

检 验 报 告  
Certificate of Analysis

No. COA20250311060

产品名称 Product Name	多项免疫复合定值质控品 Immunoassay Multi Control (H)	REF	N/A
批号 Lot No.	2025020111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005944-00	包装规格 Package Size	3×2.0 mL
生产日期 Manufacture Date	2025-03-10	有效期 Expiry date	2026-03-09
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	质控品为清澈透明液体，无沉淀、无悬浮物、无絮状物。 分装瓶为透明塑料管，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；标贴信息正确、完整。塑料外盖与塑料管身配合后无泄漏；塑料外盖无明显划痕、崩缺。  The controls are clear liquid without precipitate, suspension and floccules. The containers are lucite plastic bottles with tightly closed caps. 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.	符合标准/Qualified	符合/Pass
2、装量 Volume			
装量 Volume	≥2.0mL	2.0; 2.0; 2.0	符合/Pass
3、性能 Performance			
准确度 Accuracy	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.	Cortisol:20.611 ;20.202 ;20.922	符合/Pass



	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.	C-Peptide:9.145 ;9.017 ;8. 862	
	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.	DHEA-S:538.892 ;540.082 ;54 6.100	
	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.	Insulin:92.135 ;89.078 ;87. 781	
	CV≤8.0% CV≤8.0%	Cortisol:2.6%	
	CV≤8.0% CV≤8.0%	C-Peptide:1.2%	
瓶内均一性 Uniformity in bottle			符合/Pass
	CV≤8.0% CV≤8.0%	DHEA-S:0.9%	
	CV≤8.0% CV≤8.0%	Insulin:2.0%	
	质控品的乙型肝炎病毒表面抗原、人类免疫缺陷 病毒抗体（HIV-I型和HIV-II型）、丙型肝炎病 毒抗体、梅毒螺旋体抗体检测结果均为阴性。		
生物安全性 Biosafety	The controls are free from Hepatitis B Surface Antigen (HBsAg), Treponema Pallidum (TP) , antibody to Hepatitis C (HCV), and antibody to HIV-1/HIV-2 by using the CE-marked or equivalent method.	阴性/Negative	符合/Pass
	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。		
质控参考值表 Quality Control Target Value Sheet	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	邓月Deng Yue		批准（检验工程师）： Approved by(Quality Engineer)	林朋Lin Peng	
日期： Date	2025-03-11		日期： Date	2025-03-11	

