

检验报告
Certificate of Analysis

No. COA20250322039

产品名称 Product Name	甲状旁腺素校准品 PTH Calibrators	REF	N/A
批号 Lot No.	2025030111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-008553-00	包装规格 Package Size	C0:1×2.0 mL, C1:1×2.0 mL, C2:1×2.0 mL
生产日期 Manufacture Date	2025-03-21	有效期 Expiry date	2026-03-20
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	<p>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、校准卡完整、清晰牢固；盒中不含说明书，盒贴上印有 only for local production字句；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。</p> <p>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, and calibration cards, is complete and clear; No instructions in the box and there is "only for local production" on the box label. The content of labels is correct and complete. The containers are without leakage and obvious defect or breakdown.</p>	符合标准/Qualified	符合/Pass
2、装量 Volume			
	C0≥2.0mL	2.1 mL	
装量 Volume			符合/Pass
	C1≥2.0mL	2.1 mL	



C2≥2.0mL
2.1 mL

3、性能
Performance

SD≤1.00 pg/mL
SD≤1.00 pg/mL
C0:0.12 pg/mL

瓶内均一性
Uniformity in bottle
CV≤8.0%
CV≤8.0%
C1:3.1%
符合/Pass

CV≤8.0%
CV≤8.0%
C2:1.2%

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

赋值准确性
Accuracy
偏倚在±10.0%范围内。
The Bias of Trueness Control Sample is H:-4.1% less than ±10.0%.
符合/Pass
偏倚在±10.0%范围内。
The Bias of Trueness Control Sample is L:-1.2% less than ±10.0%.

结论
Summary
合格/PASS

备注
Remarks

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Analysis Approved by(Quality Engineer)
日期：2025-03-22 日期：2025-03-22
Date Date

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