

Certificate of Analysis

产品名称 Product Name	肌酸激酶检测试剂盒 (IFCC推荐法) Creatine Kinase (CK) Test Kit(IFCC)			物料编码 Material Code	71322
批号 Lot No.	60223022T	包装规格 Package	R1: 48mL×2 R2: 12mL×2;	生产日期 Manufacture Date	2026.2.28
组装批量 Lot Size	R1: 48mL×2 R2: 12mL×2;	销售区域 Market Area	中国/China	效期 Expiry Date	2027.2.27
取样量 Sample Amount	1盒	送检日期 Sampling Date	2026.2.28	检验日期 Analysis Date	2026.2.28
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 componets 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 componets are complete.Labels are clear and correct.	符合标准 Qualified
	R1为无色澄清液体 R1 is colorless clear liquid			R1为无色澄清液体 R1 is colorless clear liquid	
	R2为无色或淡黄色澄清液体 R2 is colorless clear liquid			R2为无色澄清液体 R2 is colorless liquid	
装量 Volume	R1≥48mL, R2≥12mL R1≥48mL, R2≥12mL			R1 48.3 ml R2 12.2ml	符合标准 Qualified
空白吸光度 Blank Absorbance	在340nm波长、1cm光径条件下, 试剂空白吸光度小于0.4 Reagent blank absorbance≤0.4, (340nm, 1cm optical path)			0.1144	符合标准 Qualified
准确度 Accuracy	相对偏差不超过10% relative deviation≤10%			2.19%	符合标准 Qualified
线性范围 Linear Range	线性范围: [25,1000]U/L内, r不小于0.990 range: [25,1000]U/L,r≥0.990			0.9991	符合标准 Qualified
重复性 Reproducibility	重复性CV不大于5% repcatability CV≤5%			1.85%	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 Approve d By	王荷莲
签名/日期 Signature / Date	2026.2.28	签名/日期 Signature / Date	2026.2.28	签名/日期 Signature / Date	2026.2.28