



# 凝血试剂出厂检验报告

## Coagulation Reagent Inspection Report

|                          |                                          |                                                                                                                                                                                                  |                         |                                                           |
|--------------------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|-----------------------------------------------------------|
| 产品名称<br>Product Name     |                                          | 凝血酶时间测定试剂盒（液体）（凝固法）<br>Thrombin Time Assay Reagent Kit(Liquid) (Coagulation Method)                                                                                                              |                         |                                                           |
| 规格<br>Specification      |                                          | 5.0mL×10                                                                                                                                                                                         | 产品型号<br>Product Model   | /                                                         |
| 批号<br>Batch No.          |                                          | 20250609                                                                                                                                                                                         | 有效期<br>Expiration date  | 2026.06.08                                                |
| 生产日期<br>Production Date  |                                          | 2025.06.09                                                                                                                                                                                       | 检验日期<br>Inspection Date | 2025.06.20                                                |
| 检验项目<br>Inspection Items |                                          | 检验标准<br>Inspection Standard                                                                                                                                                                      |                         | 判定<br>Judgment                                            |
| 1                        | 外观<br>Appearance                         | a) 试剂盒外观应整洁，文字符号标识清晰；<br>b) TT试剂应为澄清透明均匀液体。<br><br>a) Appearance of Reagent Pack is clean and tidy, symbols are easy to recognize.<br>b) TT Reagent is colorless transparent homogeneous liquid. |                         | 符合<br><br>Meet with the requirement<br><br>合格<br><br>Pass |
| 2                        | 装量<br>Net volume                         | 液体试剂的净含量应不少于标示值。<br>Liquid Reagent Load volume should be more than labeled value.                                                                                                                |                         | 符合<br><br>Meet with the requirement<br><br>合格<br><br>Pass |
| 3                        | 正常血浆测量值<br>Test Result of Normal control | 用正常血浆测试，所得结果均值应不大于20s<br>Use control plasma to test, the result should be less than 20s                                                                                                          |                         | 17.7s<br><br>合格<br><br>Pass                               |
| 4                        | 准确度<br>Accuracy                          | /                                                                                                                                                                                                |                         | /                                                         |
| 5                        | 重复性<br>Repeatability                     | 用质控血浆重复测试所得结果的变异系数（CV）应不超过5.0%<br>Use Control plasma to test repeatability CV%: Less than 5.0%                                                                                                   |                         | 1.12%<br><br>合格<br><br>Pass                               |
| 结论<br>Conclusion         |                                          | 合格<br>Pass                                                                                                                                                                                       |                         |                                                           |
| 检验员<br>Inspector         |                                          | 邱志成                                                                                                                                                                                              | 复核人<br>Reviewer         | 高曼姿                                                       |
| 日期<br>Date               |                                          | 2025.06.20                                                                                                                                                                                       | 日期<br>Date              | 2025.06.20                                                |

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-Q8502

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