

结果判定

Conclusion

符合/Pass

符合/Pass

## 检验报告 Certificate of Analysis

No. COA20250412002

产品名称 **Product Name** 

降钙素原校准品 PCT Calibrators

型号

REF

N/A

批号 Lot No.

2025030111

Model of the Reagent

Package Size

N/A

物料编码

**Material Code** 

105-010219-00

 $C0:1\times1.2$  mL,  $C1:1\times1.0$  mL,  $C2:1\times1.$ 

生产日期 Manufacture

Standard basis

有效期 2025-04-10

Date

**Expiry date** 

2026-10-09

标准依据

产品检验规范 Specification for Product Inspection

符合标准/Qualified

检测项目 检测结果 接受标准 Subjects 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; C0为白色外盖, C1为黄色外盖, C2为红色外 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;塑料外盖 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 floccules. The containers are white plastic bottles with tightly closed

caps; CO is white cap, C1 is yellow cap, C2 is red cap; The whole package, including labels for boxes and bottles, pack inserts and calibration cards, is 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

外观和性状

Appearance

C1≥1.0mL

1.1 mL

装量 Volume

1.1 mL

C2≥1.0mL

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





C0≥1.2mL 1.3 mL

3、性能 Performance

> SD≤0.016 ng/mL SD≤0.016 ng/mL

C0:0.001 ng/mL

瓶内均一性

CV ≤ 8.0% Uniformity in CV≤ 8.0% bottle

C1:2.5%

符合/Pass

CV≤ 8.0%

CV≤ 8.0%

C2:0.5%

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。

The calibrators are free from

生物安全性 Biosafety

Hepatitis B Surface Antigen (HBsAg), Treponema Pallidum (TP) , antibody to Hepatitis C (HCV), and antibody to  $\ensuremath{\text{H{\sc I}}}$ 

 $V-1/\mathrm{HIV}-2$  by using the CE-marked or equivalent method.

阴性/Negative

符合/Pass

通用机型 通用机型

偏倚在±10.0%范围内

The Bias of Trueness Control Sample is H:1.2%

less than  $\pm 10.0\%$ .

赋值准确性 Accuracy

符合/Pass

偏倚在±10.0%范围内

The Bias of Trueness Control Sample is L:-0.8%

less than  $\pm 10.0\%$ .

CL-8000i机型

CL-8000i机型

偏倚在±10.0%范围内

The Bias of Trueness Control Sample is H:-2.3%

less than  $\pm 10.0\%$ .

偏倚在±10.0%范围内

The Bias of Trueness Control Sample is L:-0.5%

less than  $\pm 10.0\%$ .

## 深圳迈瑞生物医疗电子股份有限公司

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结论 合格/PASS **Summary** 

备注

Remarks

检验:

陈素兰Chen Sulan

陈素兰 Charlialan

批准(检验工程师):

Approved by(Quality Engineer) 林朋Lin Peng

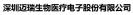
林朋 Lingeng

**Analysis** 日期:

2025-04-11 Date

日期: Date

2025-04-12



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