



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name	α-羟丁酸脱氢酶测定试剂盒(α-酮丁酸底物法) α-Hydroxybutyrate Dehydrogenase Assay Reagent Kit (α-Oxobutyric Method)			
规格 Specification	R1: 50ml×4, R2: 25ml×2	产品型号 Product Model	/	
批号 Batch No.	20250627	有效期 Expiration Date	2026/6/26	
生产日期 Production Date	2025.06.27	检验日期 Inspection Date	2025.07.11	
试剂批号 Reagent batch number	20250627	试剂有效期 Expiration date of Reagent	2026/6/26	
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	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	相对偏差不得超过±10% The relative deviation should not exceed ±10%.		1.51%	合格 Pass
4 重复性 Repeatability	变异系数CV≤5% Coefficient of Variation (CV) ≤ 5%		低值: Low-level: 2.60% 高值: High-level: 0.88%	合格 Pass
5 线性范围 Linearity range	在5U/L~1000U/L (37℃) 范围内，相关系数(r)应≥0.99 Within the range of 5U/L ~ 1000U/L (37℃), the correlation coefficient (r) should be ≥ 0.99.		0.9995	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	2025.07.11	日期 Date	2025.07.11	

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