

检验报告  
Certificate of Analysis

No. COA20250228052

产品名称 Product Name	风湿三项 (ASO/CRP/RF) 复合质控品 ASO/CRP/RF Triple Control	REF	N/A
批号 Lot No.	059225002	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004650-00	包装规格 Package Size	L:3×1 mL+H:3×1 mL
生产日期 Manufacture Date	N/A	有效期 Expiry date	2026-08-09
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	分装瓶为白色半透明硬质塑料瓶，盖有塑料旋盖；盒贴、瓶贴、标签标识应完整、清晰。 The bottle should be a semi-transparent hard plastic bottle with a plastic lid;the packet sticker, bottle sticker, label identification, and instructions should be complete and clear.	分装瓶为白色半透明硬质塑料瓶，盖有塑料旋盖；盒贴、瓶贴、标签标识应完整、清晰。 The bottle were a semi-transparent hard plastic bottle with a plastic lid;the packet sticker, bottle sticker, label identification, and instructions were complete and clear.	符合/Pass
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	瓶内为澄清透明的液体，无沉淀、悬浮物和絮状物 Clear liquid without precipitate, suspension and floccule	瓶内为澄清透明的液体，无沉淀、悬浮物和絮状物 Clear liquid without precipitate, suspension and floccule	符合/Pass
2、装量 Volume			
装量 Volume	Control (2 level) ≥1mL	水平1: 1mL; 水平2: 1mL	符合/Pass
3、性能 Performance			

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ASO II : 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 387.0(252~522)IU/mL

Testing results of Quality control should be within target range.

ASO II : 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 128(83~173)IU/mL

Testing results of Quality control should be within target range.

CRP II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 52.9(37.0~68.8)mg/L

Testing results of Quality control should be within target range.

CRP II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 21.6(15.0~28.2)mg/L

Testing results of Quality control should be within target range.

RF II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 58.3(37.9~78.7)IU/mL

Testing results of Quality control should be within target range.

RF II: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 24.9(16.2~33.6)IU/mL

Testing results of Quality control should be within target range.

RF III: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 77.8(50.5~105.1)IU/mL

Testing results of Quality control should be within target range.

RF III: 质控品测定结果应在给定的参考范围内。 靶值范围/target range: 32.6(21.2~44.0)IU/mL

Testing results of Quality control should be within target range.

瓶内SD/SD within<8.0 IU/mL或瓶内CV%/CV% within<6.0%

瓶内SD/SD within<8.0 IU/mL或瓶内CV%/CV% within<6.0%

瓶内SD/SD within<8.0 mg/L或瓶内CV%/CV% within<5.0%

ASO II-Control H:测试结果1: 396.1; 测试结果2: 393.3; 测试结果3: 394.6

ASO II-Control L:测试结果1: 129.4; 测试结果2: 129.5; 测试结果3: 130.2

CRP II-Control H:测试结果1: 53.5; 测试结果2: 53.7; 测试结果3: 53.1

CRP II-Control L:测试结果1: 21.5; 测试结果2: 22.1; 测试结果3: 22.0

RF II-Control H:测试结果1: 56.6; 测试结果2: 57.2; 测试结果3: 57.4

RF II-Control L:测试结果1: 25.7; 测试结果2: 25.2; 测试结果3: 25.3

RF III-Control H:测试结果1: 79.36; 测试结果2: 78.05; 测试结果3: 80.03

RF III-Control L:测试结果1: 33.00; 测试结果2: 33.32; 测试结果3: 33.63

ASO II-Control H:SD:1.8 CV: 0.5%

ASO II-Control L:SD:0.8 CV: 0.6%

CRP II-Control H:SD:1.0 CV: 1.8%

符合/Pass

符合/Pass

参考值及参考范围  
Reference and  
reference range

瓶内均一性  
Inter-vial  
homogeneity

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瓶内SD/SD within<8.0 mg/L或瓶内CV%/CV% within<5.0%  
CRP II-Control L:SD:0.4 CV: 1.6%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%  
RF II-Control H:SD:0.6 CV: 1.0%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%  
RF II-Control L:SD:0.3 CV: 1.3%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%  
RF III-Control H:SD:0.3 CV: 0.4%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%  
RF III-Control L:SD:0.4 CV: 1.2%

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

黄小凤Huang Xiaofeng



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

黄振腾Huang Zhenteng



日期 :  
Date

2025-02-28

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Date

2025-02-28

