

检验报告
Certificate of Analysis

No. COA20250107005

产品名称 Product Name	乙型肝炎病毒表面抗原(HBsAg)测定试剂盒(化学发光免疫分析法) Hepatitis B Surface Antigen(CLIA)	REF	N/A
批号 Lot No.	2024090141	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004229-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2024-12-14	有效期 Expiry date	2026-06-13
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	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		
外观和性状 Appearance	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
2、装量 Volume			
	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.
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相对偏差±10.0%范围之内

Relative deviation is in the range of $\pm 10.0\%$; H:-5.3%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 $r \geq 0.99$ Relative deviation is in the range of $\pm 20.0\%$, the correlation coefficient r is ≥ 0.99 L1:-19.9% ;L2:-19.5% ;L3:-17.2% ;L4:-16.6% ;L5:-17.3% ;L6:-17.7% ;L7:-17.3% ;L8:-15.1% ;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 $r \geq 0.99$ Relative deviation is in the range of $\pm 20.0\%$, the correlation coefficient r is ≥ 0.99 L1:-16.6% ;L2:-16.6% ;L3:-18.8% ;L4:-15.4% ;L5:-16.9% ;L6:-15.6% ;L7:-14.8% ;L8:-12.4% ;L9:-12.3% ;L10:-13.5%; r:1.00adr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
quantityadw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/mLThe Limit of detection is ≤ 0.05 IU/mL. 0.00 IU/mL

符合/Pass

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线性 Linearity	在0.05 IU/mL~250.0 IU/mL范围内，其相关系数r应 ≥0.99 Within the range of 0.05 IU/mL-250.0 IU/mL, the correlation coefficient r is ≥0.99.	1.00	符合/Pass
重复性 Repeatability	变异系数CV≤ 10% The coefficient of variation is ≤10% .	H:1%	符合/Pass
阳性参考品符合率 Positive reference rate	阳性参考品符合率3/3 Positive reference rate:3/3	3/3	符合/Pass
阴性参考品符合率 Negative reference rate	阴性参考品符合率20/20 Negative reference rate: 20/20	20/20	符合/Pass

结论
Summary合格/PASS

备注
Remarks

检验： Analysis	黄凯芹Huang Kaiqin		批准（检验工程师）： Approved by(Quality Engineer)	胡凤Hu Feng	
日期： Date	2025-01-07		日期： Date	2025-01-07	

