

## 检验报告 Certificate of Analysis

No. COA20241022004

 产品名称
 乙型肝炎病毒核心抗体校准品
 REF

 Product Name
 Anti-HBc Calibrators

批号 型号 Lot No. Model of the Reagent  $^{N/A}$ 

 物料编码
 包装规格

 Material Code
 105-004302-00
 Package Size

 C0:1×2.0 mL, C1:1×2.0 mL

**生产日期 Agy Manufacture Agy** 

 Principle

 Parameter

 Parameter

 Parameter

 Parameter

 Parameter

 Parameter

 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 校准品各组分齐全、完整、液体无渗漏; 中文包 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 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 calibrators are clear liquid without precipitate, suspension and floccules. 2、装量 Volume C0≥2.0mL 2 0 mL 装量 符合/Pass Volume  $C1 \ge 2.0 \text{mL}$ 2.0 mL 3、性能 Performance

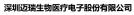
校准品CO的COI值与标定值相对偏差应在±15%

准确度 范围内

Accuracy The relative deviation of Calibrator CO should be less than  $\pm$  15%.

CO:-1%

符合/Pass



SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
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符合/Pass

校准品C1的C0I值与标定值绝对偏差应在±0.

15C0I范围内。

The absolute deviation of Calibrator C1 should be less than  $\pm 0.15$  COI.

C1:-0.02 COI

阴性/Negative

CV≤10%

CV≤10%

瓶内均一性 Uniformity in bottle

符合/Pass

CO:1%

SD≤0.1

C1:0.0 SD≤0.1

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

生物安全性 Hepatitis B Surface Antigen (HBsAg), Biosafety

antibody to HIV-1/HIV-2, antibody to Hepatitis C (HCV), and Treponema Pallidum (TP), by using the CE-marked

or equivalent method.

结论 Summary

合格/PASS

备注 Remarks

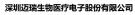
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**Analysis** 

袁丽娜Yuan Lina ものの Yuanlina 批准(检验工程师):
Approved by(Quality Engineer) 李冠林Li GuanLin 追記棋 Li Guanlin

日期: 日期: 2024-10-22

2024-10-22 Date Date



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