

Zhuhai Biori Biotechnology Co.,Ltd

珠海宝锐生物科技有限公司

Certificate of Analysis

产品检验报告

Product 产品名称	Mycoplasma DNA Detection Kit (qPCR) 支原体 (Mycoplasma) DNA 检测试剂盒 (PCR-荧光探针法)	Lot No. 批号	20250604
Specification 规格	50 Reactions	Test Date 检验日期	2025.06.12
Test purpose 请检目的	All items	Expiry date 有效期至	2027.06.02
Standard 请检依据	Enterprise Standard	Storage 储存条件	≤-20°C

TEST RESULT

检验结果

Content 检验项目	Specification 企业标准	Results 检验结果
Appearance 外观检验	Clear liquid, no precipitation, no suspended matter, no flocculent. The packaging is intact, no damage, no leakage, and the batch number is correct. 各液体组分应无渗漏且密封完好无破损。	Conforms 符合规定
Filling Volume 装量检验	The volume of each composition should meet the minimum requirements as specified in the technical guidelines. My qPCR MIX 应不低于 1.0mL/管, My 内标应不低于 1.0mL/管, 阴性对照应不低于 1.5mL/管, My 阳性对照应不低于 1.5mL/管。	Conforms 符合规定
Negative Concordance Rate 阴性符合率	Test My Negative Control, the negative concordance rate (-/-) shall be 4/4. 检测 My 阴性对照, 阴性符合率 (-/-) 为 4/4。	Conforms 符合规定
Positive Concordance Rate 阳性符合率	Detection of My positive control, the positive concordance rate (+/+) is 4/4. 检测 My 阳性对照, 阳性符合率 (+/+) 为 4/4。	Conforms 符合规定
Limit of Detection (LOD) 检测限	Test My Limit of Detection, Positive Percent Agreement (+/+) shall be no less than 23/24. 检测 My 检测限, 阳性符合率 (+/+) 不低于 23/24。	Conforms 符合规定
Internal Standard Ct Value 内标出值	Operate in strict accordance with the kit instruction manual, detect the kit internal standard, and the Ct value shall be ≤35. 严格按照试剂盒说明书进行操作, 检测试剂盒内标, Ct 出值 ≤35。	Conforms 符合规定
Test conclusion 检验结论	Complying with Enterprise Standard. 本品按企业标准检验, 结果符合规定。	

Analyzed by (检验人):

杨丹芳

Reviewed by (复核人):

赵章记

