

N/A

N/A

 2×50 tests

2026-07-02

检验报告 Certificate of Analysis

No. COA20250104003

促卵泡生成素 (FSH) 测定试剂盒 (化学发光免疫 产品名称

分析法) **Product Name**

Follicle Stimulating Hormone (CLIA)

批号 찍목

2024110111 Lot No.

物料编码 105-004222-00 **Material Code**

生产日期

标准依据

Standard basis

Manufacture 2025-01-03

Date

产品检验规范 Specification for Product Inspection

Model of the Reagent

检测项目 接受标准 检测结果 结果判定 Subjects Accept criteria Results **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 Rb组分为清澈透明的液体,无沉淀、无悬浮物、 无絮状物; 外观和性状 符合标准/Qualified 符合/Pass

REF

包装规格

有效期

Package Size

Expiry date

Reagent Componets are complete, no Appearance 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.

2、装量 Volume

Rb≥3.5mL

3.7 mL

装量 符合/Pass Volume

> Ra≥3.8mL 4.0 mL

3、性能 Performance

相对偏差在±10%范围内

准确度 Relative deviation is in the range of H:7%

Accuracy $\pm 10\%$. 符合/Pass

深圳迈瑞生物医疗电子股份有限公司

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相对偏差在±10%范围内

Relative deviation is in the range of L:6%

 $\pm 10\%.$

最低检测限

最低检测限应≤ 0.2 mIU/mL

Limit of Detection

The Limit of detection is≤0.2 mIU/mL.

0.0 mIU/mL

符合/Pass

试剂盒在1.0mIU/m1~200mIU/m1区间内,其相

线性

Linearity

关系数r应不低于0.9900

Within the range of 1.0 mIU/mL-200 mI 0.9975U/mL, the correlation coefficient r is

符合/Pass

≥0.9900.

变异系数CV应≤10%

The coefficient of variation is $\leq 10\%$ H:2%

重复性

Repeatability

符合/Pass

变异系数CV应≤10%

The coefficient of variation is $\leq 10\%$ L:1%

结论

Summary

合格/PASS

备注

Remarks

检验: 黄凯芹Huang

Analysis

Kaiqin

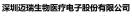
日期:

2025-01-04 Date

林朋 lingeng

日期: Date

2025-01-04



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