

液态心肌标志物质控品水平2

货号: CQ 5052
规格: 3 x 3 ml

批号: 4315CK
效期: 2020-06-28

GTIN: 05055273207453

产品用途

本品适用于体外诊断中临床生化或免疫系统的心肌标志物检测的质量控制。

产品说明

朗道供应三种浓度水平的液态心肌标志物质控品（水平 1: CQ5051；水平 2: CQ5052；水平 3: CQ5053）。为肌酸激酶同工酶（质量），地高辛，D-二聚体，超敏 CRP，肌红蛋白，肌钙蛋白 I，肌钙蛋白 T 和 N 端脑钠肽前体提供靶值和范围。

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。

本产品含有叠氮化钠，避免摄取或接触皮肤或粘膜。在皮肤接触的情况下，用大量的水冲洗受影响的区域。如与眼睛接触，或进食，应立即求医。

叠氮钠能够与铅和铜质管道发生反应，形成潜在的爆炸性叠氮化合物。因此，在处理该质控品的时候应用大量的水冲洗，防止叠氮化合物的形成。裸露的金属表面要用 10% 的氢氧化钠清洗干净。

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。但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。

健康和安数据表可根据需求提供。

保存和稳定性

未开瓶: 2~8°C 冷藏保存可保存到效期，肌红蛋白和 CK-MB 可能会在效期内逐渐下降。

开瓶后: 建议 2~8°C 冷藏保存。如果原瓶保存并且未被污染，2~8°C 可保存 30 天。每次取出所需用量，用后剩余的样品不可以返回原瓶。

使用说明

该液态心肌标志物质控品为液体即用型。

规格包装

水平2 3 x 3 ml

赋值

每一批质控品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。

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LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

| Range | | | | | |
|-----------------------|--------------|--------|-------|--------------------|--|
| Analyte | unit | Target | low | high | methods |
| CK-MB Mass 肌酸激酶同工酶 | ng/ml = µg/l | 5.07 | 3.55 | 6.59 | Abbott Architect |
| | ng/ml = µg/l | 9.19 | 6.43 | 11.9 | Siemens Centaur XP/XPT/Classic |
| | ng/ml = µg/l | 7.19 | 5.03 | 9.35 | Siemens Dimension |
| | ng/ml = µg/l | 5.78 | 4.05 | 7.51 | Roche Elecsys Modular E170 Cobas 6000/e411 |
| | ng/ml = µg/l | 8.33 | 5.83 | 10.8 | Beckman Coulter Access |
| | ng/ml = µg/l | 7.40 | 5.18 | 9.62 | Siemens Stratus CS |
| | ng/ml = µg/l | 4.36 | 3.05 | 5.67 | Ortho Vitros ECi |
| | ng/ml = µg/l | 7.18 | 5.03 | 9.33 | BioMerieux Vidas |
| | ng/ml = µg/l | 8.60 | 6.02 | 11.2 | Beckman DxI800 |
| | ng/ml = µg/l | 5.83 | 4.08 | 7.58 | Roche h232 |
| | ng/ml = µg/l | 10.2 | 7.14 | 13.3 | Radiometer AQT90 Flex |
| ng/ml = µg/l | 7.53 | 5.27 | 9.79 | Siemens Centaur CP | |
| D-Dimer D-二聚体 | µg/l FEU | 1700 | 1275 | 2125 | Biomerieux Vidas Exclusion II |
| | µg/l FEU | 7892 | 5919 | 9865 | Mitsubishi Pathfast D-Dimer |
| | µg/l | 689 | 517 | 861 | Roche/ Stago STA-R Evolution |
| | µg/l | 1005 | 754 | 1256 | Roche Cobas h232 D-Dimer |
| | µg/l | 753 | 565 | 941 | Roche Integra D-DI 2 |
| | µg/l | 879 | 659 | 1099 | Alere Biosite Triage D-Dimer |
| | µg/l | 862 | 647 | 1078 | Abbott Architect Quantia D-Dimer |
| | µg/l | 1350 | 1013 | 1688 | Siemens Stratus CS |
| | µg/l | 615 | 461 | 769 | Siemens Immulite 2000 D-Dimer |
| | µg/l | 919 | 689 | 1149 | Radiometer AQT90 Flex D-Dimer |
| | µg/l FEU | 2348 | 1761 | 2935 | Siemens Innovance D-Dimer |
| | µg/l | 667 | 500 | 834 | Roche Cobas D-DI 2 |
| | µg/l FEU | 2470 | 1853 | 3088 | HemosIL D-Dimer HS 500 |
| | µg/l | 755 | 566 | 944 | HemosIL D-Dimer |
| µg/l | 797 | 598 | 996 | HemosIL D-Dimer HS | |
| Digoxin 地高辛 | nmol/l | 1.51 | 1.21 | 1.81 | Chemiluminescence 化学发光法 |
| | ng/ml | 1.18 | 0.945 | 1.42 | |
| | nmol/l | 1.42 | 1.14 | 1.70 | Enzyme Immunoassay 酶免疫分析法 |
| | ng/ml | 1.11 | 0.890 | 1.33 | |
| | nmol/l | 1.29 | 1.03 | 1.55 | Turbidimetric 透射比浊法 |
| | ng/ml | 1.01 | 0.804 | 1.22 | |
| | nmol/l | 1.44 | 1.15 | 1.73 | KIMS |
| | ng/ml | 1.12 | 0.898 | 1.34 | |
| hsCRP 高敏 C 反应蛋白 | mg/l | 1.90 | 1.52 | 2.28 | Nephelometric (IFCC Cal.) 散射比浊法 |
| | mg/l | 2.08 | 1.66 | 2.50 | Turbidimetric (IFCC Cal.) 透射比浊法 |
| | mg/l | 2.08 | 1.66 | 2.50 | Turbidimetric (Non IFCC Cal.) 透射比浊法 |
| | mg/l | 1.89 | 1.51 | 2.27 | Randox Immunoturbidimetric 朗道免疫透射比浊法 |
| Myoglobin 肌红蛋白 | ng/ml = µg/l | 85.4 | 59.8 | 111 | Abbott Architect |

