

## 心肌多项标志物检测用质控品

货号: CQ3259

包装: 3x1x2 ml

批号: 483221 (4324CK-4326CK)

效期: 2022-08

### 产品描述

本品为心肌多项标志物检测用质控品, 又称三水平心肌质控品, 适用于体外诊断中临床生化或免疫检测系统的心肌标志物检测的质量控制。

### 安全预防措施和警告

本产品仅用于体外诊断。禁止用口吸。按照实验室常规预防措施对试剂进行处理。

该质控品采用人基质血清, 对所有捐献者的血清均进行了 HIV(HIV1、HIV2) 抗体、肝炎 B 表面抗原(HbsAg) 和肝炎 C 病毒(HCV) 抗体的测试, 发现均呈阴性。所采用的方法均经 FDA 认证。

然而, 既然没有一种方法能够完全保证其没有传染物质, 因此该质控品和所有的病人样品均应当按照能够传播疾病的样品小心处理。

### 保存和稳定性

复溶后, 建议 2~8℃ 冷藏保存。如果原瓶保存并且未被污染, 2~8℃ 可保存 5 天, -20℃ 冷冻可保存 28 天, 只能冻融 1 次, 肌钙蛋白 I 于 -20℃ 冷冻保存可稳定 14 天。每次取出所需用量, 用后剩余的样品不可以返回原瓶。

未开瓶, 2~8℃ 可保存至效期末。

### 使用说明

该三水平心肌质控品为冻干品。

1. 小心打开瓶盖, 用 2 ml 的蒸馏水在 20℃~25℃ 的条件下复溶, 盖好瓶盖, 静置 30 分钟, 轻轻旋转, 确保所有干粉充分溶解。不要震荡, 避免产生气泡;
2. 参考各个仪器的质控说明;
3. 冷冻保存未使用的材料。再次使用前, 确保材料混合均匀。

### 包装规格

三水平心肌质控品

| 浓度水平 | 水平 1     | 水平 2     | 水平 3     |
|------|----------|----------|----------|
| 包装规格 | 1 x 2 ml | 1 x 2 ml | 1 x 2 ml |

### 需要自备的材料

移液管, 蒸馏水

### 赋值

每一批质控血清都要送到大量的外部实验室, 然后将结果与朗道实验室内部得到的结果用相同的统计分析进行赋值。在实验室建立起自己的靶值和 SD 范围前, 质控范围值用来协助实验室进行质量控制。

