

化学发光试剂出厂检验报告



Chemiluminescence Reagent Inspection Report

产品名称 Product Name		B型利钠肽（BNP）测定试剂盒（化学发光免疫分析法） B-Type Natriuretic Peptide (BNP) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		50测试/盒 50Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250703	有效期 Expiration Date	2026.07.02	
生产日期 Production Date		2025.07.03	检验日期 Inspection Date	2025.07.07	
检验项目 Inspection Items		检验标准 Inspection Standard		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. 校准品和质控品应为冻干疏松体，复溶后液体组分澄清无沉淀。 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. Calibrators and quality control materials should be lyophilized loose bodies, and the liquid components should be clear without precipitation after reconstitution.		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±10%；质控品相对偏差不超过±20% The relative deviation of enterprise reference standards should not exceed ±10; number of quality control product relative deviation less than ±20%.		Q1: -1.74% Q2: 2.45% 准确性样本1 Accuracy1: -2.69% 准确性样本2 Accuracy2: 1.05%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 1.49% 高值 High-level: 2.20%	合格 Pass
5	线性范围 Linearity range	5-5000pg/mL内， $r \geq 0.990$ Within the range of 5-5000pg/mL, the correlation coefficient (r) should be ≥ 0.99 .		结果 Result: $r = 0.9996$	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		2025.07.07	日期 Date	2025.07.07	

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