

检验报告
Certificate of Analysis

No. COA20250319002

产品名称 Product Name	总25-羟基维生素D校准品 25-OH-Vitamin D Total Calibrators	REF	N/A
批号 Lot No.	2025020111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-008549-00	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	2025-03-16	有效期 Expiry date	2026-03-15
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			
外观和性状 Appearance			
装量 Volume	C0≥2.0mL	2.0 mL	符合/Pass
	C1≥2.0mL	2.0 mL	



C2≥2.0mL
2.0 mL

3、性能
Performance

SD≤3.00 ng/mL
SD≤3.00 ng/mL
C0:0.24 ng/mL

瓶内均一性
Uniformity in bottle
CV≤8.0%
CV≤8.0%
C1:2.1%
符合/Pass

CV≤8.0%
CV≤8.0%
C2:1.5%

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

偏倚在±10.0%范围内。
The Bias of Trueness Control Sample is VD-T II-H:-0.7% less than ±10.0%.

偏倚在±10.0%范围内。
The Bias of Trueness Control Sample is VD-T II-L:-2.7% 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 VD-T-H:-2.1% less than ±10.0%.

偏倚在±10.0%范围内。
The Bias of Trueness Control Sample is VD-T-L:4.9% less than ±10.0%.

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	2025-03-18	日期： Date	2025-03-19

