检 验 报 告
Certificate of Analysis

No. COA20240615061

产品名称 Product Name	总前列腺特异性抗原校准品 Total PSA Calibrators	**REF**	N/A
批号 Lot No.	2024050111	**型号 Model of the Reagent**	N/A
物料编码 Material Code	105-004288-00	**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	2024-06-14	**有效期 Expiry date**	2025-12-13
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			
外观和性状 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;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			
装量 Volume	C0≥2.0mL	2.0 mL	符合/Pass
	C1≥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

	C2≥2.0mL	2.0 mL	

3、性能
Performance

	C0≤0.15ng/mL Calibrator C0 is ≤0.15 ng/mL.	C0:0.00 ng/mL	
准确度 Accuracy	C1和C2的相对偏差应在±15.0%范围内。 The relative deviation of C1 and C2 are in the range of ± 15.0%.	C1:-0.7%	符合/Pass
	C1和C2的相对偏差应在±15.0%范围内。 The relative deviation of C1 and C2 are in the range of ± 15.0%.	C2:-0.4%	
瓶内均一性 Uniformity in bottle	CV≤10.0% The CV of C1 and C2 is ≤10.0%	C1:0.9%	符合/Pass
	CV≤10.0% The CV of C1 and C2 is ≤10.0%	C2:1.5%	
生物安全性 Biosafety	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 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： **Analysis**	邓月Deng Yue	邓月 YengYue	**批准（检验工程师）：** **Approved by(Quality Engineer)**	胡凤Hu Feng	胡凤 HuFeng
日期： **Date**	2024-06-15		**日期：** **Date**	2024-06-15	

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