

检验报告  
Certificate of Analysis

No. COA20250412002

产品名称 Product Name	降钙素原校准品 PCT Calibrators	REF	N/A
批号 Lot No.	2025030111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-010219-00	包装规格 Package Size	C0:1×1.2 mL, C1:1×1.0 mL, C2:1×1.0 mL
生产日期 Manufacture Date	2025-04-10	有效期 Expiry date	2026-10-09
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；C0为白色外盖，C1为黄色外盖，C2为红色外盖；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; C0 is white cap, C1 is yellow cap, C2 is red cap; 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			
	C1≥1.0mL	1.1 mL	
装量 Volume			符合/Pass
	C2≥1.0mL	1.1 mL	

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CO≥1.2mL  
1.3 mL

3、性能  
Performance

SD≤0.016 ng/mL  
SD≤0.016 ng/mL  
CO:0.001 ng/mL

瓶内均一性  
Uniformity in bottle  
CV≤ 8.0%  
CV≤ 8.0%  
C1:2.5%  
符合/Pass

CV≤ 8.0%  
CV≤ 8.0%  
C2:0.5%

生物安全性  
Biosafety  
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。  
The calibrators 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

通用机型  
通用机型

偏倚在±10.0%范围内  
The Bias of Trueness Control Sample is H:1.2%  
less than ±10.0%.  
赋值准确性  
Accuracy  
符合/Pass

偏倚在±10.0%范围内  
The Bias of Trueness Control Sample is L:-0.8%  
less than ±10.0%.

CL-8000i机型  
CL-8000i机型

偏倚在±10.0%范围内  
The Bias of Trueness Control Sample is H:-2.3%  
less than ±10.0%.

偏倚在±10.0%范围内  
The Bias of Trueness Control Sample is L:-0.5%  
less than ±10.0%.



结论  
Summary

合格/PASS

备注  
Remarks

检验： Analysis	陈素兰Chen Sulan	陈素兰 ChenSulan	批准（检验工程师）： Approved by(Quality Engineer)	林朋Lin Peng	林朋 LinPeng
日期： Date	2025-04-11		日期： Date	2025-04-12	

