

检验报告  
Certificate of Analysis

No. COA20250326009

产品名称 Product Name	垂体泌乳素(PRL)测定试剂盒(化学发光免疫分析法) Prolactin (CLIA)	REF	N/A
批号 Lot No.	2024080112	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004224-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2024-10-26	有效期 Expiry date	2026-04-25

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 : 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:1%	符合/Pass

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相对偏差在±10%范围内  
Relative deviation is in the range of L:-1%  
±10%.

最低检测限  
Limit of  
Detection  
最低检测限应≤ 0.47 ng/mL  
The Limit of detection is≤0.47 ng/mL. 0.01 ng/mL  
符合/Pass

线性  
Linearity  
在0.94 ng/ml~200 ng/ml范围内，其相关系数  
r应 ≥0.9900  
Within the range of 0.94 ng/mL-200 ng/  
mL, the correlation coefficient r is  
≥0.9900. 0.9999  
符合/Pass

重复性  
Repeatability  
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:1%  
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结论  
Summary  
合格/PASS

备注  
Remarks

检验 : 邓月Deng Yue 邓月 Deng Yue  
Analysis  
日期 : 2025-03-26  
Date  
批准 ( 检验工程师 ) : 林朋Lin Peng 林朋 LinPeng  
Approved by(Quality Engineer)  
日期 : 2025-03-26  
Date

