

## 冻存管最终质量检查表 Freezing Tubes Quality Final Check list

| 目录号<br>Catalog Number                   |                                                                                                                                                | FCT511320                                                                                                         |                    | 规格<br>Specifications    |                                                             | 2ml             |       |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|--------------------|-------------------------|-------------------------------------------------------------|-----------------|-------|
| 批号<br>Lot Number                        |                                                                                                                                                | 230412-539-A                                                                                                      |                    | 有效期<br>Expiration Date  |                                                             | 2028-04-12      |       |
| 生产日期<br>Manufacture Date                |                                                                                                                                                | 2023-04-12                                                                                                        |                    | 检验日期<br>Inspection Date |                                                             | 2023-04-15      |       |
| 检验项目及结果<br>Inspection Item and Result   |                                                                                                                                                |                                                                                                                   |                    |                         |                                                             |                 |       |
| 检验项目及标准<br>Inspection Item and Standard |                                                                                                                                                | 接收水平<br>Acceptance Level                                                                                          |                    |                         | 检验结果<br>Inspection Result                                   |                 |       |
|                                         |                                                                                                                                                | 检验水平<br>Quality Level                                                                                             | 样品数<br>Sample Size | 收: 退<br>Ac: Re          | 结果<br>Result                                                | 判断<br>Judgement |       |
| 外观<br>Appearance                        | 产品无异色杂质、无油污、破裂、缩水变形现象, 无披锋, 包装完整<br>No heterochromatic impurities.<br>No oil, crack, shrinkage deformation, burrs.<br>With complete packaging. | 依据标准: GB/T 2828.1-2012<br>Standard: GB/T2828.1-2012<br>抽样水平: Level II, AQL 1.5<br>Sample Level: Level II, AQL 1.5 |                    |                         | 符合/Meet criteria                                            |                 | 合格/OK |
| 性能<br>Function                          | 容量: $\pm 2\%$ Capacity: within $\pm 2\%$                                                                                                       | N/A                                                                                                               |                    |                         |                                                             |                 |       |
|                                         | 密封性: -90kPa, 60 秒<br>Leakage: -90kPa, 60S                                                                                                      | C=0                                                                                                               | 10                 | 0: 1                    | 符合/Meet criteria                                            |                 | 合格/OK |
|                                         | 耐高温: 121°C, 20 分钟<br>High temperature performance: 121°C, 20min                                                                                | C=0                                                                                                               | 10                 | 0: 1                    | 符合/Meet criteria                                            |                 | 合格/OK |
|                                         | 冻存测试: -196°C, 24 小时<br>Freezable: -196°C, 24hour                                                                                               | C=0                                                                                                               | 10                 | 0: 1                    | 符合/Meet criteria                                            |                 | 合格/OK |
| 生物性能<br>Biological Performance          | 无菌<br>Sterilized(SAL= $10^{-6}$ )                                                                                                              | N/A                                                                                                               |                    |                         |                                                             |                 |       |
|                                         | 细胞毒性<br>Cytotoxicity                                                                                                                           | C=0                                                                                                               | 3                  | 0: 1                    | 样品 Samples: ---<br>阳性对照 Positive: +++<br>阴性对照 Negative: --- |                 | 合格/OK |
|                                         | 热原 $\leq 0.5$ EU/mL<br>Non-Pyrogenic ( $\leq 0.5$ EU/mL)                                                                                       | C=0                                                                                                               | 3                  | 0: 1                    | 样品 Samples: ---<br>阳性对照 Positive: +++<br>阴性对照 Negative: --- |                 | 合格/OK |
|                                         | 无酶<br>DNase & RNase Free                                                                                                                       | C=0                                                                                                               | 3                  | 0: 1                    | 样品 Samples: ---<br>阳性对照 Positive: +++<br>阴性对照 Negative: --- |                 | 合格/OK |
| 最终判断<br>Final Judgement                 |                                                                                                                                                | 接收<br>Accept                                                                                                      |                    |                         | 拒收<br>Reject                                                |                 |       |
| 签名 Signature                            |                                                                                                                                                |                                                                                                                   |                    |                         |                                                             |                 |       |
| 检验 Inspected by                         |                                                                                                                                                |                                                                                                                   |                    | 审核 Approved by          |                                                             |                 |       |
| 张 江 强                                   |                                                                                                                                                |                                                                                                                   |                    | 马 萧 萧                   |                                                             |                 |       |