



# 凝血试剂出厂检验报告

## Coagulation Reagent Inspection Report

|                          |                                          |                                                                                                                                                                                                                                                                                                                          |                         |                                                              |                |
|--------------------------|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------------------|----------------|
| 产品名称<br>Product Name     |                                          | 凝血酶原时间测定试剂盒（凝固法）<br>Prothrombin Time Assay Reagent Kit(Coagulation Method)                                                                                                                                                                                                                                               |                         |                                                              |                |
| 规格<br>Specification      |                                          | R1:4mL×10<br>R2:50mL×1                                                                                                                                                                                                                                                                                                   | 产品型号<br>Product Model   | /                                                            |                |
| 批号<br>Batch No.          |                                          | 2025032002                                                                                                                                                                                                                                                                                                               | 有效期<br>Expiration date  | 2027.03.19                                                   |                |
| 生产日期<br>Production Date  |                                          | 2025.03.20                                                                                                                                                                                                                                                                                                               | 检验日期<br>Inspection Date | 2025.04.24                                                   |                |
| 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                         | a) 试剂盒外观应整洁，文字符号标识清晰；<br>b) R1: PT试剂冻干品为疏松体，复溶后为均匀的混悬液。<br>c) R2: PT复溶液为无色透明溶液。<br>a) Appearance of Reagent Pack is clean and tidy, symbols are easy to recognize.<br>b) R1: PT Dry Powder is loose body. After dissolved, it is Homogeneous suspension.<br>c) R2: PT Buffer is colorless transparent homogeneous liquid |                         | 符合<br><br>Meet with the requirement                          | 合格<br><br>Pass |
| 2                        | 装量<br>Net volume                         | R2: PT复溶液装量负偏差应不大于标示量的5%。<br>R2: Net volume deviation of PT buffer should be less than 5% of Labeled volume                                                                                                                                                                                                              |                         | 符合<br><br>Meet with the requirement                          | 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14s<br>Use control plasma to test, the result should be less than 14s                                                                                                                                                                                                                                  |                         | 12.5s                                                        | 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%                                                                                                                                                                                                                            |                         | 正常值<br>Normal Control 0.49%<br>异常值<br>Abnormal Control 0.97% | 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               |                                          | 2025.04.24                                                                                                                                                                                                                                                                                                               | 日期<br>Date              | 2025.04.24                                                   |                |

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