

化学发光试剂出厂检验报告



Chemiluminescence Reagent Inspection Report

产品名称 Product Name		肌酸激酶同工酶 (CK-MB) 测定试剂盒 (化学发光免疫分析法) Creatine Kinase Isoenzyme (CK-MB) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		50测试/盒 50Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250605	有效期 Expiration Date	2026.06.04	
生产日期 Production Date		2025.06.05	检验日期 Inspection Date	2025.06.12	
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. 校准品和质控品为白色冻干粉固体。 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 the quality control product are white lyophilized powder solid.		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: -0.98% Q2: -3.17% 准确性样本1 Accuracy1: -4.59% 准确性样本2 Accuracy2: 3.65%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 1.84% 高值 High-level: 1.39%	合格 Pass
5	线性范围 Linearity range	0.5-300pg/mL内, $r \geq 0.990$ Within the range of 0.5-300pg/mL, the correlation coefficient (r) should be ≥ 0.99 .		结果 Result: r= 0.9985	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		2025.06.12	日期 Date 2025.06.12		

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

