



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



February 26, 2020

Revision to Test Instructions

CDC 2019 Novel Coronavirus (nCoV) Real-Time RT-PCR Diagnostic Panel (EUA200001)

Dear Public Health Partner,

CDC has received enforcement discretion from the Food and Drug Administration (FDA) for the immediate modification of testing instructions for the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel. CDC is recommending that testing with the Diagnostic Panel be performed with the N1, N2 and RP primer and probe set. The N3 primer and probe set will no longer be included in the diagnostic panel for the 2019 novel coronavirus. Please review carefully the attached supplement to the authorized Instructions for Use.

Laboratories who received the Diagnostic Panel reagents but have not attempted verification of the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel may use reagents on hand to verify performance of the modified Diagnostic Panel instructions described in the attached supplement. We have also attached the original verification recommendations to aid in your facility's verification activities. Be advised N3 should not be included in verification. If your facility is successful in verifying performance of the modified Diagnostic Panel and you have met all other internal CLIA requirements for implementation of this method, you may initiate diagnostic testing.

Laboratories that failed to verify the CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel in their facilities due to N3 reactivity that did not match expected results are encouraged to re-analyze the facility's verification data for the purpose of verifying the performance of this modified method (as described in the attached supplement to the IFU). If performance is successfully verified, and if the laboratory meets all their internal CLIA requirements/processes for introduction of the test, the laboratory may introduce the test for diagnostic use.

Laboratories that failed verification for any reason other than N3 reactivity that did not match expected results should not attempt verification of this modified version of the test with reagents

on hand. The laboratory should only attempt verification and implementation of the modified test with newly manufactured reagents from CDC, available soon.

Laboratories who verified and are currently performing diagnostic testing with the CDC 2019-nCoV Real-Time RT-PCR using N1, N2, N3 and RP may continue to offer this test for diagnostic purposes while performing the necessary verification data re-analysis and internal CLIA processes to bring the modified version of the test (using N1, N2 and RP only) into diagnostic use.

CDC is seeking an amendment to the current FDA Emergency Use Authorization to include the changes described herein. CDC will share a completely revised set of instructions for use upon authorization. Until then, this letter and its attachments serve as formal modification of the instructions for use and permission from CDC to implement the described changes under FDA enforcement discretion.

If you have any questions regarding this communication, please contact:

CDC EOC Laboratory Task Force
eocevent177@cdc.gov

Sincerely,



Incident Manager
Centers for Disease Control and Prevention
COVID Response

Enclosures: 2

- Appendix A: _CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel – Instructions for Use Supplement
- Appendix B: _ Verification Requirements