**注:** 详细赋值信息请以原版英文说明书为准, 原版说明书请在英国朗道公司官网 [www.randox.com](http://www.randox.com) 进行下载。

## 三水平心肌质控品（水平 1）

| 货号: CQ3259   |              | 批号: 4324CK |       |       | 效期: 2022-08                                |
|--------------|--------------|------------|-------|-------|--------------------------------------------|
| 规格: 1 x 2 ml |              | 范围         |       |       | 低值=靶值-2SD 高值=靶值+2SD                        |
| 分析物          | 单位           | 靶值         | 低值    | 高值    | 方法学                                        |
| 肌酸激酶 (CK)    | U/l          | 78         | 64    | 92    | DGKC推荐方法, 底物启动37°C                         |
|              | U/l          | 49         | 40    | 58    | DGKC推荐方法, 底物启动 30°C                        |
|              | U/l          | 33         | 27    | 39    | DGKC推荐方法, 底物启动 25°C                        |
|              | U/l          | 105        | 86    | 124   | 干化学法 Vitros 37°C                           |
|              | U/l          | 78         | 64    | 92    | CK-NAC (IFCC) 37°C                         |
|              | U/l          | 49         | 40    | 58    | CK-NAC (IFCC) 30°C                         |
|              | U/l          | 33         | 27    | 39    | CK-NAC (IFCC) 25°C                         |
| 肌酸激酶同工酶 (质量) | ng/ml = µg/l | 3.18       | 2.23  | 4.13  | Siemens Dimension                          |
|              | ng/ml = µg/l | 5.59       | 3.91  | 7.27  | Siemens Centaur XP/XPT/Classic             |
|              | ng/ml = µg/l | 4.14       | 2.90  | 5.38  | Roche Elecsys Modular E170 Cobas 6000/e411 |
|              | ng/ml = µg/l | 4.56       | 3.19  | 5.93  | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 5.86       | 4.10  | 7.62  | BioMerieux Vidas                           |
|              | ng/ml = µg/l | 3.54       | 2.48  | 4.60  | Abbott Architect                           |
|              | ng/ml = µg/l | 4.88       | 3.42  | 6.34  | Beckman Dxl800                             |
| 同型半胱氨酸       | µmol/l       | 10.4       | 8.32  | 12.5  | Abbott Architect                           |
|              | µmol/l       | 14.7       | 11.8  | 17.6  | Roche Cobas 6000/8000                      |
|              | µmol/l       | 13.5       | 10.8  | 16.2  | 酶法                                         |
| 肌红蛋白         | ng/ml = µg/l | 47.8       | 33.5  | 62.1  | 罗氏电化学发光法 (Roche Elecsys)                   |
|              | ng/ml = µg/l | 42.2       | 29.5  | 54.9  | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 60.3       | 42.2  | 78.4  | Abbott Architect                           |
|              | ng/ml = µg/l | 41.4       | 29.0  | 53.8  | Beckman Dxl800                             |
|              | ng/ml = µg/l | 76.9       | 53.8  | 100   | 朗道免疫比浊法                                    |
| 肌钙蛋白 I       | ng/ml = µg/l | 0.776      | 0.621 | 0.931 | Siemens Stratus CS                         |
|              | ng/l = pg/ml | 776        | 621   | 931   |                                            |
|              | ng/ml = µg/l | 0.850      | 0.680 | 1.02  | Siemens Centaur XP/XPT/Classic             |
|              | ng/l = pg/ml | 850        | 680   | 1020  |                                            |
|              | ng/ml = µg/l | 1.04       | 0.832 | 1.25  | Ortho Vitros ECI                           |
|              | ng/l = pg/ml | 1040       | 832   | 1248  |                                            |
|              | ng/ml = µg/l | 0.372      | 0.298 | 0.446 | Biomerieux Vidas Ultra                     |
|              | ng/l = pg/ml | 372        | 298   | 446   |                                            |
|              | ng/ml = µg/l | 0.217      | 0.174 | 0.260 | Mitsubishi Chemical Pathfast               |
|              | ng/l = pg/ml | 217        | 174   | 260   |                                            |
|              | ng/ml = µg/l | 0.464      | 0.371 | 0.557 | Siemens Dimension Exl LOCI                 |
|              | ng/l = pg/ml | 464        | 371   | 557   |                                            |
|              | ng/ml = µg/l | 0.479      | 0.383 | 0.575 | Abbott Architect STAT hs                   |
|              | ng/l = pg/ml | 479        | 383   | 575   |                                            |
|              | ng/ml = µg/l | 0.204      | 0.163 | 0.245 | Beckman Dxl - AccuTnl+3                    |
|              | ng/l = pg/ml | 204        | 163   | 245   |                                            |
|              | ng/ml = µg/l | 0.238      | 0.190 | 0.286 | Beckman Access - AccuTnl+3                 |
|              | ng/l = pg/ml | 238        | 190   | 286   |                                            |
|              | ng/ml = µg/l | 0.658      | 0.526 | 0.790 | Siemens Centaur CP                         |
|              | ng/l = pg/ml | 658        | 526   | 790   |                                            |

## 三水平心肌质控品（水平1）

| 货号: CQ3259   |              | 批号: 4324CK |       |       | 效期: 2022-08                    |
|--------------|--------------|------------|-------|-------|--------------------------------|
| 规格: 1 x 2 ml |              | 范围         |       |       | 低值=靶值-2SD    高值=靶值+2SD         |
| 分析物          | 单位           | 靶值         | 低值    | 高值    | 方法学                            |
| 肌钙蛋白I        | ng/ml = µg/l | 0.745      | 0.596 | 0.894 | bioMerieux VIDAS hs Troponin I |
|              | ng/l = pg/ml | 745        | 596   | 894   |                                |
| 肌钙蛋白T        | ng/ml = µg/l | 0.037      | 0.026 | 0.048 | Roche Cobas Troponin T HS      |
|              | ng/l = pg/ml | 37.0       | 26.0  | 48.0  |                                |
|              | ng/ml = µg/l | 0.035      | 0.025 | 0.046 | Roche Cobas Troponin T hs STAT |
|              | ng/l = pg/ml | 35.0       | 25.0  | 45.0  |                                |

