



检验报告

Certificate of Analysis

产品名称 Product Name		肌红蛋白 (Myo) 测定试剂盒 (化学发光免疫分析法) Myoglobin (Myo) Reagent Kit (Chemiluminescent Immunoassay)					
产品型号 Product Model		/		包装规格 Package Size	50测试/盒 50Tests/Kit		
批 号 Lot No.		20250722		有效期 Expiry Date	2026.07.21		
生产日期 Manufacture Date		2025.07.22		检验日期 Inspection Date	2025.07.31		
检验项目 Subjects		检验标准 Inspection Standards			检验结果 Results	结果判定 Conclusion	
1	外观 Appearance	①试剂M为棕褐色悬浊液,久置后,棕褐色磁珠沉于底部,上清液为澄明液体 The reagent M is a brown brown suspension, after a long time, the brown brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid ②试剂R为无色澄明液体 Reagent R is a colorless clear liquid ③校准品和质控品为白色冻干粉固体 The calibration and the quality control product are white lyophilized powder solid			符合 Meet with the requirement	合格 Pass	
2	净含量 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	企业参考品相对偏差不超过±10%;质控品相对偏差不超过±20% The relative deviation of enterprise reference standards should not exceed ±10%; number of quality control product relative deviation less than ±20%			Q1	4.14%	合格 Pass
					Q2	9.34%	
					准确性样本1 Accuracy1	2.33%	
					准确性样本2 Accuracy2	7.41%	
4	重复性 Repeatability	CV≤8%			低值 Low-level	4.79%	合格 Pass
					高值 High-level	3.34%	
5	线性范围 Linearity range	3-1000 ng/mL内, r≥0.9900 Within the range of 3-1000 ng/mL, the correlation coefficient (r) should be ≥ 0.9900			0.9996	合格 Pass	
检验结论 Inspection Conclusion		合格 Pass					
报告人 Reporter		钟宗崇		日期 Date	2025.07.31		
批准(检验工程师) Approved by (Quality Engineer)		高曼姿		日期 Date	2025.07.31		
备注 Remarks		若无内容填写应用“/”。 If there is no information, please fill with“/”.					

