



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name		低密度脂蛋白胆固醇测定试剂盒（直接法-表面活性剂清除法） Low Density Lipoprotein Cholesterol Assay Reagent Kit (Direct-Surfactant Clearance Method)			
规格 Specification		R1: 50ml×3, R2: 25ml×2	产品型号 Product Model	/	
批号 Batch No.		20250620	有效期 Expiration Date	2026/6/19	
生产日期 Production Date		2025.06.20	检验日期 Inspection Date	2025.07.08	
试剂批号 Reagent batch number		20250620	试剂有效期 Expiration date of Reagent	2026/6/19	
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无色、R2淡黄色的澄清液体，无混浊，无未溶解物 R1 is colorless, clear liquid and R2 is yellowish, clear 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%.		-6.62%	合格 Pass
4	重复性 Repeatability	变异系数CV≤6% Coefficient of Variation (CV) ≤ 6%		2.49%	合格 Pass
5	线性范围 Linearity range	在0.13mmol/L~11.6mmol/L(5mg/dL~450mg/dL)(37℃)范围内，相关系数(r)应≥0.99 Within the range of 0.13mmol/L ~ 11.6mmol/L (5mg/dL ~ 450mg/dL) (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		2025.07.08	日期 Date	2025.07.08	

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