



生化试剂出厂检验报告

Chemistry Reagent Inspection Report

产品名称 Product Name		免疫球蛋白M (IgM) 测定试剂盒 (免疫比浊法) Immunoglobulin M (IgM) Assay Reagent Kit (Immunoturbidimetric)			
规格 Specification		R1: 45ml×1, R2: 15ml×1, 校 准: 1ml×1	产品型号 Product Model	/	
批 号 Batch No.		20250427	有效期 Expiration Date	2026/4/26	
生产日期 Production Date		2025. 04. 27	检验日期 Inspection Date	2025. 04. 30	
试剂批号 Reagent batch number		20250427	试剂有效期 Expiration date of Reagent	2026/4/26	
校准/质控批号 Calibrator/Control batch number		20250427	校准有效期 Expiration date of Calibrator	2026/10/26	
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微黄色, 澄清液体, 无沉淀及絮状物 R1 is colorless, R2 is 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 content 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±15% The relative deviation should not exceed ± 15%.		1. 19%	合格 Pass
4	重复性 Repeatability	变异系数CV≤4% Coefficient of Variation (CV) ≤4%		0. 61%	合格 Pass
5	线性范围 Linearity range	在0. 03g/L~5. 2g/L (37℃) 范围内, 相关系数 (r) 应≥0. 990 Within the range of 0. 03g/L~5. 2g/L (37℃), the correlation coefficient (r) should be ≥ 0. 990.		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. 04. 30	日期 Date	2025. 04. 30	

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