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

| Analyte | unit | Target | Range | | methods |
|-----------------------|--------------|--------|-------|-------|--|
| | | | low | high | |
| Myoglobin 肌紅蛋白 | ng/ml = µg/l | 80.3 | 56.2 | 104 | Siemens Centaur XP/XPT/Classic |
| | ng/ml = µg/l | 82.8 | 58.0 | 108 | Siemens Dimension |
| | ng/ml = µg/l | 61.9 | 43.3 | 80.5 | Beckman Dxl800 |
| | ng/ml = µg/l | 64.8 | 45.4 | 84.2 | Roche Elecsys |
| | ng/ml = µg/l | 69.9 | 48.9 | 90.9 | Roche Hitachi |
| | ng/ml = µg/l | 59.8 | 41.9 | 77.7 | Beckman Coulter Access |
| | ng/ml = µg/l | 42.4 | 29.7 | 55.1 | Siemens Stratus CS |
| | ng/ml = µg/l | 71.0 | 49.7 | 92.3 | BioMerieux Vidas |
| | ng/ml = µg/l | 64.8 | 45.4 | 84.2 | Siemens Dimension Vista LOCI |
| | ng/ml = µg/l | 72.1 | 50.5 | 93.7 | Siemens Centaur CP |
| NT-ProBNP N-端脑钠肽前体 | pmol/l | 13.5 | 10.1 | 16.9 | Siemens Centaur XP/XPT/Classic |
| | pg/ml | 114 | 85.6 | 142 | |
| | pmol/l | 70.6 | 53.0 | 88.3 | Siemens Immulite 2000 |
| | pg/ml | 598 | 449 | 747 | |
| | pmol/l | 19.1 | 14.3 | 23.9 | Siemens Stratus CS |
| | pg/ml | 162 | 121 | 203 | |
| | pmol/l | 16.9 | 12.7 | 21.1 | BioMerieux Vidas |
| | pg/ml | 143 | 108 | 178 | |
| | pmol/l | 16.5 | 12.4 | 20.6 | Roche Elecsys Modular E170 Cobas 6000/e411 |
| | pg/ml | 140 | 105 | 175 | |
| | pmol/l | 59.0 | 44.3 | 73.8 | Mitsubishi Chemical Pathfast |
| | pg/ml | 500 | 375 | 625 | |
| | pmol/l | 30.6 | 23.0 | 38.3 | Ortho Vitros 3600/5600/ECi |
| | pg/ml | 259 | 195 | 323 | |
| | pmol/l | 9.66 | 7.25 | 12.1 | Roche h232 |
| | pg/ml | 81.8 | 61.4 | 102 | |
| | pmol/l | 6.88 | 5.16 | 8.60 | Siemens Dimension Vista LOCI |
| | pg/ml | 58.3 | 43.7 | 72.9 | |
| Troponin I 肌钙蛋白 I | ng/ml = µg/l | 0.048 | 0.038 | 0.058 | Siemens Centaur XP/XPT/Classic |
| | ng/l = pg/ml | 48.0 | 38.0 | 58.0 | |
| | ng/ml = µg/l | 0.208 | 0.166 | 0.250 | Ortho Vitros ECi |
| | ng/l = pg/ml | 208 | 166 | 250 | |
| | ng/ml = µg/l | 0.135 | 0.108 | 0.162 | Biomerieux Vidas Ultra |
| | ng/l = pg/ml | 135 | 108 | 162 | |
| | ng/ml = µg/l | 0.019 | 0.015 | 0.023 | Mitsubishi Chemical Pathfast |
| | ng/l = pg/ml | 19.0 | 15.0 | 23.0 | |
| | ng/ml = µg/l | 0.060 | 0.048 | 0.072 | Abbott Architect STAT hs |
| | ng/l = pg/ml | 60.0 | 48.0 | 72.0 | |
| | ng/ml = µg/l | 0.034 | 0.027 | 0.041 | Beckman Dxl - AccuTnl+3 |
| | ng/l = pg/ml | 34.0 | 27.0 | 41.0 | |
| | ng/ml = µg/l | 0.042 | 0.034 | 0.050 | Siemens Centaur CP |
| | ng/l = pg/ml | 42.0 | 34.0 | 50.0 | |

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

| Analyte | unit | Target | Range | | methods |
|----------------------|--------------|--------|-------|-------|---|
| | | | low | high | |
| Troponin I 肌钙蛋白 I | ng/ml = µg/l | 0.146 | 0.117 | 0.175 | bioMerieux VIDAS hs Troponin I |
| | ng/l = pg/ml | 146 | 117 | 175 | |
| | ng/ml = µg/l | 0.083 | 0.066 | 0.100 | Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH) |
| | ng/l = pg/ml | 83.0 | 66.0 | 100 | |