

化学发光试剂出厂检验报告



Chemiluminescence Reagent Inspection Report

产品名称 Product Name		睾酮 (TESTO) 测定试剂盒 (化学发光免疫分析法) Testosterone (TESTO) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		50测试盒 50 Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250516	有效期 Expiration Date	2026.05.15	
生产日期 Production Date		2025.05.16	检验日期 Inspection Date	2025.06.06	
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（黄）褐色悬浊液，久置后，棕（黄）褐色磁珠沉于底部，上清液为澄明液体； ②. 试剂R为无色或淡黄色澄明液体； ③. 校准品和质控品为无色或淡黄色澄明液体。 ①. The reagent M is a brown (yellow) brown suspension, after a long time, the brown (yellow) brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid; ②. Reagent R is a colorless or yellowish clear liquid; ③. The calibration and the quality control product for colorless or yellowish 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±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: 5.28% Q2: 0.58% 准确性样本1 Accuracy1: 4.79% 准确性样本2 Accuracy2: -0.19%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 5.77% 高值 High-level: 2.93%	合格 Pass
5	线性范围 Linearity range	0.1-15 ng/mL内，r≥0.990 Within the range of 0.1-15 ng/mL, the correlation coefficient (r) should be ≥ 0.990.		结果 Result: r=0.9994	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		2025.06.06	日期 Date	2025.06.06	

注：若无内容填写应用“/”。
 Note: If there is no information, please fill with "/".