

N/A

检验报告 Certificate of Analysis

No. COA20250228052

产品名称 **REF** 风湿三项(ASO/CRP/RF)复合质控品 **Product Name** ASO/CRP/RF Triple Control

批号 型号 059225002

N/A Lot No. Model of the Reagent 物料编码

105-004650-00 $L:3\times1$ mL+H:3×1 mL **Material Code** Package Size 生产日期

有效期 Manufacture N/A 2026-08-09 **Expiry date** Date

标准依据 产品检验规范 Specification for Product Inspection

检测项目	接受标准	检测结果	结果判定
Subjects 1、外观性状 Appearance	Accept criteria	Results	Conclusion
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 2、装量	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
Volume			
装量 Volume	Control(2 level)≥1mL	水平1: 1mL;水平2: 1mL	符合/Pass

3、性能 Performance

Standard basis

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区科技南十二路迈瑞大厦 邮编: 518057 电话: 0755-8188 8998 传真: 0755-26582680 Adress: 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





ASO II: 质控品测定结果应在给定的参考范围 靶值范围/target range: 387.0(252 ASO Ⅱ-Control H:测试结果1: ~522) III/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 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 CRP Ⅱ-Control H:测试结果1: $^{\sim}68.8)\,\mathrm{mg/L}$

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 CRP Ⅱ-Control L:测试结果1: $^{\sim}28.2)\,\mathrm{mg/L}$

Testing results of Quality control should be within target range.

reference range RF II: 质控品测定结果应在给定的参考范围 靶值范围/target range: 58.3(37.9 RF II-Control H:测试结果1: 5 内。 ~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 靶值范围/target range: 24.9(16.2 RF Ⅱ-Control L:测试结果1: 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 RF III-Control H:测试结果1:7 ~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 靶值范围/target range: 32.6(21.2 RF III-Control L:测试结果1: 3 ~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%

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

53.5; 测试结果2:53.7; 测试结 果3:53.1

21.5; 测试结果2: 22.1; 测试结 果3: 22.0

6.6; 测试结果2: 57.2; 测试结果

3: 57.4

5.7; 测试结果2: 25.2; 测试结果 3: 25.3

9.36; 测试结果2:78.05; 测试 结果3:80.03

3.00; 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%

深圳迈瑞生物医疗电子股份有限公司

瓶内均一性

Inter-vial

homogeneity

参考值及参考范围

Reference and

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. 地址: 深圳市南山区高新技术产业园区科技南十二路迈瑞大厦 邮编: 518057 电话: 0755-8188 8998 传真: 0755-26582680 Adress: 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 Website: www.mindray.com

符合/Pass

符合/Pass





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%

HBsAg、HIV抗体、HCV抗体、梅毒螺旋体TP抗体

检测应为阴性。

生物安全性 Biosafetv

HBsAg , HIV antibody, HCV antibody, and 阴性/negative TP antibody testing results of the

control should be negative.

符合/Pass

结论 **Summary**

合格/PASS

各注

Remarks

检验: 黄小凤Huang Analysis Xiaofeng

日期:

2025-02-28 Date

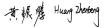
批准 (检验工程师): 黄振腾Hua Approved by(Quality Engineer) Zhenteng

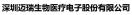
日期:

Date

黄振腾Huang

2025-02-28





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