

# 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

<b>Product</b> 产品名称	RCL Gene Copy Number Detection Kit (qPCR) RCL 残留 DNA 检测试剂盒 (PCR-荧光探针法)	<b>Lot No.</b> 批号	20250819
<b>Specification</b> 规格	100 Reactions	<b>Test Date</b> 检验日期	2025.08.22
<b>Test purpose</b> 请检目的	All items	<b>Expiry date</b> 有效期至	2027.08.17
<b>Standard</b> 请检依据	Enterprise Standard	<b>Storage</b> 储存条件	≤-20°C
<b>TEST RESULT</b> 检验结果			
<b>Content</b> 检验项目	<b>Specification</b> 企业标准	<b>Results</b> 检验结果	
<b>Appearance</b> 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	
<b>Filling Volume</b> 装量检验	The volume of each composition should meet the minimum requirements as specified in the technical guidelines. RCL qPCR MIX1 装量应不低于 0.9mL/管, RCL qPCR MIX2 装量应不低于 0.2mL/管, RCL 阴性对照装量应不低于 1.0mL/管, RCL 校准品 ST1-ST6 装量应不低于 0.5mL/管。	Conforms 符合规定	
<b>Negative Concordance Rate</b> 阴性符合率	The negative control should be tested three times with the detection reagent kit, and the results should be negative. 检测 RCL 阴性对照, 阴性符合率 (-/-) 为 3/3。	Conforms 符合规定	
<b>Precision</b> 精密度	The coefficient of variation (CV%) for low-value precision should be ≤20%; for high-value precision, it should be ≤15%. 检测 RCL 准确度/精密度参考品 Z1-Z4, Z1 的 CV 值应≤20%, Z2-Z4 的 CV 值应≤15%。	Conforms 符合规定	
<b>Accuracy</b> 准确度	The deviation in low-value accuracy should be ≤20%; the deviation in high-value accuracy should be ≤15%. 检测 RCL 准确度/精密度参考品 Z1-Z4, Z1 的准确度偏差应≤20%, Z2-Z4 的准确度偏差应≤15%。	Conforms 符合规定	
<b>Amplification Efficiency</b> 扩增效率	For calibration standards ST1-ST6, the amplification efficiency of the detection reagent kit should be between 95% and 105%, the slope should be in the range of -3.2 to -3.45. 检测试剂盒校准品 ST1-ST6, 其扩增效率应在 95%-105%之间, 即斜率应在-3.2 至-3.45 范围内。	Conforms 符合规定	
<b>Linear Correlation</b> 线性相关性	For calibrators ST1-ST6 of the detection kit, the linear correlation coefficient $r$ should be $\geq 0.99$ . 检测试剂盒校准品 ST1-ST6, 线性相关系数 $ r $ 应 $\geq 0.99$ 。	Conforms 符合规定	
<b>Internal Standard Ct Value</b> 内标出值	Operate in strict accordance with the internal standard plasmid, detect the kit internal standard, and the Ct value should be $< 30$ . 严格按照试剂盒说明书进行操作, 检测内标质粒 ZL1014 (1.0E+04copies/μL), Ct 出值 $< 30$ 。	Conforms 符合规定	
<b>Test conclusion</b> 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): 赵军记

BP-QN10-100

# Zhuhai Biori Biotechnology Co.,Ltd

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## Certificate of Analysis

产品检验报告

<b>Product</b> 产品名称	Sf9&AcNPV Residual DNA Detection Kit (qPCR) Sf9&AcNPV 残留 DNA 检测试剂盒 (PCR-荧光探针法)	<b>Lot No.</b> 批号	20260422
<b>Specification</b> 规格	100 Reactions	<b>Test Date</b> 检验日期	2026.04.28
<b>Test purpose</b> 请检目的	All items	<b>Expiry date</b> 有效期至	2028.04.20
<b>Standard</b> 请检依据	Enterprise Standard	<b>Storage</b> 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. Sf9&AcNPV qPCR MIX 装量应不低于 1.0mL, Sf9&AcNPV 内标装量应不低于 1.0mL, Sf9&AcNPV 阴性对照装量应不低于 1.0mL, Sf9&AcNPV 校准品 ST1-ST6 装量应不低于 0.5mL。	Conforms 符合规定
Negative Concordance Rate 阴性符合率	The negative control should be tested three times with the detection reagent kit, and the results should be negative. 检测 Sf9&AcNPV 阴性对照, 阴性符合率 (-/-) 为 3/3。	Conforms 符合规定
Precision 精密度	The coefficient of variation (CV%) for low-value precision should be ≤20%; for high-value precision, it should be ≤15%. 检测 Sf9&AcNPV 准确度/精密度参考品 Z1-Z4, Z1 的 CV 值应≤20%, Z2-Z4 的 CV 值应≤15%。	Conforms 符合规定
Accuracy 准确度	The deviation in low-value accuracy should be ≤ 20%; the deviation in high-value accuracy should be ≤15%. 检测 Sf9&AcNPV 准确度/精密度参考品 Z1-Z4, Z1 的准确度偏差应≤20%, Z2-Z4 的准确度偏差应≤15%。	Conforms 符合规定
Amplification Efficiency 扩增效率	For calibration standards ST1-ST6, the amplification efficiency of the detection reagent kit should be between 95% and 105%, the slope should be in the range of -3.2 to -3.45. 检测试剂盒校准品 ST1-ST6, 其扩增效率应在 95%-105%之间, 即斜率应在-3.2 至-3.45 范围内。	Conforms 符合规定
Linear Correlation 线性相关性	For calibrators ST1-ST6 of the detection kit, the linear correlation coefficient $r$ $\geq$ 0.99. 检测试剂盒校准品 ST1-ST6, 线性相关系数 $ r $ 应 $\geq$ 0.99。	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 should 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
<b>Test conclusion</b> 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): 赵真纯

BP-QN21-100