检 验 报 告
Certificate of Analysis

No. COA20240718010

产品名称 Product Name	总甲状腺素校准品 Total T4 Calibrators	**REF**	N/A
批号 Lot No.	2024060111	**型号 Model of the Reagent**	N/A
物料编码 Material Code	105-004280-00	**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	2024-07-17	**有效期 Expiry date**	2026-01-16
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.
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	C2≥2.0mL	2.0 mL	

3、性能
Performance

	CV≤8%或SD≤0.4 μg/dL CV ≤8% or SD≤0.4 μg/dL	C0:CV:0%;SD:0.0	
瓶内均一性 Uniformity in bottle	CV≤8%或SD≤0.4 μg/dL CV ≤8% or SD≤0.4 μg/dL	C1:CV:1%;SD:0.0	符合/Pass
	CV≤8%或SD≤0.4 μg/dL CV ≤8% or SD≤0.4 μg/dL	C2:CV:1%;SD:0.3	
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
赋值准确性 Accuracy	偏倚应在±7.0%范围内 The bias of trueness control sample is less than ±7.0%.	H:0.6%	符合/Pass
	偏倚应在±7.0%范围内 The bias of trueness control sample is less than ±7.0%.	L:4.1%	

结论
Summary

合格/PASS

备注
Remarks

检验：
Analysis
袁丽娜Yuan Lina Yuanlina

批准（检验工程师）：
Approved by(Quality Engineer)
林朋Lin Peng 林朋 LinPeng

日期：
Date
2024-07-18

日期：
Date
2024-07-18

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Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Quality Control (2)