

检验报告
Certificate of Analysis

No. COA20250318024

产品名称 Product Name	叶酸(Folate)测定试剂盒(化学发光免疫分析法)	REF	N/A
批号 Lot No.	2025010111	型号 Model of the Reagent	N/A
物料编码 Material Code	105-008683-00	包装规格 Package Size	50 tests
生产日期 Manufacture Date	2025-03-18	有效期 Expiry date	2026-03-17
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、准确、牢固； Ra组分为棕色含固体微粒的液体，无板结、无絮状物； Rb、Rc、PT1、PT2组分为清澈透明的液体，无沉淀、无悬浮物、无絮状物 Reagent Componets are complete, no leakage. Packing label is clear, accurate and firm. Ra: Brown liquid free of aggregates and floccules after re-suspension of microparticles. Rb、Rc、PT1 and PT2: Clear liquid free of particulate matters and floccules.	符合标准/Qualified	符合/Pass
2、装量 Volume			
	Rb≥3.5mL	3.8 mL	
装量 Volume	Rc≥3.5mL	3.9 mL	符合/Pass
	PT1≥3.5mL	3.9 mL	

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Ra≥3.8mL	3.9 mL
PT2≥6.3mL	6.6 mL

3、性能
Performance

准确度 Accuracy	相对偏差±10%范围内 Relative deviation is in the range of ±10%	H:2%	符合/Pass
	相对偏差±10%范围内 Relative deviation is in the range of ±10%	L:-2%	
检出限 Detection	低于检出限数值（0.8ng/ml）检测结果的数量 小于等于3个，无高于定量限（3.20ng/ml）的 检测结果 The number of test results which below the limit of blank (0.8 ng/ml) ≤ 3. No test result is higher than the lower limit of the reference range (3.20 ng/mL)	低于空白限数值的检测结果： The number of test results which below the limit of blank: 0; 高于参考区间下限检测 结果： The number of test result is higher than the lower limit of the reference range: 0	符合/Pass
线性 Linearity	在1.0ng/mL~20ng/mL范围内，其相关系数（ r）≥0.9900 Within the range of 1.0 ng/mL-20 ng/m L, the correlation coefficient r is ≥ 0.9900.	0.9953	符合/Pass
重复性 Repeatability	变异系数CV≤6% The coefficient of variation is ≤6%.	H:1%	符合/Pass
	变异系数CV≤6% The coefficient of variation is ≤6%.	L:3%	

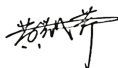
结论
Summary 合格/PASS

备注
Remarks



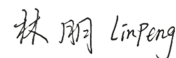
检验：
Analysis

黄凯芹Huang
Kaiqin

 Huang Kaiqin

批准（检验工程师）：
Approved by(Quality Engineer)

林朋Lin Peng

 Lin Peng

日期：
Date

2025-03-18

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深圳迈瑞生物医疗电子股份有限公司

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