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CDC Clinician Outreach and Communication Activity

Shipping of CDC 2019 Novel Coronavirus Diagnostic Test Kits Begins

Distribution of CDC Diagnostic Test Kits Will Expand Laboratory Capacity to Detect 2019-nCoV

A CDC-developed laboratory test kit to detect 2019 novel coronavirus (2019-nCoV) began shipping on February 6, 2020, to select qualified U.S. and international laboratories. Distribution of the tests will help improve the global capacity to detect and respond to the 2019 novel coronavirus.

The test kit, called the Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCov) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel (CDC 2019-nCoV Real Time RT-PCR), is designed for use with an existing RT-PCR testing instrument that is commonly used to test for seasonal influenza.

The CDC 2019 novel coronavirus test is intended for use with upper and lower respiratory specimens collected from people who meet CDC criteria for 2019-nCoV testing. The test uses a technology that can provide results in four hours from initial sample processing to result.

The test kit has not been FDA cleared or approved, however, distribution and use of the test kits follow the U.S. Food and Drug Administration (FDA) February 4, 2020, issuance of an Emergency Use Authorization (EUA). The tests are being shipped through the International Reagent Resource (IRR), a CDC-established mechanism that distributes laboratory reagents domestically and globally.

Initially, about 200 test kits will be distributed to U.S. domestic laboratories and a similar amount will be distributed to select international laboratories. Each test kit can test approximately 700 to 800 patient specimens. Additional test kits will be produced and made available for ordering in the future from the IRR. At this time, each laboratory that places an order will receive one 2019-nCoV test kit.

The IRR is accepting orders for 2019-nCoV tests from qualified laboratories. This includes 115 qualified U.S. laboratories, such as state and local public health

laboratories and Department of Defense (DoD) laboratories, as well as 191 qualified international laboratories, such as the World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV under Section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Check the CDC 2019 Novel Coronavirus Website for the latest information and guidance on 2019-nCoV. The CDC will continue to update its guidance as the 2019-nCoV situation evolves.

Read the entire CDC Press Release for more information.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety, and security. Whether diseases start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

The Emergency Risk Communication Branch in the Division of Emergency Operations, Center for Preparedness and Response is responsible for the management of all COCA products.

For information about this update or other clinical issues, or to send your feedback, please contact us at coca@cdc.gov

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