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FDA Responds To Coronavirus By Getting Out First Emergency-Use Novel Coronavirus Diagnostic

by Sue Darcey

The US agency on 4 February issued its first Emergency Use Authorization of a 2019-novel coronavirus test by enabling emergency use of the Centers for Disease Control and Prevention's 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The move will allow use of the test at any CDC-qualified lab across the US.

The US Food and Drug Administration on 4 February gave its stamp of approval under its Emergency Use Authorization (EUA) process to a 2019-novel coronavirus test that was developed and already in use by Centers for Disease Control and Prevention (CDC) laboratories.

The authorization permits *any* CDC-qualified state or local laboratory in the US to apply the RT-PCR diagnostic assay to newly suspected coronavirus cases across the US.

> ***"Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic tool." – Stephen Hahn***

"Since this outbreak first emerged, we've been working closely with our partners across the US 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

Hahn said in announcing the authorization. "Our collaboration with the CDC has been vital to rapidly developing and facilitating access to this diagnostic tool."

Hahn also reiterated the FDA's primary role in the coronavirus epidemic to help stem the spread of the disease is to approve medical countermeasures, including diagnostics and vaccines. The agency "remains deeply committed to utilizing our regulatory tools and leveraging our technical ... expertise to advance the availability of critical medical products," he said. (Also see "*FDA 'Stands Ready' To Fight Coronavirus Via Emergency-Use Test Kits While WHO Mulls Virus Spread, Gets Out Guidance*" - Medtech Insight, 23 Jan, 2020.)

How CDC Test Works

The CDC 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 patients who test positive should work with their health care provider to manage their symptoms and determine how to best protect the people around them.

However, the FDA cautioned that negative results do *not* preclude 2019-nCoV infection and should not be used as the sole basis for treatment or other patient-management decisions. Instead, negative results must be combined with clinical observations, patient history and epidemiological information about the patient's recent activities.

HHS Emergency Statement Triggers Call For More Tests

On 31 January, US Health and Human Services Secretary Alex Azar declared a US public health *emergency* on the potential threat that the coronavirus poses, and reiterated that the government is leveraging all available resources to help prevent, mitigate and respond to the threat.

But just by declaring the coronavirus a threat in the US and calling it a "public emergency," the HHS announcement triggers the FDA's ability to put out a call for commercial test developers to submit their own preliminary or final tests to the agency's swifter-than-usual EUA approval process.

As a result, US and international diagnostic companies are now free to submit their preliminary 2019-nCoV tests – or final assays to detect the novel-2019 coronavirus – to the FDA for EUA approval, the agency says, and asks that interested diagnostic companies email *CDRH-EUA-Templates@fda.hhs.gov* for further information, as well as templates to fill out regarding what information they should supply about their coronavirus tests.