## 三水平心肌质控品（水平 2）

| 货号: CQ3259   |              | 批号: 4325CK |      |      | 效期: 2022-08                                |
|--------------|--------------|------------|------|------|--------------------------------------------|
| 规格: 1 x 2 ml |              | 范围         |      |      | 低值=靶值-2SD 高值=靶值+2SD                        |
| 分析物          | 单位           | 靶值         | 低值   | 高值   | 方法学                                        |
| 肌酸激酶 (CK)    | U/l          | 257        | 211  | 303  | DGKC推荐方法, 底物启动37°C                         |
|              | U/l          | 161        | 132  | 190  | DGKC推荐方法, 底物启动 30°C                        |
|              | U/l          | 109        | 90   | 128  | DGKC推荐方法, 底物启动 25°C                        |
|              | U/l          | 348        | 285  | 411  | 干化学法 Vitros 37°C                           |
|              | U/l          | 252        | 207  | 297  | CK-NAC (IFCC) 37°C                         |
|              | U/l          | 158        | 130  | 186  | CK-NAC (IFCC) 30°C                         |
|              | U/l          | 107        | 88   | 126  | CK-NAC (IFCC) 25°C                         |
| 肌酸激酶同工酶 (活性) | U/l          | 14.8       | 11.8 | 17.8 | 干化学法 Vitros 37°C                           |
|              | U/l          | 18.3       | 14.6 | 22.0 | 免疫抑制法, 底物启动37°C                            |
|              | U/l          | 10.6       | 8.49 | 12.7 | 免疫抑制法, 底物启动30°C                            |
|              | U/l          | 6.50       | 5.18 | 7.82 | 免疫抑制法, 底物启动25°C                            |
|              | U/l          | 17.4       | 13.9 | 20.9 | 免疫抑制法, 样本启动 37°C                           |
|              | U/l          | 10.1       | 8.08 | 12.1 | 免疫抑制法, 样本启动30°C                            |
|              | U/l          | 6.18       | 4.93 | 7.43 | 免疫抑制法, 样本启动25°C                            |
|              | U/l          | 17.6       | 14.1 | 21.1 | 免疫抑制法(IFCC) 37°C                           |
|              | U/l          | 10.2       | 8.19 | 12.2 | 免疫抑制法 (IFCC) 30°C                          |
|              | U/l          | 6.25       | 5.01 | 7.49 | 免疫抑制法(IFCC) 25°C                           |
|              | U/l          | 21.4       | 17.1 | 25.7 | 朗道免疫抑制法, 底物启动37°C                          |
|              | U/l          | 12.4       | 9.94 | 14.9 | 朗道免疫抑制法, 底物启动 30°C                         |
|              | U/l          | 7.60       | 6.07 | 9.12 | 朗道免疫抑制法, 底物启动25°C                          |
|              | U/l          | 18.7       | 15.0 | 22.4 | 朗道免疫抑制法, 样本启动 37°C                         |
|              | U/l          | 10.9       | 8.72 | 13.0 | 朗道免疫抑制法, 样本启动30°C                          |
|              | U/l          | 6.64       | 5.33 | 7.95 | 朗道免疫抑制法, 样本启动25°C                          |
| 肌酸激酶同工酶 (质量) | ng/ml = µg/l | 18.3       | 12.8 | 23.8 | Siemens Centaur XP/XPT/Classic             |
|              | ng/ml = µg/l | 13.5       | 9.45 | 17.6 | Roche Elecsys Modular E170 Cobas 6000/e411 |
|              | ng/ml = µg/l | 17.5       | 12.3 | 22.8 | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 12.4       | 8.68 | 16.1 | Ortho Vitros ECI                           |
|              | ng/ml = µg/l | 14.1       | 9.87 | 18.3 | Abbott Architect                           |
|              | ng/ml = µg/l | 19.1       | 13.4 | 24.8 | Beckman Dxl800                             |
| 同型半胱氨酸       | µmol/l       | 38.6       | 30.9 | 46.3 | HPLC                                       |
|              | µmol/l       | 16.2       | 13.0 | 19.4 | Abbott Architect                           |
|              | µmol/l       | 25.1       | 20.1 | 30.1 | Roche Cobas 6000/8000                      |
|              | µmol/l       | 21.1       | 16.9 | 25.3 | 酶法                                         |
| 肌红蛋白         | ng/ml = µg/l | 114        | 79.8 | 148  | 罗氏电化学发光法 (Roche Elecsys)                   |
|              | ng/ml = µg/l | 96.9       | 67.8 | 126  | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 147        | 103  | 191  | Abbott Architect                           |
|              | ng/ml = µg/l | 105        | 73.5 | 137  | Beckman Dxl800                             |
|              | ng/ml = µg/l | 44.6       | 31.2 | 58.0 | Biosite Triage Meter Plus                  |
|              | ng/ml = µg/l | 187        | 131  | 243  | Randox Immunoturbidimetric                 |
| 肌钙蛋白I        | ng/ml = µg/l | 4.67       | 3.74 | 5.60 | Siemens Centaur XP/XPT/Classic             |
|              | ng/l = pg/ml | 4670       | 3740 | 5600 |                                            |
|              | ng/ml = µg/l | 5.62       | 4.50 | 6.74 | Ortho Vitros ECI                           |
|              | ng/l = pg/ml | 5620       | 4500 | 6740 |                                            |

