

检验报告
Certificate of Analysis

No. COA20241128060

产品名称 Product Name	甲状腺相关自身抗体质控品 Anti-thyroid Antibodies Control (L)	REF	N/A
批号 Lot No.	2024100111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005931-00	包装规格 Package Size	3×2.0 mL
生产日期 Manufacture Date	2024-11-27	有效期 Expiry date	2026-05-26
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；分装容器为透明塑料管，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书、质控卡、参考值表完整、清晰牢固。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 pipe with tightly closed caps. The labels, introduction, control card, reference table are complete and clear. 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.	Anti-Tg:22.175 ;22.453 ;21.801	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.

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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.	Anti-TP0:5.019 ;5.073 ;5.280	
瓶内均一性 Uniformity in bottle	质控品均一性变异系数CV≤8.0% CV≤8.0%	Anti-Tg:2.0%	符合/Pass
	质控品均一性变异系数CV≤8.0% CV≤8.0%	Anti-TP0:1.0%	
生物安全性 Biosafety	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。 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
质控参考值表 Quality Control Target Value Sheet	质控品应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 can 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	李冠林Li GuanLin 李冠林 Li Guanlin	批准（检验工程师）： Approved by(Quality Engineer)	胡凤Hu Feng 胡凤 HuFeng
日期： Date	2024-11-28	日期： Date	2024-11-28

