

化学发光试剂出厂检验报告



Chemiluminescence Reagent Inspection Report

产品名称 Product Name		肌钙蛋白I (cTnI) 测定试剂盒 (化学发光免疫分析法) Troponin I (cTnI) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		50测试/盒 50Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250604	有效期 Expiration Date	2026.06.03	
生产日期 Production Date		2025.06.04	检验日期 Inspection Date	2025.06.10	
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	①. 试剂M为棕褐色悬浊液, 久置后, 棕褐色磁珠沉于底部, 上清液为澄明液体; ②. 试剂R为无色澄明液体; ③. 校准品和质控品为无色澄明液体。 ①. The reagent M is a brown brown suspension, after a long time, the brown brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid; ②. Reagent R is colorless clear liquid; ③. The calibration and quality control should be colorless clear liquid.		符合 Meet with the requirement	合格 Pass
2	净含量 Net volume	液体试剂的净含量应不少于标示值 The net volume of liquid reagents should not be less than the indicated value.		符合 Meet with the requirement	合格 Pass
3	准确度 Accuracy	企业参考品相对偏差不超过±15%; 质控品相对偏差不超过±20% The relative deviation of enterprise reference standards should not exceed ±15%; number of quality control product relative deviation less than ±20%.		Q1: 2.63% Q2: 4.32% 准确性样本1 Accuracy1: 5.00% 准确性样本2 Accuracy2: -3.21%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 2.92% 高值 High-level: 2.85%	合格 Pass
5	线性范围 Linearity range	0.01~50 ng/mL内, $r \geq 0.990$ Within the range of 0.01~50 ng/mL, the correlation coefficient (r) should be ≥ 0.990 .		结果 Result: $r = 0.9971$	合格 Pass
结论 Conclusion		合格 Pass			
检验员 Inspector		钟宗崇	复核人 Reviewer	高曼姿	
日期 Date		2025.06.10	日期 Date	2025.06.10	

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-Q8504

REV: A. 2/ 保存期限: 10年/Storage Life: 10 years

