK Size 1 x 1ml Expiry 2025-12-28

| Analyte        | unit         | Target | Range |       | methods                                    |
|----------------|--------------|--------|-------|-------|--|
|                |              |        | low   | high  |  |
| CK Total       | U/l          | 870    | 713   | 1027  | Vitros 37°C                                |
|                | U/l          | 661    | 542   | 780   | CK-NAC (IFCC) 37°C                         |
|                | U/l          | 414    | 339   | 489   | CK-NAC (IFCC) 30°C                         |
|                | U/l          | 281    | 230   | 332   | CK-NAC (IFCC) 25°C                         |
| CK-MB Activity | U/l          | 104    | 83.2  | 125   | Immunoinhibition substrate start 37°C      |
|                | U/l          | 60.4   | 48.4  | 72.4  | Immunoinhibition substrate start 30°C      |
|                | U/l          | 36.9   | 29.5  | 44.3  | Immunoinhibition substrate start 25°C      |
|                | U/l          | 102    | 81.6  | 122   | Immunoinhibition serum start 37°C          |
|                | U/l          | 59.3   | 47.4  | 71.2  | Immunoinhibition serum start 30°C          |
|                | U/l          | 36.2   | 29.0  | 43.4  | Immunoinhibition serum start 25°C          |
|                | U/l          | 108    | 86.4  | 130   | Immunoinhibition (IFCC) 37°C               |
|                | U/l          | 62.8   | 50.2  | 75.4  | Immunoinhibition (IFCC) 30°C               |
| CK-MB Mass     | ng/ml = µg/l | 108    | 75.6  | 140   | Roche Elecsys Modular E170 Cobas 6000/e411 |
|                | ng/ml = µg/l | 113    | 79.1  | 147   | Abbott Architect / Alinity                 |
| Homocysteine   | µmol/l       | 39.4   | 31.5  | 47.3  | Abbott Architect                           |
|                | µmol/l       | 67.6   | 54.1  | 81.1  | Roche Cobas 6000/8000                      |
|                | µmol/l       | 40.3   | 32.2  | 48.4  | Enzymatic                                  |
| Myoglobin      | ng/ml = µg/l | 270    | 189   | 351   | Abbott Architect                           |
| Troponin I     | ng/ml = µg/l | 51.1   | 40.9  | 61.3  | Ortho Vitros ECI                           |
|                | ng/l = pg/ml | 51100  | 40900 | 61300 |  |
|                | ng/ml = µg/l | 46.9   | 37.5  | 56.3  | Tosoh Series                               |
|                | ng/l = pg/ml | 46900  | 37500 | 56300 |  |
|                | ng/ml = µg/l | 44.0   | 35.2  | 52.8  | Abbott i STAT                              |
|                | ng/l = pg/ml | 44000  | 35200 | 52800 |  |
|                | ng/ml = µg/l | 3.14   | 2.51  | 3.77  | Roche Elecsys/E170/c6000/e411              |
|                | ng/l = pg/ml | 3140   | 2510  | 3770  |  |
|                | ng/ml = µg/l | 7.93   | 6.34  | 9.52  | Abbott Architect STAT hs                   |
|                | ng/l = pg/ml | 7930   | 6340  | 9520  |  |
|                | ng/ml = µg/l | 23.0   | 18.4  | 27.6  | Siemens Centaur CP/XP/XPT TNIH             |
|                | ng/l = pg/ml | 23000  | 18400 | 27600 |  |
|                | ng/ml = µg/l | 12.8   | 10.2  | 15.4  | Beckman Access 2/DxC600i Hs                |
| ng/l = pg/ml   | 12800        | 10200  | 15400 |       |  |
| Troponin T     | ng/ml = µg/l | 0.992  | 0.694 | 1.290 | Roche Cobas Troponin T HS                  |
|                | ng/l = pg/ml | 992    | 694   | 1290  |  |
|                | ng/ml = µg/l | 0.592  | 0.414 | 0.770 | Roche Cobas h232                           |
|                | ng/l = pg/ml | 592    | 414   | 770   |  |
|                | ng/ml = µg/l | 0.977  | 0.684 | 1.270 | Roche Cobas Troponin T hs STAT             |
|                | ng/l = pg/ml | 977    | 684   | 1270  |  |
|                | ng/ml = µg/l | 1.230  | 0.861 | 1.600 | Roche Cobas e801 TnT hs                    |
|                | ng/l = pg/ml | 1230   | 861   | 1599  |  |