

新型冠状病毒 (2019-nCoV) 核酸检测试剂盒 (三重荧光 RT-PCR 法)

2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit

成品检验报告

(Certificate of Analysis)

产品名称 (Product Name)	新型冠状病毒 (2019-nCoV) 核酸检测试剂盒 (三重荧光 RT-PCR 法) (2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit)		
产品货号 (Catalog)	CD302-02	规格 (Specification)	100 人份/盒 (100 tests/kit)
产品批号 (Lot Number)	7E460E0	生产日期 (Production Date)	2020-05-06
检验日期 (Test Date)	2020-05-08	失效日期 (Expiry Date)	2020-11-05
储存条件 (Storage Condition)	-30~-15℃避光 (-30~-15℃ away from light)	运输条件 (Transport condition)	冰袋低温运输 (Low-temperature Transport with Ice Bags)
检测项目 (Test Items)	检测标准 (Qualified Standard)		检测结果 (Test Results)
1、外观 (Appearance)	试剂盒各组分齐全, 完整; 标签清晰准确 (Various components of kit are through and complete; the label is clear and accurate)		☒ 合格 (Pass) ☐ 不合格 (Fail)
2、阳性参考品符合率 (Coincidence rate of positive reference)	检测结果均为阳性, 阳性参考品符合率为 100% (All test results are positive, and the coincidence rate of positive reference is 100%)		☒ 合格 (Pass) ☐ 不合格 (Fail)
3、阴性参考品符合率 (Coincidence rate of negative reference)	检测结果均为阴性, 阴性参考品符合率为 100% (All test results are negative, and the coincidence rate of negative reference is 100%)		☒ 合格 (Pass) ☐ 不合格 (Fail)

4、检测限 (Limit of detection)	200 copies/ml	☒ 合格 (Pass) ☐ 不合格 (Fail)	
5、精密度 (Precision)	用精密度参考品 CV1 和 CV2 进行检测, 批内和批间的 Ct 值的变异系数 (CV) $\leq 5.0\%$ (Use the precision references CV1 and CV2 for test, and the intra-assay and inter-assay coefficient of variation (CV) of Ct $\leq 5.0\%$)	☒ 合格 (Pass) ☐ 不合格 (Fail)	
检验结论: (Test Conclusion:)	☒ 合格 (Pass) ☐ 不合格 (Fail)		
检验人: (Tested by:)	王萱瑶	复核人: (Reviewed by:)	任顺利