## 三水平心肌质控品（水平 2）

| 货号: CQ3259   |              | 批号: 4325CK |       |       | 效期: 2022-08                    |           |
|--------------|--------------|------------|-------|-------|--------------------------------|-----------|
| 规格: 1 x 2 ml |              | 范围         |       |       | 低值=靶值-2SD                      | 高值=靶值+2SD |
| 分析物          | 单位           | 靶值         | 低值    | 高值    | 方法学                            |           |
| 肌钙蛋白 I       | ng/ml = µg/l | 7.45       | 5.96  | 8.94  | Abbott i STAT                  |           |
|              | ng/l = pg/ml | 7450       | 5960  | 8940  |                                |           |
|              | ng/ml = µg/l | 1.49       | 1.19  | 1.79  | Roche Elecsys/E170/c6000/e411  |           |
|              | ng/l = pg/ml | 1490       | 1190  | 1790  |                                |           |
|              | ng/ml = µg/l | 1.16       | 0.928 | 1.39  | Mitsubishi Chemical Pathfast   |           |
|              | ng/l = pg/ml | 1160       | 928   | 1392  |                                |           |
|              | ng/ml = µg/l | 1.61       | 1.29  | 1.93  | Siemens Dimension Exl LOCI     |           |
|              | ng/l = pg/ml | 1610       | 1290  | 1930  |                                |           |
|              | ng/ml = µg/l | 1.63       | 1.30  | 1.96  | Abbott Architect STAT hs       |           |
|              | ng/l = pg/ml | 1630       | 1300  | 1960  |                                |           |
|              | ng/ml = µg/l | 0.820      | 0.656 | 0.984 | Beckman Dxl - AccuTnl+3        |           |
|              | ng/l = pg/ml | 820        | 656   | 984   |                                |           |
|              | ng/ml = µg/l | 0.882      | 0.706 | 1.06  | Beckman Access - AccuTnl+3     |           |
|              | ng/l = pg/ml | 882        | 706   | 1058  |                                |           |
|              | ng/ml = µg/l | 3.97       | 3.18  | 4.76  | Siemens Centaur CP             |           |
|              | ng/l = pg/ml | 3970       | 3180  | 4760  |                                |           |
|              | ng/ml = µg/l | 3.66       | 2.93  | 4.39  | bioMerieux VIDAS hs Troponin I |           |
|              | ng/l = pg/ml | 3660       | 2930  | 4390  |                                |           |
| 肌钙蛋白 T       | ng/ml = µg/l | 0.464      | 0.325 | 0.603 | Roche Cobas Troponin T HS      |           |
|              | ng/l = pg/ml | 464        | 325   | 603   |                                |           |
|              | ng/ml = µg/l | 0.273      | 0.191 | 0.355 | Roche h232                     |           |
|              | ng/l = pg/ml | 273        | 191   | 355   |                                |           |
|              | ng/ml = µg/l | 0.443      | 0.310 | 0.576 | Roche Cobas Troponin T hs STAT |           |
|              | ng/l = pg/ml | 443        | 310   | 576   |                                |           |

