

检验报告
Certificate of Analysis

No. COA20250306060

产品名称 Product Name	癌胚抗原(CEA)校准品 CEA Calibrators	REF	N/A
批号 Lot No.	2025020111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004282-00	包装规格 Package Size	C0:1×2.0 mL, C1:1×2.0 mL, C2:1×2.0 mL
生产日期 Manufacture Date	2025-03-05	有效期 Expiry date	2026-06-04
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	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。塑料外盖与塑料瓶身配合无泄露；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;The package, including the labels, 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.	符合标准/Qualified	符合/Pass
2、装量 Volume			
	C0≥2.0mL	2.1 mL	
装量 Volume	C1≥2.0mL	2.1 mL	符合/Pass
	C2≥2.0mL	2.1 mL	

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科技南十二路迈瑞大厦 邮编：518057 电话：0755-8188 8998 传真：0755-26582680
Address: 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



3、性能

Performance

CL-8000i机型

CL-8000i机型

C0≤0.2ng/mL

Calibrator C0 is ≤0.2 ng/mL.

C0:0.0 ng/mL

准确度
Accuracy

C1的相对偏差应在±7.0%范围内

The relative deviation of C1 is in the range of ± 7.0%.

C1:-3.7%

符合/Pass

C2的相对偏差应在±7.0%范围内

The relative deviation of C2 is in the range of ± 7.0%.

C2:-3.4%

通用机型

通用机型

C0≤0.2ng/mL

Calibrator C0 is ≤0.2 ng/mL.

C0:0.0 ng/mL

C1的相对偏差应在±7.0%范围内

The relative deviation of C1 is in the range of ± 7.0%.

C1:-0.9%

C2的相对偏差应在±7.0%范围内

The relative deviation of C2 is in the range of ± 7.0%.

C2:-1.2%

瓶内均一性
Uniformity in
bottle

CV≤10.0%

The CV of C1 is ≤10.0%

C1:0.8%

符合/Pass

CV≤10.0%

The CV of C2 is ≤10.0%

C2:1.1%

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、梅毒螺旋体抗体检测结果均为阴性。

生物安全性
Biosafety

The calibrators are free from Hepatitis B Surface Antigen (HBsAg), antibody to HIV-1/HIV-2, antibody to Hepatitis C (HCV), and Treponema Pallidum (TP) by using the CE-marked or equivalent method.

阴性/Negative

符合/Pass

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结论
Summary

合格/PASS

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)	李冠林Li GuanLin	李冠林 LiGuanlin
日期： Date	2025-03-06		日期： Date	2025-03-06	

