



化学发光试剂出厂检验报告

Chemiluminescence Reagent Inspection Report

产品名称 Product Name		游离前列腺特异性抗原 (fPSA) 测定试剂盒 (化学发光免疫分析法) Free Prostate-specific Antigen (fPSA) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		100T/盒 100Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250407	有效期 Expiration Date	2026. 04. 06	
生产日期 Production Date		2025. 04. 07	检验日期 Inspection Date	2025. 04. 09	
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, 上清液为澄清液体; ②. 试剂R为无色或乳白色澄清液体; ③. 校准品和质控品为无色或乳白色澄清液体。 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 colorless or milky clear liquid; ③.The calibration and quality control should be colorless or milky 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得超过±10%; 质控品相对偏差不得超过±20% The relative deviation of enterprise reference standards should not exceed ±10%; number of quality control product relative deviation less than ±20%.		Q1: -7.25% Q2: 5.54% 准确性样本1 Accuracy1: -1.45% 准确性样本2 Accuracy2: 1.23%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 7.35% 高值 High-level: 1.24%	合格 Pass
5	线性范围 Linearity range	0.01~50ng/mL内, $r \geq 0.9900$ Within the range of 0.01~50ng/mL, the correlation coefficient (r) should be ≥ 0.9900 .		结果 Result: $r = 0.9998$	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. 04. 09	日期 Date	2025. 04. 09	

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