## 三水平心肌质控品（水平 3）

| 货号: CQ3259   |              | 批号: 4326CK |       |       | 效期: 2022-08                                |
|--------------|--------------|------------|-------|-------|--------------------------------------------|
| 规格: 1 x 2 ml |              | 范围         |       |       | 低值=靶值-2SD 高值=靶值+2SD                        |
| 分析物          | 单位           | 靶值         | 低值    | 高值    | 方法学                                        |
| 肌酸激酶 (CK)    | U/l          | 657        | 539   | 775   | DGKC推荐方法, 底物启动37°C                         |
|              | U/l          | 411        | 337   | 485   | DGKC推荐方法, 底物启动 30°C                        |
|              | U/l          | 279        | 229   | 329   | DGKC推荐方法, 底物启动 25°C                        |
|              | U/l          | 831        | 681   | 981   | 干化学法 Vitros 37°C                           |
|              | U/l          | 640        | 525   | 755   | CK-NAC (IFCC) 37°C                         |
|              | U/l          | 401        | 329   | 473   | CK-NAC (IFCC) 30°C                         |
|              | U/l          | 272        | 223   | 321   | CK-NAC (IFCC) 25°C                         |
| 肌酸激酶同工酶 (活性) | U/l          | 114        | 91.2  | 137   | 干化学法 Vitros 37°C                           |
|              | U/l          | 117        | 93.6  | 140   | 免疫抑制法, 底物启动37°C                            |
|              | U/l          | 68.0       | 54.4  | 81.6  | 免疫抑制法, 底物启动30°C                            |
|              | U/l          | 41.5       | 33.2  | 49.8  | 免疫抑制法, 底物启动25°C                            |
|              | U/l          | 117        | 93.6  | 140   | 免疫抑制法, 样本启动 37°C                           |
|              | U/l          | 68.0       | 54.4  | 81.6  | 免疫抑制法, 样本启动30°C                            |
|              | U/l          | 41.5       | 33.2  | 49.8  | 免疫抑制法, 样本启动25°C                            |
|              | U/l          | 116        | 92.8  | 139   | 免疫抑制法(IFCC) 37°C                           |
|              | U/l          | 67.4       | 53.9  | 80.9  | 免疫抑制法 (IFCC) 30°C                          |
|              | U/l          | 41.2       | 32.9  | 49.5  | 免疫抑制法(IFCC) 25°C                           |
|              | U/l          | 123        | 98.4  | 148   | 朗道免疫抑制法, 底物启动37°C                          |
|              | U/l          | 71.5       | 57.2  | 86.0  | 朗道免疫抑制法, 底物启动 30°C                         |
|              | U/l          | 43.7       | 34.9  | 52.5  | 朗道免疫抑制法, 底物启动25°C                          |
|              | U/l          | 117        | 93.6  | 140   | 朗道免疫抑制法, 样本启动 37°C                         |
|              | U/l          | 68.0       | 54.4  | 81.4  | 朗道免疫抑制法, 样本启动30°C                          |
|              | U/l          | 41.5       | 33.2  | 49.7  | 朗道免疫抑制法, 样本启动25°C                          |
| 肌酸激酶同工酶 (质量) | ng/ml = µg/l | 139        | 97.3  | 181   | Siemens Centaur XP/XPT/Classic             |
|              | ng/ml = µg/l | 116        | 81.2  | 151   | Roche Elecsys Modular E170 Cobas 6000/e411 |
|              | ng/ml = µg/l | 161        | 113   | 209   | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 127        | 88.9  | 165   | Abbott Architect                           |
|              | ng/ml = µg/l | 164        | 115   | 213   | Beckman Dxl800                             |
|              | ng/ml = µg/l | 27.6       | 19.3  | 35.9  | Biosite Triage Meter Plus                  |
| 同型半胱氨酸       | µmol/l       | 36.2       | 29.0  | 43.4  | Abbott Architect                           |
|              | µmol/l       | 56.5       | 45.2  | 67.8  | Roche Cobas 6000/8000                      |
|              | µmol/l       | 37.9       | 30.3  | 45.5  | Enzymatic                                  |
| 肌红蛋白         | ng/ml = µg/l | 193        | 135   | 251   | Roche Elecsys                              |
|              | ng/ml = µg/l | 164        | 115   | 213   | Beckman Coulter Access                     |
|              | ng/ml = µg/l | 276        | 193   | 359   | Abbott Architect                           |
|              | ng/ml = µg/l | 176        | 123   | 229   | Beckman Dxl800                             |
|              | ng/ml = µg/l | 108        | 75.6  | 140   | Biosite Triage Meter Plus                  |
|              | ng/ml = µg/l | 326        | 228   | 424   | Randox Immunoturbidimetric                 |
| 肌钙蛋白 I       | ng/ml = µg/l | 29.7       | 23.7  | 35.6  | Siemens Centaur XP/XPT/Classic             |
|              | ng/l = pg/ml | 29663      | 23700 | 35626 |                                            |
|              | ng/ml = µg/l | 35.7       | 28.6  | 42.9  | Ortho Vitros ECI                           |
|              | ng/l = pg/ml | 35729      | 28600 | 42858 |                                            |

