

检验报告
Certificate of Analysis

No. COA20250314040

产品名称 Product Name	肌钙蛋白 I 校准品 Troponin I Calibrators	REF	N/A
批号 Lot No.	2025010101	型号 Model of the Reagent	N/A
物料编码 Material Code	105-005910-00	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	2025-03-13	有效期 Expiry date	2026-09-12
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	<p>校准品复融前外观呈现粉末块状固体，不起泡，不塌陷，复融后为清澈透明液体，无沉淀、无悬浮物、无絮状物；分装瓶为棕色的玻璃瓶，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；塑料外盖与玻璃瓶身配合后无泄漏；塑料外盖无明显划痕、崩缺。</p> <p>The calibrators are solid power without bubble or collapse before dissolved. And are clear liquid free of precipitate, suspension and floccules after dissolved.</p>	符合标准/Qualified	符合/Pass
外观和性状 Appearance	<p>The containers are brownish glass bottles with tightly closed caps; 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.</p>		
3、性能 Performance			
瓶内均一性 Uniformity in bottle	<p>SD≤0.040 ng/mL</p> <p>SD≤0.040 ng/mL</p>	C0:0.001 ng/mL	符合/Pass



赋值准确性 Accuracy	CV≤ 8.0% CV≤ 8.0%。	C1:1.0%
	CV≤ 8.0% CV≤ 8.0%。	C2:0.6%
	CL-8000i机型 偏差在±10.0%范围内。 The Bias of Trueness Control Sample is H:-1.0% less than ±10.0%.	CL-8000i机型
	通用机型 偏差在±10.0%范围内。 The Bias of Trueness Control Sample is L:-4.0% less than ±10.0%.	通用机型
	通用机型 偏差在±10.0%范围内。 The Bias of Trueness Control Sample is H:2.0% less than ±10.0%.	
	通用机型 偏差在±10.0%范围内。 The Bias of Trueness Control Sample is L:-2.4% less than ±10.0%.	

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

 Linpeng

日期：
Date

2025-03-14

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