

检验报告  
Certificate of Analysis

No. COA20240617025

|                          |                                             |                            |                                       |
|--------------------------|---------------------------------------------|----------------------------|---------------------------------------|
| 产品名称<br>Product Name     | 甲胎蛋白(AFP)校准品<br>AFP Calibrators             | REF                        | N/A                                   |
| 批号<br>Lot No.            | 2024050111                                  | 型号<br>Model of the Reagent | N/A                                   |
| 物料编码<br>Material Code    | 105-004283-00                               | 包装规格<br>Package Size       | C0:1×2.0 mL, C1:1×2.0 mL, C2:1×2.0 mL |
| 生产日期<br>Manufacture Date | 2024-06-15                                  | 有效期<br>Expiry date         | 2025-12-14                            |
| 标准依据<br>Standard basis   | 产品检验规范 Specification for Product Inspection |                            |                                       |

| 检测项目<br>Subjects     | 接受标准<br>Accept criteria                                                                                                                                                                                                                                                                                                                                                                                                                                            | 检测结果<br>Results | 结果判定<br>Conclusion |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--------------------|
| 1、外观性状<br>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后无泄露；塑料外盖无明显划痕、崩缺。<br>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<br>Volume       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                 |                    |
|                      | C0≥2.0mL                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2.0 mL          |                    |
| 装量<br>Volume         | C1≥2.0mL                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2.0 mL          | 符合/Pass            |
|                      | C2≥2.0mL                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2.0 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

|                               |                                                                                                                                                                                                                                                                            |              |         |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|---------|
|                               | C0≤0.5ng/mL<br>Calibrator C0 is ≤0.5 ng/mL.                                                                                                                                                                                                                                | C0:0.0 ng/mL |         |
| 准确度<br>Accuracy               | C1的相对偏差应在±10.0%范围内。<br>The relative deviation of C1 is in the range of ± 10.0%.                                                                                                                                                                                            | C1:-1.8%     | 符合/Pass |
|                               | C2的相对偏差应在±10.0%范围内。<br>The relative deviation of C2 is in the range of ± 10.0%.                                                                                                                                                                                            | C2:-0.5%     |         |
| 瓶内均一性<br>Uniformity in bottle | CV≤10.0%<br>The CV of C1 is ≤10.0%                                                                                                                                                                                                                                         | C1:1.5%      | 符合/Pass |
|                               | CV≤10.0%<br>The CV of C2 is ≤10.0%                                                                                                                                                                                                                                         | C2:1.0%      |         |
| 生物安全性<br>Biosafety            | 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。<br>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 |

结论  
Summary 合格/PASS

备注  
Remarks

|                 |            |                                                                                     |                                             |            |                                                                                       |
|-----------------|------------|-------------------------------------------------------------------------------------|---------------------------------------------|------------|---------------------------------------------------------------------------------------|
| 检验：<br>Analysis | 邓月Deng Yue |  | 批准（检验工程师）：<br>Approved by(Quality Engineer) | 林朋Lin Peng |  |
| 日期：<br>Date     | 2024-06-17 |                                                                                     | 日期：<br>Date                                 | 2024-06-17 |                                                                                       |

