

检验报告
Certificate of Analysis

No. COA20250426049

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.	059225004	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			



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(252~522)IU/mL

Testing results of Quality control should be within target range.

ASO II-Control H:测试结果1: 378.8; 测试结果2: 381.2; 测试结果3: 380.2

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.

ASO II-Control L:测试结果1: 124.1; 测试结果2: 123.9; 测试结果3: 124.2

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-Control H:测试结果1: 54.6; 测试结果2: 54.9; 测试结果3: 55.0

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.

CRP II-Control L:测试结果1: 22.2; 测试结果2: 23.3; 测试结果3: 22.1

参考值及参考范围
Reference and
reference range

符合/Pass

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-Control H:测试结果1: 54.6; 测试结果2: 54.3; 测试结果3: 54.5

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: 29.5(19.1~39.9)IU/mL

Testing results of Quality control should be within target range.

RF II-Control L:测试结果1: 3.4; 测试结果2: 23.3; 测试结果3: 23.3

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-Control H:测试结果1: 73.71; 测试结果2: 73.36; 测试结果3: 73.25

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.

RF III-Control L:测试结果1: 30.68; 测试结果2: 30.99; 测试结果3: 31.19

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

ASO II-Control H:SD:1.2 CV: 0.3%

瓶内均一性
Inter-vial
homogeneity

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

ASO II-Control L:SD:0.4 CV: 0.4%

符合/Pass

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

CRP II-Control H:SD:1.1 CV: 2.0%

深圳迈瑞生物医疗电子股份有限公司

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD.

地址: 深圳市南山区高新技术产业园科技南十二路迈瑞大厦 邮编: 518057 电话: 0755-8188 8998 传真: 0755-26582680

Address: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China

Tel: +86 755 8188 8998 Fax: +86 755 26582680 Website: www.mindray.com



瓶内SD/SD within<8.0 mg/L或瓶内CV%/CV% within<5.0%
CRP II-Control L:SD:0.2 CV: 1.0%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%
RF II-Control H:SD:1.2 CV: 2.3%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%
RF II-Control L:SD:0.4 CV: 1.9%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%
RF III-Control H:SD:0.4 CV: 0.6%

瓶内SD/SD within<2.0 IU/mL或瓶内CV%/CV% within<8.0%
RF III-Control L:SD:0.2 CV: 0.7%

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		批准 (检验工程师) : Approved by(Quality Engineer)	黄小凤Huang Xiaofeng	
日期 : Date	2025-04-26		日期 : Date	2025-04-26	

