



检验报告

Certificate of Analysis

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|--|-------------------------|---|-------------------------|---------------------------------|--------------------|
| 产品名称 Product Name | | 乳酸脱氢酶测定试剂盒（乳酸底物法） Lactate Dehydrogenase Assay Reagent Kit (Lactate Substrate Method) | | | |
| 产品型号 Product Model | | / | 包装规格 Package Size | R1: 50ml×4 R2: 25ml×2 | |
| 批 号 Lot No. | | 20251106 | 有效期 Expiry Date | 2026.11.05 | |
| 生产日期 Manufacture Date | | 2025.11.06 | 检验日期 Inspection Date | 2025.11.25 | |
| 检验项目 Subjects | | 检验标准 Inspection Standards | | 检验结果 Results | 结果判定 Conclusion |
| 1 | 外观 Appearance | R1、R2均为无色透明液体，无混浊，无未溶解物 R1 and R2 are both colorless, transparent liquid, without cloudiness or undissolved materials | | 符合 Meet with the requirement | 合格 Pass |
| 2 | 净含量 Volume | 液体试剂的净含量应不少于标示值 The net volume of liquid reagents should not be less than the indicated value | | 符合 Meet with the requirement | 合格 Pass |
| 3 | 准确度 Accuracy | 相对偏差不超过±10% The relative deviation should not exceed ±10% | | 0.38% | 合格 Pass |
| 4 | 重复性 Repeatability | 变异系数CV≤5% Coefficient of Variation (CV) ≤ 5% | 低值 Low-level | 3.82% | 合格 Pass |
| | | | 高值 High-level | 2.57% | 合格 Pass |
| 5 | 线性范围 Linearity range | 在10 U/L~1000 U/L (37℃) 范围内，相关系数 (r) 应≥0.99 Within the range of 10 U/L ~ 1000 U/L (37℃), the correlation coefficient (r) should be ≥ 0.99 | | 0.9996 | 合格 Pass |
| 检验结论 Inspection Conclusion | | 合格 Pass | | | |
| 报告人 Reporter | | 邱志成 | 日期 Date | 2025.11.25 | |
| 批准（检验工程师） Approved by (Quality Engineer) | | 高曼姿 | 日期 Date | 2025.11.25 | |
| 备注 Remarks | | 若无内容填写应用“/”。 If there is no information, please fill with“/”. | | | |



表格编号/Form Number: RT-RFM-Q8506

REV: A.0/ 保存期限: 10年/Storage Life: 10 years