



化学发光试剂出厂检验报告

Chemiluminescence Reagent Inspection Report

产品名称 Product Name		降钙素原 (PCT) 测定试剂盒 (化学发光免疫分析法) Procalcitonin (PCT) Reagent Kit (Chemiluminescent Immunoassay)		
规格 Specification		50测试/盒 50Tests/Kit	产品型号 Product Model	/
批号 Batch No.		20250609	有效期 Expiration Date	2026.06.08
生产日期 Production Date		2025.06.09	检验日期 Inspection Date	2025.06.13
检验项目 Inspection Items		检验标准 Inspection Standard		检验结果 Inspection Results
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
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
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: 3.45% Q2: 8.09% 准确性样本1 Accuracyl: 1.44% 准确性样本2 Accuracy2: 4.30%
4	重复性 Repeatability	CV≤8%		低值 Low-level: 1.87% 高值 High-level: 3.78%
5	线性范围 Linearity range	0.02-100 ng/mL内, $r \geq 0.9900$ Within the range of 0.02-100 ng/mL, the correlation coefficient (r) should be ≥ 0.99 .		结果 Result: $r = 0.9989$
结论 Conclusion		合格 Pass		
检验员 Inspector		钟宗崇	复核人 Reviewer	高曼姿
日期 Date		2025.06.13	日期 Date	2025.06.13

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