



检验报告

Certificate of Analysis

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)			
产品型号 Product Model		/	包装规格 Package Size	R1: 4mL×5 R2: 100mL×1 R3: 1mL×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	2025.12.16	
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: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 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:咪唑缓冲液为无色透明均匀液体 c) R2:Imidazole buffer is a 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	/		/	/
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%		5.28%	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 3.52% 异常值 Abnormal Control 1.81%	合格 Pass
检验结论 Inspection Conclusion		合格 Pass			
报告人 Reporter		钟宗崇	日期 Date	2025.12.16	
批准 (检验工程师) Approved by (Quality Engineer)		高曼姿	日期 Date	2025.12.16	
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