



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name		尿素测定试剂盒（尿素酶-谷氨酸脱氢酶法） Urea Assay Reagent Kit (Urease-GLDH Method)		
规格 Specification		R1: 50ml×4, R2: 25ml×2	产品型号 Product Model	/
批号 Batch No.		20250421	有效期 Expiration Date	2026/4/20
生产日期 Production Date		2025. 04. 21	检验日期 Inspection Date	2025. 04. 28
试剂批号 Reagent batch number		20250421	试剂有效期 Expiration date of Reagent	2026/4/20
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		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 both 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	相对偏差不超过±10% The relative deviation should not exceed ±10%.		0.14% 合格 Pass
4	重复性 Repeatability	变异系数CV≤5% Coefficient of Variation (CV) ≤ 5%.		低值: 1.38% Low-level: 高值: 1.00% High-level: 合格 Pass
5	线性范围 Linearity range	在0.2mmol/L~50mmol/L (37℃) 范围内，相关系数(r)应≥0.990 Within the range of 0.2mmol/L ~ 50mmol/L (37℃), the correlation coefficient (r) should be ≥ 0.990.		0.9978 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. 28	日期 Date	2025. 04. 28

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