## 三水平心肌质控品（水平 3）

| 货号：CQ3259   |              | 批号：4326CK |       |       | 效期：2022-08                     |           |
|-------------|--------------|-----------|-------|-------|--------------------------------|-----------|
| 规格：1 x 2 ml |              | 范围        |       |       | 低值=靶值-2SD                      | 高值=靶值+2SD |
| 分析物         | 单位           | 靶值        | 低值    | 高值    | 方法学                            |           |
| 肌钙蛋白I       | ng/ml = µg/l | 28.8      | 23.0  | 34.6  | Abbott i STAT                  |           |
|             | ng/l = pg/ml | 28794     | 23000 | 34588 |                                |           |
|             | ng/ml = µg/l | 6.16      | 4.93  | 7.39  | Roche Elecsys/E170/c6000/e411  |           |
|             | ng/l = pg/ml | 6160      | 4930  | 7390  |                                |           |
|             | ng/ml = µg/l | 7.58      | 6.06  | 9.10  | Mitsubishi Chemical Pathfast   |           |
|             | ng/l = pg/ml | 7580      | 6060  | 9100  |                                |           |
|             | ng/ml = µg/l | 6.73      | 5.38  | 8.08  | Siemens Dimension Exl LOCI     |           |
|             | ng/l = pg/ml | 6730      | 5380  | 8080  |                                |           |
|             | ng/ml = µg/l | 7.28      | 5.82  | 8.74  | Abbott Architect STAT hs       |           |
|             | ng/l = pg/ml | 7280      | 5820  | 8740  |                                |           |
|             | ng/ml = µg/l | 4.84      | 3.87  | 5.81  | Beckman Dxl - AccuTnl+3        |           |
|             | ng/l = pg/ml | 4840      | 3870  | 5810  |                                |           |
|             | ng/ml = µg/l | 5.29      | 4.23  | 6.35  | Beckman Access - AccuTnl+3     |           |
|             | ng/l = pg/ml | 5290      | 4230  | 6350  |                                |           |
|             | ng/ml = µg/l | 24.4      | 19.5  | 29.3  | Siemens Centaur CP             |           |
|             | ng/l = pg/ml | 24385     | 19500 | 29270 |                                |           |
|             | ng/ml = µg/l | 32.5      | 26.0  | 39.1  | bioMerieux VIDAS hs Troponin I |           |
|             | ng/l = pg/ml | 32546     | 26000 | 39092 |                                |           |
| 肌钙蛋白T       | ng/ml = µg/l | 1.200     | 0.840 | 1.560 | Roche Cobas Troponin T HS      |           |
|             | ng/l = pg/ml | 1200      | 840   | 1560  |                                |           |
|             | ng/ml = µg/l | 0.553     | 0.387 | 0.719 | Roche h232                     |           |
|             | ng/l = pg/ml | 553       | 387   | 719   |                                |           |
|             | ng/ml = µg/l | 1.160     | 0.812 | 1.510 | Roche Cobas Troponin T hs STAT |           |
|             | ng/l = pg/ml | 1160      | 812   | 1508  |                                |           |