



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name	总胆汁酸测定试剂盒（第V代循环酶法） Bile Acids Assay Reagent Kit (5th Generation Colorimetric Method)			
规格 Specification	R1: 50ml×3, R2: 50ml×1, 校准/Cal: 1ml×1	产品型号 Product Model	/	
批号 Batch No.	20250703	有效期 Expiration Date	2026/7/2	
生产日期 Production Date	2025. 07. 03	检验日期 Inspection Date	2025. 07. 08	
试剂批号 Reagent batch number	20250703	试剂有效期 Expiration date of Reagent	2026/7/2	
校准/质控批号 Calibrator/ Control batch number	20250703	校准有效期 Expiration date of Calibrator	2027/1/2	
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淡黄色, R2无色或微黄色的澄清液体, 无沉淀及絮状物 R1 is yellowish, clear liquid and R2 is colorless or slightly yellowish, clear liquid, without sediments or floccules.		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%.		-2.41%	合格 Pass
4 重复性 Repeatability	变异系数CV≤5% Coefficient of Variation (CV) ≤5%		低值: 1.43 Low-level: 高值: 1.22 High-level:	合格 Pass
5 线性范围 Linearity range	在5 μmol/L~190μmol/L (37℃) 范围内, 相关系数(r) 应≥0.9900 Within the range of 5mmmol/L ~ 45mmol/L (37℃), the correlation coefficient (r) should be ≥ 0.990.		0.9981	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