

检验报告
Certificate of Analysis

No. COA20250312016

产品名称 Product Name	总前列腺特异性抗原(t-PSA)测定试剂盒(化学发光免疫分析法) Total Prostate Specific Antigen (CLIA)	REF	N/A
批号 Lot No.	2025010112	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004219-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2025-03-06	有效期 Expiry date	2026-09-05
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±10.0%范围内 Relative deviation is in the range of ±10.0%.	H:-0.3%	符合/Pass

深圳迈瑞生物医疗电子股份有限公司
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD.
地址：深圳市南山区高新技术产业园科技南十二路迈瑞大厦 邮编：518057 电话：0755-8188 8998 传真：0755-26582680
Adress: Mindray Building, Keji 12th Road South, High-Tech Industrial Park,Nanshan, Shenzhen, 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680 Website: www.mindray.com



相对偏差在±10.0%范围内
Relative deviation is in the range of L:1.2%
±10.0%.

最低检测限 Limit of Detection	最低检测限应≤ 0.008 ng/mL The Limit of detection is≤0.008ng/mL.	0.000 ng/mL	符合/Pass
--------------------------------	--------------------------------------------------------------	-------------	---------

线性 Linearity	在0.016ng/mL~100ng/mL范围内，其相关系数r 应 ≥0.9900 Within the range of 0.016 ng/mL-100 n 0.9998 g/mL, the correlation coefficient r is ≥0.9900.		符合/Pass
-----------------	-----------------------------------------------------------------------------------------------------------------------------------------------------	--	---------

重复性 Repeatability	变异系数CV应≤10.0% The coefficient of variation is ≤10. H:0.9% 0%.		符合/Pass
	变异系数CV应≤10.0% The coefficient of variation is ≤10. L:0.9% 0%.		

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	2025-03-12	日期： Date	2025-03-12

