

检验报告  
Certificate of Analysis

No. COA20250403125

产品名称 Product Name	乙型肝炎病毒表面抗原质控品(阴性) HBsAg Negative Control	REF	N/A
批号 Lot No.	2025020111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005181-00	包装规格 Package Size	3×2.0 mL
生产日期 Manufacture Date	2025-03-25	有效期 Expiry date	2026-09-24
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	质控品各组分齐全、完整、液体无渗漏；包装标签清晰，无破损；质控品为清澈透明液体，无沉淀、无悬浮物、无絮状物。 All components are involved and complete. The control containers is without leakage. The package labels are clear and without breakage. The control are clear liquid without precipitate, suspension and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume			
装量 Volume	≥2.0mL	2.1; 2.1; 2.1	符合/Pass
3、性能 Performance			
准确度 Accuracy	通用机型 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.	通用机型 0.000 ;0.000 ;0.001	符合/Pass
	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.	CL-8000i机型 0.002 ;0.000 ;0.003	

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瓶内均一性 Uniformity in bottle	SD≤0.02 IU/mL SD≤0.02 IU/mL	0.00 IU/mL	符合/Pass
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生物安全性 Biosafety	质控品的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 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
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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
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结论 Summary	合格/PASS
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备注  
Remarks

检验： Analysis	陈素兰Chen Sulan	陈素兰 ChenSulan	批准（检验工程师）： Approved by(Quality Engineer)	林朋Lin Peng	林朋 Linpeng
日期： Date	2025-04-03		日期： Date	2025-04-03	

