



# 检验报告

## Certificate of Analysis

|                                                |                         |                                                                                                                                                                                                                                                                                                                                                                                 |  |                         |                                 |                    |            |
|------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-------------------------|---------------------------------|--------------------|------------|
| 产品名称<br>Product Name                           |                         | 游离三碘甲状腺原氨酸（FT3）测定试剂盒（化学发光免疫分析法）<br>Free Triiodothyronine (FT3) Reagent Kit (Chemiluminescent Immunoassay)                                                                                                                                                                                                                                                                       |  |                         |                                 |                    |            |
| 产品型号<br>Product Model                          |                         | /                                                                                                                                                                                                                                                                                                                                                                               |  | 包装规格<br>Package Size    | 50Tests/Kit                     |                    |            |
| 批 号<br>Lot No.                                 |                         | 20250912                                                                                                                                                                                                                                                                                                                                                                        |  | 有效期<br>Expiry Date      | 2026. 09. 11                    |                    |            |
| 生产日期<br>Manufacture Date                       |                         | 2025. 09. 12                                                                                                                                                                                                                                                                                                                                                                    |  | 检验日期<br>Inspection Date | 2025. 09. 25                    |                    |            |
| 检验项目<br>Subjects                               |                         | 检验标准<br>Inspection Standards                                                                                                                                                                                                                                                                                                                                                    |  |                         | 检验结果<br>Results                 | 结果判定<br>Conclusion |            |
| 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>The reagent M is a brown brown suspension,after a long time,the brown brown magentic beads are deposited on the bottom,and the supernatant liquid should be clear liquid<br><br>②试剂R为无色澄清液体<br>Reagent R is a colorless clear liquid<br><br>③校准品和质控品为无色澄清液体<br>The calibration and the quality control product for colorless clear liquid |  |                         | 符合<br>Meet with the requirement | 合格<br>Pass         |            |
| 2                                              | 净含量<br>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±10%；质控品相对偏差不超过±20%<br>The relative deviation of enterprise reference standards should not exceed ±10;number of quality control product relative deviation less than ±20%                                                                                                                                                                                           |  |                         | Q1                              | -13.22%            | 合格<br>Pass |
|                                                |                         |                                                                                                                                                                                                                                                                                                                                                                                 |  |                         | Q2                              | -13.51%            |            |
|                                                |                         |                                                                                                                                                                                                                                                                                                                                                                                 |  |                         | 准确性样本1<br>Accuracy1             | -0.18%             |            |
|                                                |                         |                                                                                                                                                                                                                                                                                                                                                                                 |  |                         | 准确性样本2<br>Accuracy2             | 2.06%              |            |
| 4                                              | 重复性<br>Repeatability    | CV≤8%                                                                                                                                                                                                                                                                                                                                                                           |  |                         | 低值<br>Low-level                 | 6.92%              | 合格<br>Pass |
|                                                |                         |                                                                                                                                                                                                                                                                                                                                                                                 |  |                         | 高值<br>High-level                | 2.28%              |            |
| 5                                              | 线性范围<br>Linearity range | 1.5-50 pmol/L内，r≥0.9900<br>Within the range of 1.5-50 pmol/L,the correlation coefficient (r) should be ≥ 0.9900                                                                                                                                                                                                                                                                 |  |                         | 0.9965                          |                    | 合格<br>Pass |
| 检验结论<br>Inspection Conclusion                  |                         | 合格<br>Pass                                                                                                                                                                                                                                                                                                                                                                      |  |                         |                                 |                    |            |
| 报告人<br>Reporter                                |                         | 李庆琴                                                                                                                                                                                                                                                                                                                                                                             |  | 日期<br>Date              | 2025. 09. 25                    |                    |            |
| 批准（检验工程师）<br>Approved by<br>（Quality Engineer） |                         | 高曼姿                                                                                                                                                                                                                                                                                                                                                                             |  | 日期<br>Date              | 2025. 09. 25                    |                    |            |
| 备注<br>Remarks                                  |                         | 若无内容填写应用“/”。<br>If there is no information, please fill with“/”.                                                                                                                                                                                                                                                                                                                |  |                         |                                 |                    |            |

