



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（液体）（凝固法） Fibrinogen Assay Reagent Kit(Liquid) (Coagulation Method)		
规格 Specification		R1: 2mL×5 R2: 100mL×1 R3: 1mL×1	产品型号 Product Model	/
批号 Batch No.		20250624	有效期 Expiration date	2026.06.23
生产日期 Production Date		2025.06.24	检验日期 Inspection Date	2025.07.15
检验项目 Inspection Items		检验标准 Inspection Standard		判定 Judgment
1	外观	a) 试剂盒外观应整洁, 文字符号标识清晰; b) 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。		符合
	Appearance	a) Appearance of Reagent Pack is clean and tidy, symbols are easy to recognize. b) 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		Meet with the requirement Pass
2	装量 Net 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 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%		2.07% 合格 Pass
5	重复性	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 1.71% 合格
	Repeatability			异常值 Abnormal Control 1.05% 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