

## 化学发光试剂出厂检验报告



## Chemiluminescence Reagent Inspection Report

|                          |                         |                                                                                                                                                                                                                                                                                                                                                                                                          |                         |                                                                                       |                |
|--------------------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------|----------------|
| 产品名称<br>Product Name     |                         | 肌酸激酶同工酶 (CK-MB) 测定试剂盒 (化学发光免疫分析法)<br>Creatine Kinase Isoenzyme (CK-MB) Reagent Kit (Chemiluminescent Immunoassay)                                                                                                                                                                                                                                                                                        |                         |                                                                                       |                |
| 规格<br>Specification      |                         | 50T/盒<br>50Tests/Kit                                                                                                                                                                                                                                                                                                                                                                                     | 产品型号<br>Product Model   | /                                                                                     |                |
| 批号<br>Batch No.          |                         | 20250427                                                                                                                                                                                                                                                                                                                                                                                                 | 有效期<br>Expiration Date  | 2026.04.26                                                                            |                |
| 生产日期<br>Production Date  |                         | 2025.04.27                                                                                                                                                                                                                                                                                                                                                                                               | 检验日期<br>Inspection Date | 2025.04.29                                                                            |                |
| 检验项目<br>Inspection Items |                         | 检验标准<br>Inspection Standard                                                                                                                                                                                                                                                                                                                                                                              |                         | 检验结果<br>Inspection Results                                                            | 判定<br>Judgment |
| 1                        | 外观<br>Appearance        | ①. 试剂M为棕褐色悬浊液, 久置后, 棕褐色磁珠沉于底部, 上清液为澄清液体;<br>②. 试剂R为无色澄清液体;<br>③. 校准品和质控品均为冻干疏松体.<br>①. The reagent M is a brown brown suspension, after a long time, the brown brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid;<br>②. Reagent R is colorless clear liquid;<br>③. Both the calibrator and the quality control substance are lyophilized loose solids. |                         | 符合<br>Meet with the requirement                                                       | 合格<br>Pass     |
| 2                        | 净含量<br>Net volume       | 液体试剂的净含量应不少于标示值<br>The net volume of liquid reagents should not be less than the indicated value.                                                                                                                                                                                                                                                                                                        |                         | 符合<br>Meet with the requirement                                                       | 合格<br>Pass     |
| 3                        | 准确度<br>Accuracy         | 企业参考品相对偏差不得超过±10%; 质控品相对偏差不得超过±20%<br>The relative deviation of enterprise reference standards should not exceed ±10; number of quality control product relative deviation less than ±20%.                                                                                                                                                                                                               |                         | Q1: 3.58%<br>Q2: -0.50%<br>准确性样本1<br>Accuracy1: -7.48%<br>准确性样本2<br>Accuracy2: -9.57% | 合格<br>Pass     |
| 4                        | 重复性<br>Repeatability    | CV≤8%                                                                                                                                                                                                                                                                                                                                                                                                    |                         | 低值<br>Low-level: 1.48%<br>高值<br>High-level: 1.98%                                     | 合格<br>Pass     |
| 5                        | 线性范围<br>Linearity range | 0.5-300pg/mL内, $r \geq 0.990$<br>Within the range of 0.5-300pg/mL, the correlation coefficient (r) should be $\geq 0.99$ .                                                                                                                                                                                                                                                                               |                         | 结果<br>Result: $r = 0.9995$                                                            | 合格<br>Pass     |
| 结论<br>Conclusion         |                         | 合格<br>Pass                                                                                                                                                                                                                                                                                                                                                                                               |                         |                                                                                       |                |
| 检验员<br>Inspector         |                         | 钟宗崇                                                                                                                                                                                                                                                                                                                                                                                                      | 复核人<br>Reviewer         | 高曼姿                                                                                   |                |
| 日期<br>Date               |                         | 2025.04.29                                                                                                                                                                                                                                                                                                                                                                                               | 日期<br>Date              | 2025.04.29                                                                            |                |

注: 若无内容填写应用“/”。

Note: If there is no information, please fill with“/”.

表格编号/Form Number: RT-RFM-Q8504

REV: A.2/ 保存期限: 10年/Storage Life: 10 years