FDA issues EUA for first 2019 novel coronavirus diagnostic

Feb. 14, 2020—The FDA issued an emergency use authorization to enable emergency use of the Centers for Disease Control and Prevention's 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The test provides presumptive detection of 2019-nCoV from respiratory secretions, such as nasal or oral swabs.

"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," FDA Commissioner Stephen M. Hahn, MD, said in a statement from the FDA. "Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic test."

Under this EUA, the use of the 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 CDC-designated qualified laboratories and, in the U.S., those certified to perform high complexity tests. There are no commercially available diagnostic tests cleared or approved by the FDA for the detection of 2019-nCoV.