



凝血试剂出厂检验报告

Coagulation Reagent Inspection Report

产品名称 Product Name		凝血酶原时间测定试剂盒（凝固法） Prothrombin Time Assay Reagent Kit (Coagulation Method)			
规格 Specification		R1:4mL×10 R2:50mL×1	产品型号 Product Model	/	
批号 Batch No.		2025060402	有效期 Expiration date	2027.06.03	
生产日期 Production Date		2025.06.04	检验日期 Inspection Date	2025.07.15	
检验项目 Inspection Items		检验标准 Inspection Standard		检验结果 Inspection Results	判定 Judgment
1	外观 Appearance	a) 试剂盒外观应整洁, 文字符号标识清晰; b) R1: PT试剂冻干品为疏松体, 复溶后为均匀的混悬液。 c) R2: PT复溶液为无色透明溶液。 a) Appearance of Reagent Pack is clean and tidy, symbols are easy to recognize. b) R1: PT Dry Powder is loose body. After dissolved, it is Homogeneous suspension. c) R2: PT Buffer is colorless transparent homogeneous liquid		符合 Meet with the requirement	合格 Pass
2	装量 Net volume	R2: PT复溶液装量负偏差应不大于标示量的5%。 R2: Net volume deviation of PT buffer should be less than 5% of Labeled volume		符合 Meet with the requirement	合格 Pass
3	正常血浆测量值 Test Result of Normal control	用正常血浆测试, 所得结果均值应不大于14s Use control plasma to test, the result should be less than 14s		13.0s	合格 Pass
4	准确度 Accuracy	/		/	/
5	重复性 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% Use Control plasma to test repeatability CV%: Less than 5.0%		正常值 Normal Control 0.69% 异常值 Abnormal Control 0.41%	合格 Pass
结论 Conclusion		合格 Pass			
检验员 Inspector		邱志成	复核人 Reviewer	高曼姿	
日期 Date		2025.07.15	日期 Date	2025.07.15	

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