

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	Spiroplasma DNA Detection Kit (qPCR) 螺原体（Spiroplasma）DNA 检测试剂盒（PCR-荧光探针法）	Lot No. 批号	20260312
Specification 规格	50 Reactions	Test Date 检验日期	2026.03.20
Test purpose 请检目的	All items	Expiry date 有效期至	2028.03.10
Standard 请检依据	Enterprise Standard	Storage 储存条件	≤-18℃
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. 各组分应齐全、完整；各液体组分应无渗漏且密封完好无破损；标签字迹应清晰，易识别。	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. Spi qPCR MIX 应不低于 1.0mL/管, Spi 内标应不低于 1.0mL/管, 阴性对照应不低于 1.5mL/管，Spi 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 Spi Negative Control, the negative concordance rate (-/-) shall be 4/4. 检测试剂盒阴性对照，阳性符合率（-/-）为 4/4。	Conforms 符合规定	
Positive Concordance Rate 阳性符合率	Detection of Spi positive control, the positive concordance rate (+/+) is 4/4. 检测试剂盒阳性对照，阳性符合率（+/+）为 4/4。	Conforms 符合规定	
Limit of Detection (LOD) 检测限	Test Spi Limit of Detection, Positive Percent Agreement (+/+) shall be no less than 23/24. 检测 Spi 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. 检测试剂盒内标，阴性对照的 Ct 出值应不大于 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): 刘超