

检验报告  
Certificate of Analysis

No. COA20250429039

|                          |   |                            |                                       |
|--------------------------|---|----------------------------|---------------------------------------|
| 产品名称<br>Product Name     | 促黄体生成素校准品<br>LH Calibrators                 | REF                        | N/A                                   |
| 批号<br>Lot No.            | 2025040111                                  | 型号<br>Model of the Reagent | N/A                                   |
| 物料编码<br>Material Code    | 105-004292-00                               | 包装规格<br>Package Size       | C0:1×2.0 mL, C1:1×2.0 mL, C2:1×2.0 mL |
| 生产日期<br>Manufacture Date | 2025-04-28                                  | 有效期<br>Expiry date         | 2026-10-27                            |
| 标准依据<br>Standard basis   | 产品检验规范 Specification for Product Inspection |                            |                                       |

| 检测项目<br>Subjects     | 接受标准<br>Accept criteria  | 检测结果<br>Results | 结果判定<br>Conclusion |
|----------------------|--|-----------------|--------------------|
| 1、外观性状<br>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。<br>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<br>Volume       |  |                 |                    |
|                      | C0≥2.0mL   | 2.1 mL          |                    |
| 装量<br>Volume         |  |                 | 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 mIU/mL  
CV≤8% or SD≤0.4 mIU/mL  
C0:CV:211%;SD:0.0

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

CV≤8%或SD≤0.4 mIU/mL  
CV≤8% or SD≤0.4 mIU/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±10.9%范围内  
The bias of trueness control sample is H:1.7% less than ±10.9%.

偏倚应在±10.9%范围内  
The bias of trueness control sample is L:2.9% less than ±10.9%.

结论  
Summary  
合格/PASS

备注  
Remarks

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Analysis Approved by(Quality Engineer)  
日期：2025-04-29 日期：2025-04-29  
Date Date

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