

检验报告  
Certificate of Analysis

No. COA20250104003

产品名称 Product Name	促卵泡生成素 (FSH) 测定试剂盒 (化学发光免疫分析法) Follicle Stimulating Hormone (CLIA)	REF	N/A
批号 Lot No.	2024110111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004222-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2025-01-03	有效期 Expiry date	2026-07-02
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	试剂盒各组分齐全、完整、液体无渗漏； 包装标签清晰、准确、牢固； Ra组分为棕色含固体微粒的液体，无板结、无絮状物； Rb组分为清澈透明的液体，无沉淀、无悬浮物、无絮状物； Reagent Componets are complete, no leakage. Packing label is clear, accurate and firm. Ra: Brown liquid free of aggregates and floccules after re-suspension of microparticles. Rb : Clear liquid free of particulate matters and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume	Rb≥3.5mL	3.7 mL	
装量 Volume	Ra≥3.8mL	4.0 mL	符合/Pass
3、性能 Performance			
准确度 Accuracy	相对偏差在±10%范围内 Relative deviation is in the range of ±10%.	H:7%	符合/Pass

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相对偏差在±10%范围内  
Relative deviation is in the range of   L:6%  
±10%.

最低检测限  
Limit of  
Detection

最低检测限应≤ 0.2 mIU/mL  
The Limit of detection is≤0.2 mIU/mL.

0.0 mIU/mL

符合/Pass

线性  
Linearity

试剂盒在1.0mIU/ml~200mIU/ml区间内，其相  
关系数r应不低于0.9900  
Within the range of 1.0 mIU/mL-200 mI  
U/mL, the correlation coefficient r is  
≥0.9900.

0.9975

符合/Pass

重复性  
Repeatability

变异系数CV应≤10%  
The coefficient of variation is ≤10%  
.  
H:2%

变异系数CV应≤10%  
The coefficient of variation is ≤10%  
.  
L:1%

符合/Pass

结论  
Summary

合格/PASS

备注  
Remarks

检验：  
Analysis

黄凯芹Huang  
Kaiqin



批准（检验工程师）：  
Approved by(Quality Engineer)

林朋Lin Peng



日期：  
Date

2025-01-04

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