



# 生化试剂出厂检验报告

## Chemistry Reagent Inspection Report

|                                             |                         |                                                                                                                                                    |                                        |                                                             |
|---------------------------------------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------|
| 产品名称<br>Product Name                        |                         | 尿素测定试剂盒（尿素酶-谷氨酸脱氢酶法）<br>Urea Assay Reagent Kit (Urease-GLDH Method)                                                                                |                                        |                                                             |
| 规格<br>Specification                         |                         | R1: 50ml×4,<br>R2: 25ml×2                                                                                                                          | 产品型号<br>Product Model                  | /                                                           |
| 批号<br>Batch No.                             |                         | 20250711                                                                                                                                           | 有效期<br>Expiration Date                 | 2026/7/10                                                   |
| 生产日期<br>Production Date                     |                         | 2025.07.11                                                                                                                                         | 检验日期<br>Inspection Date                | 2025.07.16                                                  |
| 试剂批号<br>Reagent batch number                |                         | 20250711                                                                                                                                           | 试剂有效期<br>Expiration date of Reagent    | 2026/7/10                                                   |
| 校准/质控批号<br>Calibrator/ Control batch number |                         | /                                                                                                                                                  | 校准有效期<br>Expiration date of Calibrator | /                                                           |
| 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        | R1、R2均为无色透明液体，无混浊，无未溶解物<br>R1 and R2 are both colorless, transparent liquid, without cloudiness or undissolved materials.                          |                                        | 符合<br>Meet with the requirement                             |
| 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                             |
| 3                                           | 准确度<br>Accuracy         | 相对偏差不得超过±10%<br>The relative deviation should not exceed ±10%.                                                                                     |                                        | 0.59%<br>Pass                                               |
| 4                                           | 重复性<br>Repeatability    | 变异系数CV≤5%<br>Coefficient of Variation (CV) ≤ 5%.                                                                                                   |                                        | 低值: 1.51%<br>Low-level:<br>高值: 0.87%<br>High-level:<br>Pass |
| 5                                           | 线性范围<br>Linearity range | 在0.2mmol/L~50mmol/L (37℃) 范围内，相关系数(r)应≥0.990<br>Within the range of 0.2mmol/L ~ 50mmol/L (37℃), the correlation coefficient (r) should be ≥ 0.990. |                                        | 0.9987<br>Pass                                              |
| 结论<br>Conclusion                            |                         | 合格<br>Pass                                                                                                                                         |                                        |                                                             |
| 检验员<br>Inspector                            |                         | 莫宗儒                                                                                                                                                | 复核人<br>Reviewer                        | 高曼姿                                                         |
| 日期<br>Date                                  |                         | 2025.07.16                                                                                                                                         | 日期<br>Date                             | 2025.07.16                                                  |

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-Q8503

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