

Certificate of Analysis

产品名称 Product Name	糖化血红蛋白检测试剂盒 (胶乳增强免疫比浊法) Glycohemoglobin A1c (HbA1c) Test Kit (Latex Enhanced Immunoturbidimetric)			物料编码 Material Code	71397
批号 Lot No.	51128097F	包装规格 Package	R1:30mL×1 R2:10mL×1	生产日期 Manufacture Date	2026.2.27
组批批量 Lot Size	R1:30mL×1 R2:10mL×1	销售区域 Market Area	中国/China	效期 Expiry Date	2027.2.26
取样量 Sample Amount	1盒	送检日期 Sampling Date	2026.2.27	检验日期 Analysis Date	2026.2.27
检验依据 Inspection Basis	产品检验规程/ Inspection procedures				
检验项目 Test Items	检验标准 Quality Standard			检验结果 Result	评价 Comment
外观和性状 Appearance and Character	试剂盒组分齐全完整; 标签、标识清晰完整 Reagent components are complete. Labels are clear and correct.			试剂盒组分齐全完整; 标签、标识清晰完整 Reagent components are complete. Labels are clear and correct.	符合标准 Qualified
	R1为乳白色液体 R1 is Milky white liquid			R1为乳白色液体 R1 is Milky white liquid	
	R2为无色澄清液体 R2 is colorless clear liquid			R2为无色澄清液体 R2 is colorless clear liquid	
净含量 Volume	R1 ≥ 30 mL, R2 ≥ 10 mL			R1 30.4ml R2 10.3ml	符合标准 Qualified
试剂空白 Reagent blank	试剂空白吸光度 ≤ 1.7000, (660nm, 1cm optical path) Reagent blank absorbance ≤ 1.7, (37°C, 660nm, 1cm optical path)			0.5011	符合标准 Qualified
准确度 Accuracy	质控结果是否在靶值范围之内 Whether the quality control results are within the target range			Yes	符合标准 Qualified
线性范围 Linear Range	线性范围: 2~14%内, r 不小于 0.990 range: 2~14%, r ≥ 0.990			0.9989	符合标准 Qualified
重复性 Reproducibility	重复性 CV 不大于 10% Repeatability CV ≤ 10%			4.22%	符合标准 Qualified
结论 Conclusion	合格/Pass				
备注 Remarks					
检验 QC	陈红	复核 Checked By	王如燕	批准 Approved By	王荷莲
签名/日期 Signature / Date	2026.2.27	签名/日期 Signature / Date	2026.2.27	签名/日期 Signature / Date	2026.2.27

