

检验报告
Certificate of Analysis

No. COA20250412083

产品名称 Product Name	肌酸激酶同工酶校准品 CK-MB Calibrator	REF	N/A
批号 Lot No.	151425004	型号 Model of the Reagent	N/A
物料编码 Material Code	105-001132-00	包装规格 Package Size	3×1 mL
生产日期 Manufacture Date	N/A	有效期 Expiry date	2026-09-30
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			
包装检验 Package	分装瓶为棕色硬质玻璃瓶，盖有橡胶瓶内塞和塑料外盖；盒贴、瓶贴、标签标识、说明书应完整、清晰。橡胶瓶内塞与玻璃配合后应无泄漏；塑料外盖应无明显划痕、崩缺。 The bottle should be a brown hard glass bottle with a rubber inner plug and a plastic outer lid; the packet sticker, bottle sticker, label identification, and instructions should be complete and clear. Make sure there is no leakage after the rubber inner plug fit the bottle, and there is no obvious scratches or damages to the plastic outer lid.	分装瓶为棕色硬质玻璃瓶，盖有橡胶瓶内塞和塑料外盖；盒贴、瓶贴、标签标识、说明书完整、清晰。橡胶瓶内塞与玻璃配合后无泄漏；塑料外盖无明显划痕、崩缺。 The bottle were a brown hard glass bottle with a rubber inner plug and a plastic outer lid; the packet sticker, bottle sticker, label identification, and instructions were complete and clear. Make sure there is no leakage after the rubber inner plug fit the bottle, and there is no obvious scratches or damages to the plastic outer lid.	符合/Pass
参考值表 Reference value table	校准品应可提供所包含检测项目的参考值表。 For the calibrator, provide a reference value table for the testing items included.	校准品提供所包含检测项目的参考值表。For the calibrator, provide a reference value table for the testing items included.	符合/Pass
颜色性状 Apparent properties	瓶内为白色冻干粉末。复溶后为清澈透明无色液体，无沉淀、无悬浮物和絮状物 Original:White powder;Reconstituted:Clear and colorless liquid without precipitate, suspension and floccule	瓶内为白色冻干粉末。复溶后为清澈透明无色液体，无沉淀、无悬浮物和絮状物 Original:White powder;Reconstituted:Clear and colorless liquid without precipitate, suspension and floccule	符合/Pass



2、装量
Volume

装量 Volume	每瓶肌酸激酶同工酶校准品重量（含瓶重）应不少于6g。 The weight of each bottle of calibrator (including boottle weight) should be not less than 6g.	8 g	符合/Pass
--------------	--	-----	---------

3、性能
Performance

瓶内均一性 Inter-vial homogeneity	瓶内SD/ SD within<3.00 U/L或瓶内CV%/ C V% within<2.0%	SD:0.45 CV:0.32%	符合/Pass
------------------------------------	---	------------------	---------

生物安全性 Biosafety	HBsAg、HIV抗体、HCV抗体、梅毒螺旋体TP抗体检测应为阴性。 HBsAg , HIV antibody, HCV antibody, and TP antibody testing results of the calibrator should be negative.	阴性/negative	符合/Pass
--------------------	---	-------------	---------

赋值准确性 Accuracy	允许偏倚界限值（绝对偏倚或相对偏倚）：± 2.40 U/L或±10.0% Absolute bias or relative bias: ±2.40 U/L or ±10.0%	Reference serum1:绝对偏倚/ Absolute bias:-0.23;相对偏倚/ Relative bias:-1.43%	符合/Pass
	允许偏倚界限值（绝对偏倚或相对偏倚）：± 2.40 U/L或±10.0% Absolute bias or relative bias: ±2.40 U/L or ±10.0%	Reference serum2:绝对偏倚/ Absolute bias:-0.10;相对偏倚/ Relative bias:-0.24%	

结论 Summary	合格/PASS
---------------	---------

备注
Remarks

检验： Analysis	徐江明Xu Jiangming		批准（检验工程师）： Approved by(Quality Engineer)	黄小凤Huang Xiaofeng	
日期： Date	2025-04-12		日期： Date	2025-04-12	

