

检验报告

Certificate of Analysis (COA)

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| 试剂盒名称 Product Name | T7 RNA 聚合酶检测试剂盒 (酶联免疫吸附法·一步法) T7 RNA Polymerase ELISA Kit | 批号 LOT | 20260509 |
| | | 生产日期 production date | 20260509 |
| 检验项目 Test Item | 成品检验 Finished Product Full Inspection | 有效期 expiration date | 20270508 |
| 检验依据 Test Basis | 企业标准 Enterprise Standard | 报告日期 Report Date | 20260512 |
| 规格 Specification/Model | 96 Tests/盒 96 Tests/Kit | 保存条件 Storage conditions | box1: -20±5℃, box2: 2-8℃ |

| 检验项目 Test Item | 企业标准 Enterprise Standard | 检验结果 Test results |
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| 外观检验 Appearance | 1、标识应清晰，易识别； 2、试剂盒内各组分应齐全、完整，液体无渗漏、无絮状物； 3、铝箔袋应无破损漏气现象。 1.Labels shall be clear and easy to identify; 2.All components in the kit shall be complete and intact, with no liquid leakage or floc; 3.Aluminum foil bags shall be free from damage and air leakage. | 符合标准 Qualified |
| 包装内容及数量 Packaging contents and quantities | T7 RNA 聚合酶标准品1管，抗T7 酶标结合物工作液1 瓶，浓缩洗液（20×）1瓶，样本稀释液1瓶、显色液1 瓶，终止液1 瓶，抗T7 RNA聚合酶抗体预制酶标板1块，封板膜2 张，产品说明书1 份。 1 vial of T7 RNA polymerase concentrated standard, 1 bottle of anti-T7 detection antibody, 1 bottle of concentrated washing solution (20×), 1 bottle of sample diluent, 1 bottle of TMB substrate, 1 bottle of stop solution, 96-well plate coated with anti-T7 antibody, 2 sheets of sealing film, and 1 copy of instruction manual. | 符合标准 Qualified |
| 装量 volume | 试剂盒组成内，液体试剂成分的装量应不少于标示值。 In the composition of the kit, the volume of the liquid reagent components should be no less than the indicated value. | 符合标准 Qualified |
| 标准曲线相关系数 Correlation coefficient of the standard curve | 四参数拟合 $R^2 > 0.99$ Four-parameter fitting, $R^2 > 0.99$ | 符合标准 Qualified |
| 最高浓度孔 Maximum concentration | 检测标曲最高浓度孔（64 ng/mL），OD450-630nm信号均值 ≥ 2 The highest concentration of the detection standard curve (64 ng/mL) had an average OD value of 450-630nm ≥ 2 . | 符合标准 Qualified |
| 空白孔 Blank | 检测空白孔，OD450-630nm信号均值 ≤ 0.12 Test the blank wells, and the average signal of OD450-630nm should be ≤ 0.12 . | 符合标准 Qualified |
| 定量限 Limit of Quantitation | 检测标曲最低浓度孔孔重复测定 10 次，计算平均值与标准差，定量限不得超过 1ng/mL Repeat the lowest concentration wells of the standard curve (1 ng/ml) for 10 times, calculate the average value, and the limit of quantification should not exceed 1 ng/mL. | 符合标准 Qualified |
| 重复性 Repetition | 标曲测试，3个平行，各浓度CV应不大于10.0% Test the standard curve, 3 parallel runs. The coefficient of variation (CV) for each concentration should be no more than 10.0%. | 符合标准 Qualified |

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| 检验结论 Test conclusion | 本品按企业标准检验，结果符合规定。 This product has been tested in accordance with the enterprise standards, and the results are in compliance with the regulations. |
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检验人/Inspector: 王丹霞

复核人/Reviewer: 李飞

