

N/A

检验报告 Certificate of Analysis

REF

No. COA20250111036

抗链球菌溶血素"0"(ASO)测定试剂盒(胶乳免疫

产品名称 比浊法)

Product Name Antistreptolysin "0" Kit (Latex

Immunoturbidimetric Method)

批号 型号

Lot No. 146925001 Model of the Reagent N/A

 物料编码
 包装规格
 R1:2×40 mL+R2:2×40 mL+Calibrato

 Material Code
 Package Size
 r:1×0.5 mL

生产日期

有效期Manufacture N/A Expiry date 2026-04-23

Date

标准依据Standard basis
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
外包装检验 Outer packaging inspection	试剂外包装完整,标识清晰,密封良好,无破裂现象。 试剂瓶液体无渗漏,标签完好清晰,是无标签脱落、污损现象,批号、效期信息完整。 The reagent package is complete, clearly marked, well sealed, and free from cracking.	渗漏,标签完好清晰,是无标签脱	符合/Pass
	校准品:浅黄色液体。 Calibrator: light yellow liquid.	Calibrator:校准品: 浅黄色液 体。 Calibrator: light yellow liquid.	
外观物理性状 Appearance	R1: 澄清透明的液体,无沉淀、悬浮物和絮状物; R2: 白色混浊液体。 R1, Clear liquid without deposit, flocculate or suspended substance; R2, white turbid liquid	R1/R2:R1: 澄清透明的液体,无沉淀、悬浮物和絮状物; R2: 白色混浊液体。 R1, Clear liquid without deposit, flocculate or suspended substance; R2, white turbid liquid	符合/Pass
2、装量 Volume		•	
净含量 Volume	Calibrator≥0.5mL	0.50 mL	符合/Pass

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
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R1≥40mL

40.73 mL

R2≥40mL

40.86 mL

3、性能 Performance

Accuracy

测定校准品,测定结果与靶值的相对偏差在±1

0.0% 以内。

The bias of calibrator testing should

be within $\pm 10.0\%$.

Calibrator:1.5%

测定质控血清, 测定结果在靶值范围内。

靶值范围/target range: 112(73~151)IU/mL Control(level 1) :103.4 IU/ 准确度

Testing results of Quality control

should be within target range.

测定质控血清, 测定结果在靶值范围内。

靶值范围/target range: 257(167~ 347)IU/

Control(level 2):273.4 IU/mL

Testing results of Quality control

should be within target range.

吸光度变化率 ≥0.007 A/min (200 IU/m

分析灵敏度 L) 。

Analysis of Change of absorbance $\triangle A \geqslant 0.007$ A/min

Sensitivity

(200 IU/mL)

0.035 A/min

符合/Pass

符合/Pass

校准品均一性 校准品的均一性 CV≤6.0%。

Homogeneity of

Homogeneity of Calibrator CV≤6.0%. Calibrator

0.5%

符合/Pass

校准品的HBsAg、HIV抗体、HCV抗体、TP抗体检

calibration product should be negative

测应为阴性。

The test of hbsag, hiv antibody, hcv 生物安全性

antibody and tp antibody of the Biosafety

阴性/negative

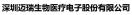
符合/Pass

试剂空白吸光度<2.0A。 空白吸光度

Reagent blank absorbance should be < 2. 1.1 A Blank

Absorbance

符合/Pass



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mindray迈瑞

空白吸光度变化率 空白吸光度变化率<0.005A/min

Absorbance Rate Reagent blank absorbance<0.005A/min

0.000 A/min

符合/Pass

试剂盒在 (20~1000) IU/mL范围内, 其回归系

数r ≥0.9900。

样本浓度≤160IU/mL时,线性绝对偏差≤±16 IU/mL;样本浓度>160IU/mL时,线性相对偏差

 $\leq \pm 10.0\%$.

线性范围 Linearity Range 9900.

In the range of $20^{\sim}1000$ IU/mL, the linear correlation coefficient $r \ge 0$.

相关系数R:0.9991;相对偏差/ Relative deviation: Max:2.5 0%, Min:-9.08%

符合/Pass

The absolute deviation should be $\leq \pm 16$

IU/mL(analyte concentrate ≤160 IU/m L); the relative deviation should be \leq $\pm 10.0\%$ (analyte concentrate >160 IU/mL

重复性 Precision

Within-run

批内变异系数 CV≤ 6.0%。

Within-run imprecision CV≤6.0%.

SD: 0.7; CV: 0.7%

符合/Pass

结论

Summary

合格/PASS

备注

Remarks

检验: 徐江明Xu

Analysis Jiangming

日期:

2025-01-11 Date

| Xu Jiang ming | 批准 (检验工程师): 黄小凤Hua | Approved by(Quality Engineer) Xiaofeng 黄小凤Huang

2025-01-11 Date

to A Huang Lianforg

