

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	AcuGenix™ Lyo-Ready Hot Start RT-LAMP Dye Master Mix-V2														
Component 组分	10×RT-LAMP Premix (DG) (Bst2.0 HS)	Lot No. 批号	20251211												
	5×RT-LAMP Lyophilization Buffer		20251211												
	50×RT-LAMP Fluorescent Dye II		20251211												
Test purpose 请检目的	All items	Test Date 检验日期	2025. 12. 11												
Standard 请检依据	Enterprise Standard	Expiry date 有效期至	2027. 06. 10												
Storage conditions 储存条件	-20±5° C														
TEST RESULT 检验结果 <table><tr><th>Content 检验项目</th><th>Specification 企业标准</th><th>Results 检验结果</th></tr><tr><td>Appearance 外观</td><td>Clear liquid, no precipitation, no suspended matter, no flocculent. The packaging is intact, no damage, no leakage, and the batch number is correct. 清澈液体，无沉淀，无悬浮物，无絮状物。包装完好，无破损、无漏液，批号无误。</td><td>Conforms 符合规定</td></tr><tr><td>Sensitivity 灵敏度</td><td>The detection rate of sensitivity standard should be consistent with RS. 待检品与对照品对企业灵敏度标准品的检出率应一致。</td><td>Conforms 符合规定</td></tr><tr><td>Difference between batches 批间差异</td><td>Test at least one concentration of enterprise quantitative standard for test and control samples; no significant intergroup difference in Ct values (<2). 对照品与待检品检测至少一个浓度企业定量标准品，组间 Ct 值应无显著性差异 (<2)。</td><td>Conforms 符合规定</td></tr></table>				Content 检验项目	Specification 企业标准	Results 检验结果	Appearance 外观	Clear liquid, no precipitation, no suspended matter, no flocculent. The packaging is intact, no damage, no leakage, and the batch number is correct. 清澈液体，无沉淀，无悬浮物，无絮状物。包装完好，无破损、无漏液，批号无误。	Conforms 符合规定	Sensitivity 灵敏度	The detection rate of sensitivity standard should be consistent with RS. 待检品与对照品对企业灵敏度标准品的检出率应一致。	Conforms 符合规定	Difference between batches 批间差异	Test at least one concentration of enterprise quantitative standard for test and control samples; no significant intergroup difference in Ct values (<2). 对照品与待检品检测至少一个浓度企业定量标准品，组间 Ct 值应无显著性差异 (<2)。	Conforms 符合规定
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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):

闪梦丹

Reviewed by (复核人):

甘茂

FHW1008-R02