Coronavirus (COVID-19) Update: FDA Issues Diagnostic Emergency Use Authorization to Hologic and LabCorp

For Immediate Release:
March 16, 2020

Today, the U.S. Food and Drug Administration took two additional significant diagnostic actions during the coronavirus outbreak (COVID-19) by issuing Emergency Use Authorizations (EUAs) to: Hologic for its Panther Fusion SARS-COV-2 Assay, and Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.

“Staff at FDA have been working nonstop to expedite the review and authorization of diagnostics during this public health emergency,” said FDA Commissioner Stephen M. Hahn, M.D. “Our device center has been in continual contact with the medical device community, in particular diagnostic developers, since January -- providing technical assistance to test developers to help facilitate the availability and distribution of tests so that health care professionals can accurately detect the COVID-19 virus. Since the beginning of this outbreak, more than 90 test developers have sought FDA guidance with the development and validation of tests they plan to bring through the EUA process. Additionally, more than 40 laboratories have notified us that they are testing or intend to begin testing soon under our new policy for laboratory-developed tests for this emergency. We stand ready to continue to support medical products in the pipeline to fight this virus.”

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###