



化学发光试剂出厂检验报告

Chemiluminescence Reagent Inspection Report

产品名称 Product Name		超敏C反应蛋白（hs-CRP）测定试剂盒（化学发光免疫分析法） Hypersensitive C-Reactive Protein (hs-CRP) Reagent Kit (Chemiluminescent Immunoassay)			
规格 Specification		50T/盒 50Tests/Kit	产品型号 Product Model	/	
批号 Batch No.		20250521	有效期 Expiration Date	2026.05.20	
生产日期 Production Date		2025.05.21	检验日期 Inspection Date	2025.05.26	
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	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； ②. 试剂R1应为无色澄明液体； ③. 试剂R2应为无色澄明液体； ④. 校准品和质控品为无色或淡黄色澄明液体。 ①.The reagent M is a brown brown suspension,after a long time,the brown brown magentic beads are deposited on the bottom,and the supernatant liquid should be clear liquid; ②.Reagent R1 is a colorless clear liquid; ③.Reagent R2 is a colorless clear liquid; ④.The calibration and quality control should be colorless clear liquid.		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	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:	4.80%	合格
			Q2:	-3.90%	
			准确性样本1 Accuracy1:	-2.09%	Pass
			准确性样本2 Accuracy2:	-9.44%	
4	重复性 Repeatability	CV≤8%	低值 Low-level:	2.57%	合格
			高值 High-level:	3.59%	Pass
5	线性范围 Linearity range	0.01~10 μg/mL内，r≥0.990 Within the range of 0.01~10 μg/mL, the correlation coefficient (r) should be ≥ 0.990.		结果 Result: r=	0.9979 合格 Pass
结论 Conclusion		合格 Pass			
检验员 Inspector		钟宗崇	复核人 Reviewer	高曼姿	
日期 Date		2025.05.26	日期 Date	2025.05.26	

注：若无内容填写应用“/”。
Note:If there is no information, please fill with“/”.