



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name		α-淀粉酶测定试剂盒 (EPS底物法) α-Amylase Assay Reagent Kit (EPS Method)		
规格 Specification		R1: 50ml×2, R2: 20ml×1	产品型号 Product Model	/
批号 Batch No.		20250328	有效期 Expiration Date	2026/3/27
生产日期 Production Date		2025.03.28	检验日期 Inspection Date	2025.04.11
试剂批号 Reagent batch number		20250328	试剂有效期 Expiration date of Reagent	2026/3/27
校准/质控批号 Calibrator/Control batch number		/	校准有效期 Expiration date of Calibrator	/
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	R1、R2均为无色透明液体，无混浊，无未溶解物 R1 and R2 are colorless, transparent liquid, without cloudiness or undissolved materials		符合 Meet with the requirement
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
3	准确度 Accuracy	相对偏差不超过±10% The relative deviation should not exceed ±10%.		2.30% 合格 Pass
4	重复性 Repeatability	变异系数CV≤6% Coefficient of Variation (CV) ≤ 6%		低值: 2.22% High-level: 1.27% 合格 Pass
5	线性范围 Linearity range	在10U/L~1600U/L (37℃) 范围内，相关系数(r) 应≥0.99 Within the range of 10U/L ~ 1600U/L (37℃), the correlation coefficient (r) should be ≥ 0.99		0.9991 合格 Pass
结论 Conclusion		合格 Pass		
检验员 Inspector		莫宗儒	复核人 Reviewer	高曼姿
日期 Date		2025.04.11	日期 Date	2025.04.11

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-Q8503

REV: A.2/ 保存期限: 10年/Storage Life: 10 years