

检 验 报 告  
Certificate of Analysis

No. COA20250211034

产品名称 Product Name	垂体泌乳素校准品 Prolactin Calibrators	REF	N/A
批号 Lot No.	2024120111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004293-00	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	2025-02-10	有效期 Expiry date	2026-02-09
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；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 package, including the labels, introduction, calibration card are 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			
装量 Volume	C0≥2.0mL	2.1 mL	符合/Pass
	C1≥2.0mL	2.1 mL	



C2≥2.0mL  
2.1 mL

3、性能  
Performance

CV≤8%或SD≤0.4 ng/mL  
CV≤8% or SD≤0.4 ng/mL  
C0:CV:162%;SD:0.0

瓶内均一性  
Uniformity in bottle  
CV≤8%或SD≤0.4 ng/mL  
CV≤8% or SD≤0.4 ng/mL  
C1:CV:1%;SD:0.1  
符合/Pass

CV≤8%或SD≤0.4 ng/mL  
CV≤8% or SD≤0.4 ng/mL  
C2:CV:1%;SD:1.0

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), antibody to HIV-1/HIV-2, antibody to Hepatitis C (HCV), and Treponema Pallidum (TP) by using the CE-marked or equivalent method.  
阴性/Negative  
符合/Pass

赋值准确性  
Accuracy  
偏倚应在±9.6%范围内  
The bias of trueness control sample is H:2.6% less than ±9.6%.  
符合/Pass  
偏倚应在±9.6%范围内  
The bias of trueness control sample is L:1.9% less than ±9.6%.

结论  
Summary  
合格/PASS

备注  
Remarks

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Analysis Approved by(Quality Engineer)  
日期：2025-02-11 日期：2025-02-11  
Date Date

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