

检验报告  
Certificate of Analysis

No. COA20250412063

产品名称 Product Name	心肌标志物复合定值质控品 Cardiac Marker Multi Control (L)	REF	N/A
批号 Lot No.	2025030101	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005941-00	包装规格 Package Size	3×2.0 mL
生产日期 Manufacture Date	2025-04-11	有效期 Expiry date	2026-10-10
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	<p>质控品复融前外观呈现粉末块状固体，不起泡，不塌陷，复融后为清澈透明液体，无沉淀、无悬浮物、无絮状物。</p> <p>分装瓶为棕色玻璃瓶，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书、参考值表完整、清晰、牢固；包装标贴上的信息完整、准确。塑料外盖与玻璃瓶身配合后无泄漏；塑料外盖无明显划痕、崩缺。</p> <p>The controls are solid power without bubble or collapse before dissolved. And are clear liquid free of precipitate, suspension and floccules after dissolved. The containers are brownish glass bottles with tightly closed caps; The package, including the labels, introduction, reference table are complete and clear. The content of labels is correct and complete. The containers are without leakage and obvious defect or breakdown.</p>	符合标准/Qualified	符合/Pass
3、性能 Performance	通用机型	通用机型	
准确度 Accuracy	<p>每次测定结果应在给定的参考范围内。</p> <p>Each determination results in the reference range in a given.</p>	BNP:74.490 ;72.400 ;72.900	符合/Pass
	<p>每次测定结果应在给定的参考范围内。</p> <p>Each determination results in the reference range in a given.</p>	CK-MB:6.530 ;6.250 ;7.370	

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区科技南十二路迈瑞大厦 邮编：518057 电话：0755-8188 8998 传真：0755-26582680  
Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China  
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	每次测定结果应在给定的参考范围内。 Each determination results in the reference range in a given.	MYO:36.780 ;39.080 ;38.650	
	每次测定结果应在给定的参考范围内。 Each determination results in the reference range in a given.	TnI:0.440 ;0.440 ;0.460	
	CL-8000i机型	CL-8000i机型	
	每次测定结果应在给定的参考范围内。 Each determination results in the reference range in a given.	TnI:0.433 ;0.424 ;0.442	
	CV≤8.0% CV≤8.0%	BNP:0.8%	
瓶内均一性 Uniformity in bottle	CV≤8.0% CV≤8.0%	CK-MB:1.7%	符合/Pass
	CV≤8.0% CV≤8.0%	MYO:1.6%	
	CV≤8.0% CV≤8.0%	TnI:3.6%	
质控参考值表 Quality Control Target Value Sheet	质控品可提供一份参考值表，包含适用型号的迈瑞化学发光免疫分析系统的检测项目参考值及参考范围。 quality control should provide target value sheet, including the control values (the target value and range) of detecting items for applied model of Mindray CL-series Chemiluminescence Immunoassay Analyzer.	符合标准/Qualified	符合/Pass
结论 Summary	合格/PASS		
备注 Remarks			



**检验：**  
**Analysis**

袁丽娜Yuan Lina

*袁丽娜 Yuanlina*

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

林朋Lin Peng

*林朋 LinPeng*

**日期：**  
**Date**

2025-04-12

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