

检验报告 Certificate of Analysis

No. COA20250123049

产品名称乙型肝炎病毒表面抗体质控品(阳性)REFProduct NameAnti-HBs Positive Control

批号 型号 No. 4 No. 4

Lot No. Model of the Reagent 物料编码

 Material Code
 105-005184-00
 Package Size
 3×2.0 mL

 生产日期
 有效期

 Manufacture
 2025-01-21
 Expiry date

标准依据 Standard basis 产品检验规范 Specification for Product Inspection

检测项目 检测结果 结果判定 接受标准 Subjects Conclusion Accept criteria Results 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 外观和性状 符合标准/Qualified 符合/Pass without leakage. The package labels Appearance are clear and without breakage. The control are clear liquid without precipitate, suspension and floccules. 2、装量 Volume ≥2.0mL 装量 符合/Pass 2.0; 2.0; 2.0 Volume 3、性能 Performance 每次测定结果应在给定的参考范围内。 准确度 Each determination results in the 21.897 ;22.561 ;21.750 符合/Pass Accuracy reference range in a given. 瓶内均一性 CV≤10% 符合/Pass Uniformity in CV≤10% bottle

深圳迈瑞生物医疗电子股份有限公司

Date

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
地址: 深圳市南山区高新技术产业园区科技南十二路迈瑞大厦 邮编: 518057 电话: 0755-8188 8998 传真: 0755-26582680
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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-2by using the CE-marked or equivalent

method.

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。

质控参考值表 Target Value Sheet

Quality control can provide target Quality Control value sheet, including the control values (the target value and range) of detecting items for applied model of

Mindray CL-series Chemiluminescence

Immunoassay Analyzer.

阴性/Negative 符合/Pass

符合标准/Qualified

符合/Pass

结论 **Summary**

合格/PASS

备注 Remarks

检验: **Analysis**

陈素兰Chen Sulan

陈素兰 Charlian

批准(检验工程师):

Approved by(Quality Engineer) 林朋Lin Peng

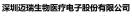
林朋 Lingeng

日期: Date

2025-01-23

Date

2025-01-23



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