

检验报告 Certificate of Analysis

REF

Package Size

Expiry date

No. COA20240904048

产品名称

人类免疫缺陷病毒抗原抗体校准品

N/A

Product Name

HIV Calibrators

批号 Lot No.

型号 2024070111 Model of the Reagent

N/A

物料编码

105-004303-00 **Material Code**

 $C0:1\times 2.0 \text{ mL}, C1:1\times 2.0 \text{ mL}$

生产日期

Manufacture

有效期 2024-09-02

2026-03-01

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 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;标贴信息正确、完整;塑料瓶盖与塑料 瓶身配合后无泄漏; 塑料外盖无明显划痕、崩 缺。 The calibrators are clear liquid without precipitate, suspension and 外观和性状 符合标准/Qualified 符合/Pass floccules. The containers are white Appearance plastic bottles with tightly closed caps; The package, including the label s, 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. 2、装量 Volume C0≥2.0mL $2.1 \, \mathrm{mL}$

 $C1 \ge 2.0 \text{mL}$

2.1 mL

3、性能

装量

Volume

Performance

CL-8000i机型 CL-8000i机型

深圳迈瑞生物医疗电子股份有限公司

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 Adress: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China Tel: +86 755 8188 8998 Fax: +86 755 26582680 Website: www.mindray.com



符合/Pass



符合/Pass

内部参考品HIV N1绝对偏差在 ± 0.1 范围内 The absolute deviation—should be less—HIV N1:0.0 than ± 0.1 .

内部参考品HIV-1N2相对偏差在±10%

The relative deviation N2 should be $$\operatorname{HIV-1}$$ N2:3%

less than $\pm 10\%$.

内部参考品HIV-1N3相对偏差在±10%

The relative deviation N3 should be $$\operatorname{HIV-1}$$ N3:8%

less than $\pm 10\%$.

准确度 Accuracy

内部参考品HIV-1N4相对偏差在±10%

The relative deviation N4 should be

less than $\pm 10\%$.

HIV-1 N4:-1%

内部参考品HIV-1N5相对偏差在±10%

The relative deviation N5 should be

less than $\pm 10\%$.

HIV-1 N5:-1%

内部参考品HIV-1N6相对偏差在±10%

The relative deviation N6 should be

HIV-1 N6:1%

less than $\pm 10\%$.

通用机型 通用机型

内部参考品HIV N1绝对偏差在±0.1范围内

The absolute deviation should be less HIV N1:0.0

than ± 0.1 .

内部参考品HIV-1N2相对偏差在±10%

The relative deviation N2 should be $$\operatorname{HIV-1}$$ N2:2%

less than $\pm 10\%$.

内部参考品HIV-1N3相对偏差在±10%

The relative deviation N3 should be $$\operatorname{HIV-1}$$ N3:1%

less than $\pm 10\%$.

内部参考品HIV-1N4相对偏差在±10%

The relative deviation N4 should be HIV-1 N4:2%

less than $\pm 10\%$.

内部参考品HIV-1N5相对偏差在±10%

The relative deviation N5 should be HIV-1 N5:1%

less than $\pm 10\%$.

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内部参考品HIV-1N6相对偏差在±10%

The relative deviation N6 should be

less than $\pm 10\%$.

HIV-1 N6:3%

SD≤0.1

SD≤0.1

C0:0.0

瓶内均一性

Uniformity in bottle

> CV≤10% CV≤10%

C1:1%

符合/Pass

符合/Pass

校准品的乙型肝炎病毒表面抗原、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 from Hepatitis B

生物安全性 Biosafety

Surface Antigen (HBsAg), 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

陈素兰Chen Sulan

陈素兰 Charolulan

批准(检验工程师):

Approved by(Quality Engineer) 林朋Lin Peng

林朋 lingeng

日期:

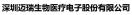
Date

2024-09-03

日期: Date

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2024-09-04



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