



# 化学发光试剂出厂检验报告

## Chemiluminescence Reagent Inspection Report

|                          |                         |                                                                                                                                                                                                                                                                                                                                                                                                                                              |                         |                                                                               |                |
|--------------------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-------------------------------------------------------------------------------|----------------|
| 产品名称<br>Product Name     |                         | 总 $\beta$ -人绒毛膜促性腺激素 (Total $\beta$ -HCG) 测定试剂盒 (化学发光免疫分析法)<br>Total $\beta$ -Human Chorionic Gonadotropin (Total $\beta$ -HCG) Reagent Kit (Chemiluminescent Immunoassay)                                                                                                                                                                                                                                                                   |                         |                                                                               |                |
| 规格<br>Specification      |                         | 50测试/盒<br>50Tests/Kit                                                                                                                                                                                                                                                                                                                                                                                                                        | 产品型号<br>Product Model   | /                                                                             |                |
| 批号<br>Batch No.          |                         | 20250709                                                                                                                                                                                                                                                                                                                                                                                                                                     | 有效期<br>Expiration Date  | 2026.07.08                                                                    |                |
| 生产日期<br>Production Date  |                         | 2025.07.09                                                                                                                                                                                                                                                                                                                                                                                                                                   | 检验日期<br>Inspection Date | 2025.07.14                                                                    |                |
| 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(黄)褐色悬浊液, 久置后, 棕(黄)褐色磁珠沉于底部, 上清液为澄清液体;<br>②. 试剂R为无色或乳白色澄清液体;<br>③. 校准品和质控品为无色或乳白色澄清液体.<br>①. The reagent M is a brown(yellow) brown suspension, after a long time, the brown(yellow) brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid;<br>②. Reagent R is colorless or milkly clear liquid;<br>③. The calibration and quality control should be colorless or milkly clear liquid. |                         | 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超过 $\pm 10\%$ ; 质控品相对偏差不超过 $\pm 20\%$<br>The relative deviation of enterprise reference standards should not exceed $\pm 10\%$ ; number of quality control product relative deviation less than $\pm 20\%$ .                                                                                                                                                                                                                       |                         | Q1: 1.84%<br>Q2: 9.76%<br>准确性样本1 Accuracy1: -1.69%<br>准确性样本2 Accuracy2: 4.98% | 合格<br>Pass     |
| 4                        | 重复性<br>Repeatability    | CV $\leq 8\%$                                                                                                                                                                                                                                                                                                                                                                                                                                |                         | 低值 Low-level: 3.50%<br>高值 High-level: 7.04%                                   | 合格<br>Pass     |
| 5                        | 线性范围<br>Linearity range | 1-2500 mIU/mL内, $r \geq 0.9900$<br>Within the range of 1-2500 mIU/mL, the correlation coefficient (r) should be $\geq 0.99$ .                                                                                                                                                                                                                                                                                                                |                         | 结果 Result: r= 0.9996                                                          | 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               |                         | 2025.07.14                                                                                                                                                                                                                                                                                                                                                                                                                                   | 日期<br>Date              | 2025.07.14                                                                    |                |

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