



# 检验报告

## Certificate of Analysis

|  |                         |  |                         |                                 |                    |
|--|-------------------------|--|-------------------------|---------------------------------|--------------------|
| 产品名称<br>Product Name                           |                         | 全段甲状旁腺素 (PTH) 测定试剂盒 (化学发光免疫分析法)<br>Parathyroid Hormone (PTH) 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.                                 |                         | 20250807   | 有效期<br>Expiry Date      | 2026. 08. 06                    |                    |
| 生产日期<br>Manufacture Date                       |                         | 2025. 08. 07   | 检验日期<br>Inspection Date | 2025. 08. 15                    |                    |
| 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（黄）褐色悬浊液，久置后，棕（黄）褐色磁珠沉于底部，上清液为澄明液体<br>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试剂R为无色或乳白色澄明液体<br>Reagent R is colorless or milkly clear liquid<br>③校准品和质控品为无色或乳白色澄明液体<br>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>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%<br>The relative deviation of enterprise reference standards should not exceed ±10%  |                         | 准确性样本1<br>Accuracy 1<br>-2.14%  | 合格<br>Pass         |
|  |                         |  |                         | 准确性样本2<br>Accuracy 2<br>2.23%   |                    |
| 4  | 重复性<br>Repeatability    | CV≤8%  |                         | 低值<br>Low-level<br>3.61%        | 合格<br>Pass         |
|  |                         |  |                         | 高值<br>High-level<br>6.31%       |                    |
| 5  | 线性范围<br>Linearity range | 1.2-4000 pg/mL内，r≥0.9900<br>Within the range of 1.2-4000 pg/mL, the correlation coefficient (r) should be ≥ 0.9900   |                         | 0.9999                          | 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. 08. 15                    |                    |
| 批准（检验工程师）<br>Approved by<br>(Quality Engineer) |                         | 高曼姿  | 日期<br>Date              | 2025. 08. 15                    |                    |
| 备注<br>Remarks                                  |                         | 若无内容填写应用“/”。<br>If there is no information, please fill with“/”.   |                         |                                 |                    |

