

检验报告
Certificate of Analysis

No. COA20241114051

产品名称 Product Name	雌三醇(E3)测定试剂盒(化学发光免疫分析法) Estradiol (CLIA)	REF	N/A
批号 Lot No.	2024100111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004226-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2024-11-13	有效期 Expiry date	2026-05-12
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试剂为棕色含固体微粒的液体，无板结、无絮状物； Rb、Rc试剂为清澈透明的液体，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、Rc : Clear liquid free of particulate matters and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume	Rb≥3.5mL	3.8 mL	
装量 Volume	Rc≥3.5mL	3.8 mL	符合/Pass
	Ra≥3.8mL	4.1 mL	
3、性能 Performance			

深圳迈瑞生物医疗电子股份有限公司

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准确度 Accuracy	相对偏差在±10%范围内 Relative deviation is in the range of H:-4% ±10%.			符合/Pass
	相对偏差在±10%范围内 Relative deviation is in the range of L:-3% ±10%.			
最低检测限 Limit of Detection	最低检测限应≤0.1 ng/mL The Limit of detection is≤ 0.1 ng/mL. 0.0 ng/mL			符合/Pass
	在0.2 ng/ml~20 ng/ml范围内，其相关系数r 应 ≥0.9900 Within the range of 0.2 ng/mL-20 ng/m 0.9932 L, the correlation coefficient r is ≥ 0.9900.			
线性 Linearity	变异系数CV应≤10% The coefficient of variation is ≤10% H:1% .			符合/Pass
	变异系数CV应≤10% The coefficient of variation is ≤10% L:2% .			
重复性 Repeatability				符合/Pass

结论
Summary

合格/PASS

备注
Remarks

检验：
Analysis

袁丽娜Yuan Lina

 Yuanlina

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

林朋Lin Peng

 Linpeng

日期：
Date

2024-11-14

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