



检验报告

Certificate of Analysis

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)			
产品型号 Product Model		/	包装规格 Package Size	R1:4mL×10 R2:50mL×1	
批 号 Lot No.		2025112001	有效期 Expiry Date	2027. 11. 19	
生产日期 Manufacture Date		2025. 11. 20	检验日期 Inspection Date	2025. 12. 12	
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	a) 试剂盒外观应整洁，文字符号标识清晰 a) Appearance of reagent pack is clean and tidy, symbols are easy to recognize b) R1:PT试剂冻干品为疏松体，复溶后为均匀的混悬液 b) R1:PT dry powder is loose body, after dissolved, it is homogeneous suspension c) R2:PT复溶液为无色透明溶液 c) R2:PT buffer is colorless transparent homogeneous liquid		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 Liquid reagent load volume should be more than labeled value		符合 Meet with the requirement	合格 Pass
3	正常血浆测量值 Normal plasma measurement value	用正常血浆测试，所得结果均值应不大于14s Use normal control plasma to test, the result should be less than 14s		12. 4s	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 1.06% 异常值 Abnormal Control 0.57%	合格 Pass
检验结论 Inspection Conclusion		合格 Pass			
报告人 Reporter		钟宗崇	日期 Date	2025. 12. 12	
批准（检验工程师） Approved by (Quality Engineer)		高曼姿	日期 Date	2025. 12. 12	
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