

检验报告
Certificate of Analysis

No. COA20250425041

产品名称 Product Name	降钙素原质控品 PCT Control (L)	REF	N/A
批号 Lot No.	2025040111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-010228-00	包装规格 Package Size	3×2.0 mL
生产日期 Manufacture Date	2025-04-24	有效期 Expiry date	2026-10-23
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	质控品为清澈透明液体，无沉淀、无悬浮物、无絮状物；分装容器为透明塑料管，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书、质控卡、参考值表完整、清晰牢固。塑料外盖与塑料管身配合后无泄漏；塑料外盖无明显划痕、崩缺。 The controls are clear liquid without precipitate, suspension and floccules. The containers are lucite pipe with tightly closed caps. The labels, introduction, control card, reference table are complete and clear. The containers are without leakage and obvious defect or breakdown.	符合标准/Qualified	符合/Pass
2、装量 Volume			
装量 Volume	≥2.0mL	2.0; 2.0; 2.0	符合/Pass
3、性能 Performance			
通用机型		通用机型	
准确度 Accuracy	每次测定结果应在给定的参考范围内。 Each determination results in the reference range in a given.	0.450 ;0.440 ;0.440	符合/Pass
	CL-8000i机型	CL-8000i机型	



每次测定结果应在给定的参考范围内。
Each determination results in the reference range in a given. 0.497 ;0.504 ;0.511

瓶内均一性
Uniformity in bottle CV≤8.0% 2.3% 符合/Pass

质控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）、丙型肝炎病毒抗体、梅毒螺旋体抗体检测结果均为阴性。

生物安全性
Biosafety The controls are free from Hepatitis B Surface Antigen (HBsAg), Treponema Pallidum (TP) , antibody to Hepatitis C (HCV), 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：袁丽娜Yuan Lina 袁丽娜 Yuanlina 批准（检验工程师）：胡凤Hu Feng 胡凤 HuFeng
Analysis Approved by(Quality Engineer)
日期：2025-04-25 日期：2025-04-25
Date Date

