

检验报告
Certificate of Analysis

No. COA20250306056

产品名称 Product Name	糖化血红蛋白质控品 HbA1c Control N	REF	N/A
批号 Lot No.	052425003	型号 Model of the Reagent	N/A
物料编码 Material Code	105-002140-00	包装规格 Package Size	4×1 mL
生产日期 Manufacture Date	N/A	有效期 Expiry date	2026-08-26
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	分装瓶为无色透明硬质玻璃瓶，盖有橡胶瓶内塞，外裹铝制的瓶颈固定；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；外裹铝制的瓶颈应无明显划痕、崩缺。 The bottle should be a transparent hard glass bottle with a rubber inner plug and covered with an aluminum bottle neck outside; 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 fits the glass bottle, and there is no obvious scratches or damage to the outer aluminium bottle neck.	分装瓶为无色透明硬质玻璃瓶，盖有橡胶瓶内塞，外裹铝制的瓶颈固定；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；外裹铝制的瓶颈无明显划痕、崩缺。 The bottle were a transparent hard glass bottle with a rubber inner plug and covered with an aluminum bottle neck outside; the packet sticker, bottle sticker, label identification and instructions were complete and clear. Make sure there is no leakage after the rubber inner plug fits the glass bottle, and there is no obvious scratches or damage to the outer aluminium bottle neck.	符合/Pass
包装检验 Package			
参考值表 Reference value table	质控品应提供本批产品的参考值和参考范围。 Provide reference values and reference ranges for this batch of products.	质控品提供本批产品的参考值和参考范围。 Provide reference values and reference ranges for this batch of products.	符合/Pass



颜色性状 Apparent properties	瓶内为褐红色冻干粉末状，复溶后应为褐红色液体，无沉淀、无悬浮物和絮状物。 Original:Reddish-brown powder; Reconstituted:Reddish-brown liquid without precipitate, suspension and floccule	瓶内为褐红色冻干粉末状，复溶后 为褐红色液体，无沉淀、无悬浮物 和絮状物。 Original:Reddish- brown powder;Reconstituted: Reddish-brown liquid without precipitate, suspension and floccule	符合/Pass
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2、装量
Volume

装量 Volume	每瓶质控品质量（含瓶重）均应不少于5.5g The weight of each bottle of control（ including boottle weight）should be not less than 5.5g.	6.1 g	符合/Pass
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3、性能
Performance

参考值及参考范围 Reference and reference range	Hb：质控品测定结果应在给定的参考范围内。 靶值范围/target range: 126(114~138) μmol/L Testing results of Quality control should be within target range.	Hb:125.43 μmol/L	符合/Pass
	HbA1c%：质控品测定结果应在给定的参考范围 内。 靶值范围/target range: 5.43%(4. 89%~5.97%) Testing results of Quality control should be within target range.	HbA1c%:5.42%	
	HbA1c：质控品测定结果应在给定的参考范围 内。 靶值范围/target range: 4.50(4.05 ~4.95) μmol/L Testing results of Quality control should be within target range.	HbA1c:4.48 μmol/L	
	Hb：瓶内SD/ SD within<6.40 μmol/L，瓶 内CV%/ CV% within<5.00%	Hb:SD:0.37;CV:0.30%	

瓶内均一性 Inter-vial homogeneity	HbA1c%：瓶内SD/ SD within<0.50 %，瓶内 CV%/ CV% within<5.00%	HbA1c%:SD:0.04%;CV:0.69%	符合/Pass
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	HbA1c：瓶内SD/ SD within<0.55 μmol/L或 瓶内CV%/ CV% within<5.00%	HbA1c:SD:0.04;CV:0.96%	
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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 阴性/negative TP antibody testing results of the control should be negative.		符合/Pass
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结论
Summary

合格/PASS

备注
Remarks

检验：
Analysis

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Jiangming

Xu Jiangming

批准（检验工程师）：
Approved by(Quality Engineer)

黄小凤Huang
Xiaofeng

Huang Xiaofeng

日期：
Date

2025-03-06

日期：
Date

2025-03-06

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