



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.		2025032001	有效期 Expiration date	2027. 03. 19	
生产日期 Production Date		2025. 03. 20	检验日期 Inspection Date	2025. 04. 23	
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		12. 6s	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. 74% 异常值 Abnormal Control 0. 86%	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. 04. 23	日期 Date	2025. 04. 23	

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