

检验报告  
Certificate of Analysis

No. COA20250414054

产品名称 Product Name	丙型肝炎病毒抗体校准品 Anti-HCV Calibrators	REF	N/A
批号 Lot No.	2025030111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005923-00	包装规格 Package Size	C0:1×2.0 mL, C1:1×2.0 mL
生产日期 Manufacture Date	2025-04-12	有效期 Expiry date	2026-04-11
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	校准品为清澈透明液体，无沉淀、无悬浮物、无絮状物；分装瓶为白色塑料瓶，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书、校准卡完整、清晰牢固；标贴信息正确、完整；塑料外盖与塑料瓶身配合后无泄漏；塑料外盖无明显划痕、崩缺。 The calibrators are clear liquid without precipitate, suspension and floccules. The containers are white plastic bottles with tightly closed caps; The whole package, including labels for boxes and bottles, pack inserts and calibration cards, is complete and clear; The content of labels is correct and complete. The containers are without leakage and obvious defect or breakdown.	符合标准/Qualified	符合/Pass
2、装量 Volume	C0≥2.0mL	2.1 mL	
装量 Volume	C1≥2.0mL	2.1 mL	符合/Pass
3、性能 Performance	CL-8000i机型	CL-8000i机型	

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准确度 Accuracy	校准品C0的COI值与标定值绝对偏差应在±0.1范围内 The absolute deviation of Calibrator C0 is less than ±0.1.	CO:0.0	符合/Pass
	校准品C1的COI值与标定值相对偏差应在±10.0%范围内。 The relative deviation of Calibrator C1 is less than ±10.0%.	C1:-4.5%	
	通用机型	通用机型	
	校准品C0的COI值与标定值绝对偏差应在±0.1范围内 The absolute deviation of Calibrator C0 is less than ±0.1.	CO:0.0	
瓶内均一性 Uniformity in bottle	校准品C1的COI值与标定值相对偏差应在±10.0%范围内。 The relative deviation of Calibrator C1 is less than ±10.0%.	C1:2.6%	符合/Pass
	SD≤0.08 SD≤0.08	CO:0.00	
	CV≤8.0% CV≤8.0%	C1:2.4%	
生物安全性 Biosafety	校准品的乙型肝炎病毒表面抗原、人类免疫缺陷病毒抗体（HIV-I型和HIV-II型）、梅毒螺旋体抗体检测结果均为阴性。 The calibrators are free from Hepatitis B Surface Antigen (HBsAg), Treponema Pallidum (TP) , and antibody to HIV-1/HIV-2 by using the CE-marked or equivalent method.	阴性/Negative	符合/Pass

结论  
Summary合格/PASS

备注  
Remarks

检验：  
Analysis

袁丽娜Yuan Lina



批准（检验工程师）：  
Approved by(Quality Engineer)

林朋Lin Peng



日期：  
Date

2025-04-14

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