

检验报告  
Certificate of Analysis

No. COA20241112028

产品名称 Product Name	乙型肝炎病毒表面抗体校准品 Anti-HBs Calibrators	REF	N/A
批号 Lot No.	2024090111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004299-00	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	2024-11-11	有效期 Expiry date	2026-05-10
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	校准品各组分齐全、完整、液体无渗漏；包装标签清晰，无破损；校准品为清澈透明液体，无沉淀、无悬浮物、无絮状物。 All components are involved and complete. The calibrator containers is without leakage. The package labels are clear and without breakage. The calibrators are clear liquid without precipitate, suspension and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume			
	C0≥2.0mL	2.0 mL	
装量 Volume	C1≥2.0mL	2.0 mL	符合/Pass
	C2≥2.0mL	2.0 mL	
3、性能 Performance			

## 深圳迈瑞生物医疗电子股份有限公司

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	校准品C0的绝对偏差在±2.0mIU/mL范围内 The absolute deviation of Calibrator C0 should be less than ±2.0mIU/mL. C0:0.6 mIU/mL		
准确度 Accuracy	校准品C1的相对偏差在±15%范围内 The relative deviation C1 should be in the range of ± 15%. C1:0%		
	校准品C2的相对偏差在±15%范围内 The relative deviation C2 should be in the range of ± 15%. C2:0%		
	SD≤2.0mIU/mL SD≤2.0mIU/mL C0:0.1 mIU/mL		
瓶内均一性 Uniformity in bottle	CV≤10% CV≤10% C1:1%		
	CV≤10% CV≤10% C2:1%		
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		

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	2024-11-12		日期： Date	2024-11-12	

