

检验报告
Certificate of Analysis

No. COA20241211030

产品名称 Product Name	乙型肝炎病毒表面抗体 (Anti-HBs) 测定试剂盒 (化学发光免疫分析法) Antibody to Hepatitis B Surface Antigen (CLIA)	REF	N/A
批号 Lot No.	2024090111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-004230-00	包装规格 Package Size	2×50 tests
生产日期 Manufacture Date	2024-12-06	有效期 Expiry date	2026-06-05
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 is composed of clear and transparent liquid.	符合标准/Qualified	符合/Pass
2、装量 Volume	Rb ≥ 3.5mL	3.8 mL	
装量 Volume	Ra ≥ 3.8mL	4.0 mL	符合/Pass
3、性能 Performance			
准确度 Accuracy	相对偏差 ± 10.0% 范围之内 Relative deviation is in the range of ± 10.0%;	H: 0.5%	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



相对偏差±10.0%范围之内
Relative deviation is in the range of L:1.4%
±10.0%;

相关系数r应≥0.99
The correlation coefficient r is ≥0. r:1.00
99

分析灵敏度 Analysis of Sensitivity	分析灵敏度应≤2mIU/mL The Limit of detection is≤2mIU/mL.	0 mIU/mL	符合/Pass
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最低检出量 Minimum detectable quantity	最低检出量:≤10.0 mIU/mL Lowest Detection Level: ≤10.0 mIU/mL	≤10.0mIU/ml	符合/Pass
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线性 Linearity	在5.0 mIU/mL~1000.0 mIU/mL范围内，其相关系数r应 ≥0.99。 Within the range of 5.0 mIU/mL-1000.0 mIU/mL, the correlation coefficient r is ≥0.99.	1.00	符合/Pass
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重复性 Repeatability	变异系数CV≤ 10% The coefficient of variation is ≤10% . 变异系数CV≤ 10% The coefficient of variation is ≤10% L:1% .	H:2%	符合/Pass
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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
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结论 Summary	合格/PASS
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备注
Remarks

检验： Analysis	陈素兰Chen Sulan	陈素兰 ChenSulan	批准（检验工程师）： Approved by(Quality Engineer)	林朋Lin Peng	林朋 LinPeng
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日期：
Date

2024-12-11

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