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USFDA approves first emergency coronavirus diagnostic test

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FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic



The U.S Food and Drug Administration (US FDA) issued an emergency use authorization (EUA) to enable emergency use of the Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel. To date, this test has been limited to use at CDC laboratories; this authorization allows the use of the test at any CDC-qualified lab across the country.

"Since this outbreak first emerged, we've been working closely with our partners across the U.S government and around the globe to expedite the development and availability of critical medical products to help end this outbreak as quickly as possible. This continues to be an evolving situation and the ability to distribute this diagnostic test to qualified labs is a critical step forward in protecting the public health," said FDA Commissioner Stephen M. Hahn, M.D. "Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic test. The FDA remains deeply committed to utilizing our regulatory tools and leveraging our technical and scientific expertise to advance the availability of critical medical products to respond to this outbreak in the most expeditious, safe and effective manner possible."

The 2019-novel coronavirus (2019-nCoV), identified in Wuhan, China in December 2019, is a new type of coronavirus that can cause severe respiratory illness in humans. Most patients with confirmed 2019-nCoV infection have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with 2019-nCoV infection. To date most reported cases of 2019-nCoV infection outside of China have been linked to residence in or travel to Wuhan, China. At this time, federal health officials continue to believe that the threat to the general American population from this virus is relatively low.

Under this EUA, the use of 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for patients who meet the CDC criteria for 2019-nCoV testing. Testing is limited to qualified laboratories designated by the CDC and, in the U.S., those certified to perform high complexity tests. The diagnostic is a reverse transcriptase polymerase chain reaction (PCR) test that provides presumptive detection of 2019-nCoV from respiratory secretions, such as nasal or oral swabs. A positive test result indicates likely infection with 2019-nCoV and infected patients should work with their health care provider to manage their symptoms and determine how to best protect the people around them. Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be

combined with clinical observations, patient history and epidemiological information.

The FDA can issue an EUA to permit the use, based on scientific data, of certain medical products that may be effective in diagnosing, treating or preventing such disease or condition when there is a determination, by the Secretary of Health and Human Services (HHS), that there is a public health emergency or a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens, and a declaration that circumstances exist justifying the medical products' emergency use.