



# 化学发光试剂出厂检验报告

## Chemiluminescence Reagent Inspection Report

|                          |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                         |                                 |
|--------------------------|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------|
| 产品名称<br>Product Name     |  | 卵泡刺激素 (FSH) 测定试剂盒 (化学发光免疫分析法)<br>Follicle Stimulating Hormone (FSH) Reagent Kit (Chemiluminescent Immunoassay)                                                                                                                                                                                                                                                                                                                                       |                         |                                 |
| 规格<br>Specification      |  | 100T/盒<br>100Tests/Kit                                                                                                                                                                                                                                                                                                                                                                                                                               | 产品型号<br>Product Model   | /                               |
| 批号<br>Batch No.          |  | 20250415                                                                                                                                                                                                                                                                                                                                                                                                                                             | 有效期<br>Expiration Date  | 2026.04.14                      |
| 生产日期<br>Production Date  |  | 2025.04.15                                                                                                                                                                                                                                                                                                                                                                                                                                           | 检验日期<br>Inspection Date | 2025.04.17                      |
| 检验项目<br>Inspection Items |  | 检验标准<br>Inspection Standard                                                                                                                                                                                                                                                                                                                                                                                                                          |                         | 检验结果<br>Inspection Results      |
| 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淡黄色澄清液体.<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 milky clear liquid;<br>③. The calibration and the quality control product for colorless or yellowish clear liquid. |                         | 符合<br>Meet with the requirement |
| 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.                                                                                                                                                                                                                                                                                                                                                    |                         | 合格<br>Pass                      |
| 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%.                                                                                                                                                                                                                                                          |                         | 合格<br>Pass                      |
| 重复性<br>Repeatability     |  | CV≤8%                                                                                                                                                                                                                                                                                                                                                                                                                                                |                         | 合格<br>Pass                      |
| 线性范围<br>Linearity range  |  | 0.1-200 mIU/mL内, r≥0.9900<br>Within the range of 0.1-200 mIU/mL, the correlation coefficient (r) should be ≥ 0.99.                                                                                                                                                                                                                                                                                                                                   |                         | 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               |  | 2025.04.17                                                                                                                                                                                                                                                                                                                                                                                                                                           | 日期<br>Date              | 2025.04.17                      |

注: 若无内容填写应用“/”。  
Note: If there is no information, please fill with“/”.