



凝血试剂出厂检验报告

Coagulation Reagent Inspection Report

产品名称 Product Name		纤维蛋白原含量测定试剂盒（凝固法） Fibrinogen Assay Reagent Kit(Coagulation Method)			
规格 Specification		R1: 2mL×5 R2: 100mL×1 R3: 1mL×1	产品型号 Product Model	/	
批号 Batch No.		20250623	有效期 Expiration date	2027.06.22	
生产日期 Production Date		2025.06.23	检验日期 Inspection Date	2025.07.09	
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: FIB试剂和R3: 定值血浆为冻干品，为白色或微黄色疏松体，复溶后为均匀的溶液； c) R2: 咪唑缓冲液为无色透明均匀液体。 a) Appearance of Reagent Pack is clean and tidy, symbols are easy to recognize. b) R1: FIB Reagent and R3: Calibrator is dry powder, which is white or light yellow loose body and is transparent homogeneous liquid after dissolving. c) R2: Imidazole buffer is a colorless transparent homogeneous liquid		符合 Meet with the requirement	合格 Pass
2	装量 Net volume	R2: 咪唑缓冲液装量负偏差应不大于标示量的3% R2: Net volume deviation of Imidazole buffer should be less than 3% 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	/		/	/
4	准确度 Accuracy	用参考物质测量，相对偏差应不超过±15% Use control plasma to test, the relative deviation should be less than 15%		7.79%	合格 Pass
5	重复性 Repeatability	用质控血浆重复测试所得结果的变异系数（CV），正常值应不超过5.0%，异常值应不超过8.0% Use Control plasma to test repeatability CV%: Less than 5.0% for Normal control, less than 8.0% for Abnormal Control.		正常值 Normal Control 2.17% 异常值 Abnormal Control 1.70%	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		2025.07.09	日期 Date	2025.07.09	

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