EUA issued for first 2019 novel coronavirus diagnostic

written by CAP TODAY
March 19, 2020

March 2020—The FDA issued an emergency use authorization for the Centers for Disease Control and Prevention's 2019-nCoV Real-Time RT-PCR Diagnostic Panel. This test had been limited to use at CDC laboratories; the authorization allows the use of the test at any CDC-qualified lab in the United States.

Under this EUA, the 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use with 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 test provides presumptive detection of 2019-nCoV from respiratory secretions, such as nasal or oral swabs.