

N/A

N/A

 2×50 tests

检验报告 Certificate of Analysis

No. COA20250107005

产品名称 乙型肝炎病毒表面抗原(HBsAg)测定试剂盒(化

Product Name 学发光免疫分析法)

Hepatitis B Surface Antigen(CLIA)

Lot No. Model of the Reagent

Material Code Package Size

生产日期 Manufacture 2024-12-14

Date 标准依据

2024-12-14 **Expiry date** 2026-06-13

有效期

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
外观和性状 Appearance 2、 装量 Volume	试剂盒各组分齐全、完整、液体无渗漏;包装标签清晰、无破损; Ra组分为棕色含固体微粒的液体; Rb、Rc组分为清澈透明的液体 Reagent Componets are complete, no leakage. Labels are clear and well- stamped.Ra is composed of brown liquid containing solid particles.Rb and Rc are composed of clear and transparent liquid.	符合标准/Qualified	符合/Pass
	Rc≥3.5mL	3.6 mL	
装量 Volume	Ra≥3.8mL	3.9 mL	符合/Pass
	Rb≥7.8mL	7.9 mL	
3、性能 Performance	CL-8000i	CL-8000i	

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





相对偏差±10.0%范围之内

Relative deviation is in the range of H:-5.3%

 $\pm 10.0\%$;

准确度 Accuracy 相对偏差±10.0%范围之内

Relative deviation is in the range of

 $\pm 10.0\%;$

L:-3.6%

符合/Pass

相对偏差±20.0%范围之内,相关系数r应≥0.

99

Relative deviation is in the range of $\pm 20.0\%$, the correlation coefficient r

is ≥0.99

L1:-19.9% ;L2:-19.5% ;L3:-1 7.2%; L4:-16.6%; L5:-17.3%; L6:-17.7%; L7:-17.3%; L8:-1 5.1%; L9:-16.6%; L10:-14.5%;

r:1.00

相对偏差±10.0%范围之内

Relative deviation is in the range of

 $\pm 10.0\%$;

H:-6.5%

相对偏差±10.0%范围之内

Relative deviation is in the range of

 $\pm 10.0\%$;

L:-4.2%

相对偏差±20.0%范围之内,相关系数r应≥0. L1:-16.6%;L2:-16.6%;L3:-1

Relative deviation is in the range of L6:-15.6%; L7:-14.8%; L8:-1 $\pm 20.0\%$, the correlation coefficient r is ≥0.99

8.8%; L4:-15.4%; L5:-16.9%; 2.4%; L9:-12.3%; L10:-13.5%;

r:1.00

adr亚型≤ 0.1 IU/mL

Lowest Detection Level: adr: 0.1 IU/mL

adr:adr<0.1IU/mL

最低检出量 Minimum

detectable quantity

adw亚型≤ 0.1 IU/mL

Lowest Detection Level: adw: 0.1 IU/mL

adw:adw<0.1IU/mL

符合/Pass

ay亚型≤ 0.2 IU/mL

Lowest Detection Level: ay: 0.2 IU/mL

ay:ay<0.2IU/mL

最低检测限

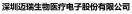
Limit of Detection

最低检测限≤0.05 IU/mL

The Limit of detection is ≤ 0.05 IU/mL.

0.00 IU/mL

符合/Pass



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



mindray迈瑞

符合/Pass

符合/Pass

在0.05 IU/mL²50.0 IU/mL范围内, 其相关系

线性 Within the range of 0.05 IU/mL-250.0 1.00 Linearity

IU/mL, the correlation coefficient r

is ≥ 0.99 .

变异系数CV≤ 10%

The coefficient of variation is $\leq 10\%$ H:1%

重复性

Repeatability

变异系数CV≤ 10%

The coefficient of variation is ≤10% L:2%

阳性参考品符合率 阳性参考品符合率3/3

reference rate

Positive reference rate:3/3

3/3

符合/Pass

阴性参考品符合率 阴性参考品符合率20/20

reference rate Negative reference rate: 20/20

20/20

符合/Pass

结论

Summary

合格/PASS

备注

Remarks

.....

检验:

黄凯芹Huang

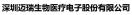
Analysis Kaiqin

日期:

2025-01-07 Date

日期: Date

2025-01-07



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

