

检验报告
Certificate of Analysis

No. COA20250401022

产品名称 Product Name	丙型肝炎病毒抗体检测试剂盒(化学发光免疫分析法) Antibody to hepatitis C virus(CLIA)	REF	N/A
批号 Lot No.	2024120113	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005672-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2025-03-19	有效期 Expiry date	2026-03-18
标准依据 Standard basis	产品检验规范 Specification for Product Inspection		

检测项目 Subjects	接受标准 Accept criteria	检测结果 Results	结果判定 Conclusion
1、外观性状 Appearance	试剂盒各组分齐全、完整、液体无渗漏；包装标签清晰、无破损； Ra试剂为棕色含固体微粒的液体，无板结、无絮状物； Rb、Rc、Rd试剂为清澈透明的液体，无沉淀、无悬浮物、无絮状物 Reagent Componets are complete, no leakage. Packing label is clear, accurate and firm. Ra: Brown liquid free of aggregates and floccules after re-suspension of microparticles. Rb、Rc and Rd: Clear liquid free of particulate matters and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume			
	Rb≥3.5mL	3.7 mL	
装量 Volume	Rd≥3.5mL	3.7 mL	符合/Pass
	Ra≥3.8mL	4.0 mL	



Rc≥6.0mL
8.2 mL

3、性能
Performance

	L1应检出阳性 L1: Positive	L1: 阳性, Positive	
灵敏度参考品 Analysis Sensitivity Reference Material	L2应检出阳性 L2: Positive	L2: 阳性, Positive	符合/Pass
	L3应检出阴性或阳性 L3: Positive or Negative	L3: 阳性, Positive	
	L4应检出阴性 L4: Negative;	L4: 阴性, Negative;	
重复性 Repeatability	CV≤ 6% CV should be ≤6%	N:5%	符合/Pass
	CV≤ 6% CV should be ≤6%	P:2%	
阳性参考品符合率 Positive reference rate	30份阳性参考品符合率 (+/+) ≥ 29/30 Positive Reference Material Coincidence Rate (+/+) : 29/30	30/30	符合/Pass
阴性参考品符合率 Negative reference rate	30份阴性参考品符合率 (-/-) ≥29/30 Negative Reference Material Coincidence Rate (-/-) : 29/30	30/30	符合/Pass

结论
Summary
合格/PASS



备注
Remarks

检验： Analysis	邓月Deng Yue		批准（检验工程师）： Approved by(Quality Engineer)	林朋Lin Peng	
日期： Date	2025-04-01		日期： Date	2025-04-01	

