

## 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<br>产品名称                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | AcuGenix™ Hot Start LAMP Probe Master Mix-V2                                                                                                                                                             |                     |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Component<br>组分                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Bst 2.0 HS                                                                                                                                                                                               | Lot No.<br>批号       | 20251211     |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 2×LAMP Premix Buffer II                                                                                                                                                                                  |                     | 20251211     |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | RNase HII                                                                                                                                                                                                |                     | 2025. 1211   |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Test purpose<br>请检目的                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | All items                                                                                                                                                                                                | Test Date<br>检验日期   | 2025. 12. 11 |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Standard<br>请检依据                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Enterprise Standard                                                                                                                                                                                      | Expiry date<br>有效期至 | 2027. 06. 10 |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Storage<br>conditions<br>储存条件                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | -20±5° C                                                                                                                                                                                                 |                     |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| <div>TEST RESULT<br/>检验结果</div> <table><tr><td>Content<br/>检验项目</td><td>Specification<br/>企业标准</td><td>Results<br/>检验结果</td></tr><tr><td>Appearance<br/>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.<br/>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<br/>符合规定</td></tr><tr><td>Sensitivity<br/>灵敏度</td><td>The detection rate of sensitivity standard should be consistent with RS.<br/>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<br/>符合规定</td></tr><tr><td>Difference between<br/>batches<br/>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 (&lt;2).<br/>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 (&lt;2)。</td><td>Conforms<br/>符合规定</td></tr></table> |                                                                                                                                                                                                          |                     |              | Content<br>检验项目 | Specification<br>企业标准 | Results<br>检验结果 | Appearance<br>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.<br>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<br>符合规定 | Sensitivity<br>灵敏度 | The detection rate of sensitivity standard should be consistent with RS.<br>待检品与对照品对企业灵敏度标准品的检出率应一致。 | Conforms<br>符合规定 | Difference between<br>batches<br>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).<br>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<br>符合规定 |
| Content<br>检验项目                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Specification<br>企业标准                                                                                                                                                                                    | Results<br>检验结果     |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Appearance<br>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.<br>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<br>符合规定    |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Sensitivity<br>灵敏度                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | The detection rate of sensitivity standard should be consistent with RS.<br>待检品与对照品对企业灵敏度标准品的检出率应一致。                                                                                                     | Conforms<br>符合规定    |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Difference between<br>batches<br>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).<br>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<br>符合规定    |              |                 |                       |                 |                  |                                                                                                                                                                                               |                  |                    |                                                                                                      |                  |                                       |                                                                                                                                                                                                          |                  |
| Test conclusion<br>检验结论                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Complying with Enterprise Standard<br>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):



HW205-P01