

检验报告  
Certificate of Analysis

No. COA20250422076

产品名称 Product Name	尿微量白蛋白质控品 MALB Control	REF	N/A
批号 Lot No.	053125004	型号 Model of the Reagent	N/A
物料编码 Material Code	105-002316-00	包装规格 Package Size	1×1 level×1 mL
生产日期 Manufacture Date	N/A	有效期 Expiry date	2026-10-13
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			
包装检验 Package	分装瓶应为白色硬质塑料瓶，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书应完整、清晰。塑料外盖应无明显划痕、崩缺。 The bottle should be a white hard plastic bottle with a plastic outer lid;the packet sticker, bottle sticker, label identification, and instructions should be complete and clear;Make sure there is no obvious scratches or damages to the plastic outer lid.	分装瓶为白色硬质塑料瓶，盖有塑料外盖；盒贴、瓶贴、标签标识、说明书完整、清晰。塑料外盖无明显划痕、崩缺。 The bottle were a white hard plastic bottle with a plastic outer lid;the packet sticker, bottle sticker, label identification, and instructions were complete and clear;Make sure there is no obvious scratches or damages to the plastic outer lid.	符合/Pass
参考值表 Reference value table	应提供本批产品的参考值表。 Provide a reference value table of quality control products.	提供本批产品的参考值表。 Provide a reference value table of quality control products.	符合/Pass
颜色性状 Apparent properties	瓶内为清澈无色液体，无沉淀、无悬浮物和絮状物 Clear and colorless liquid without precipitate, suspension and floccule	瓶内为清澈无色液体，无沉淀、无悬浮物和絮状物 Clear and colorless liquid without precipitate, suspension and floccule	符合/Pass
2、装量 Volume			
装量 Volume	Control(1 level)≥1mL	1 mL	符合/Pass

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3、性能  
Performance

参考值及参考范围 Reference and reference range	质控品测定结果应在给定的参考范围内。 靶 值范围/target range: 194(164~224)mg/L Testing results of Quality control should be within target range.	测试结果1: 198.74; 测试结果2: 194.82; 测试结果3: 199.88	符合/Pass
瓶内均一性 Inter-vial homogeneity	瓶内SD/ SD within<0.55 mg/L或瓶内CV%/ CV% within<5.0%	SD:3.32 CV:1.66%	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 control should be negative.	阴性/negative	符合/Pass

结论  
Summary 合格/PASS

备注  
Remarks

检验：  
Analysis

徐江明Xu  
Jiangming

日期：  
Date

2025-04-22

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

黄小凤Huang  
Xiaofeng

日期：  
Date

2025-04-22

