

检验报告  
Certificate of Analysis

No. COA20240816088

产品名称 Product Name	糖类抗原CA19-9校准品 CA19-9 Calibrators	REF	N/A
批号 Lot No.	2024070111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004286-00	包装规格 Package Size	C0:1×2.0 mL, C1:1×2.0 mL, C2:1×2.0 mL
生产日期 Manufacture Date	2024-08-15	有效期 Expiry date	2026-02-14
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	校准品为清澈透明液体，无沉淀、无悬浮物、无絮状物。分装瓶为白色塑料瓶，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书、校准卡完整、清晰牢固。塑料外盖与塑料瓶身配合无泄露；塑料外盖无明显划痕、崩缺。 The calibrators are clear liquid without precipitate, suspension and floccules. The containers are white plastic bottles with tightly closed caps;The package, including the labels, introduction, calibration card 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			
	C0≥2.0mL	2.1 mL	
装量 Volume	C1≥2.0mL	2.1 mL	符合/Pass
	C2≥2.0mL	2.1 mL	

## 深圳迈瑞生物医疗电子股份有限公司

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3、性能  
Performance

	C0≤3.0U/mL Calibrator C0 is ≤3.0 U/mL.	C0:0.0 U/mL	
准确度 Accuracy	C1的相对偏差应在±7.0%范围内。 The relative deviation of C1 is in the range of ± 7.0%.	C1:2.8%	符合/Pass
	C2的相对偏差应在±7.0%范围内。 The relative deviation of C2 is in the range of ± 7.0%.	C2:1.5%	
瓶内均一性 Uniformity in bottle	CV≤10.0% The CV of C1 is ≤10.0%	C1:1.3%	符合/Pass
	CV≤10.0% The CV of C2 is ≤10.0%	C2:1.5%	
生物安全性 Biosafety	校准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 calibrators are free from Hepatitis B Surface Antigen (HBsAg), antibody to HIV-1/HIV-2, antibody to Hepatitis C (HCV), and Treponema Pallidum (TP) by using the CE-marked or equivalent method.	阴性/Negative	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	2024-08-16		日期： Date	2024-08-16	

