

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	CHO residual DNA detection kit (qPCR) CHO 残留 DNA 检测试剂盒 (PCR-荧光探针法)	Lot No. 批号	20251111
Specification 规格	100 Reactions	Test Date 检验日期	2025.11.17
Test purpose 请检目的	All items	Expiry date 有效期至	2027.11.05
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. CHO qPCR MIX 装量应不低于 1.0mL/管, CHO 内标装量应不低于 1.0mL/管, CHO 阴性对照装量应不低于 1.0mL/管, CHO 校准品 ST1-ST6 装量应不低于 0.5mL/管。	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 CHO 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%. 对检测 CHO 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 CHO 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≥ 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 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



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