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ASIA EDITION

LabCorp Launches Test for Coronavirus Disease

06 March 2020 | News

The LabCorp 2019 Novel Coronavirus (COVID-19), NAA Test is for Use by Clinicians with Patients Who Meet COVID-19 Evaluation Criteria

US based LabCorp, a leading global life sciences company that is deeply integrated in guiding patient care, is making its LabCorp 2019 Novel Coronavirus (COVID-19), NAA test available from 6th March 2020 beginning at 6 p.m. ET, for ordering by physicians or other authorized healthcare providers anywhere in the U.S. The test detects the presence of the underlying virus that causes COVID-19 and is for use with patients who meet current guidance for evaluation of infection with COVID-19.

“We have been intensely focused on making testing for COVID-19 available as soon as possible, working with the government and others to address this public health crisis,” said Adam H. Schechter, president and CEO of LabCorp. “By expanding access to testing in the U.S., and preparing to support the development of vaccines and treatments for COVID-19 through our Covance Drug Development business, we are delivering on LabCorp’s mission to improve health and improve lives.”

The LabCorp 2019 Novel Coronavirus (COVID-19), NAA test was developed internally by LabCorp and is being made available pursuant to guidance issued by the U.S. Food and Drug Administration (FDA). LabCorp’s test has been validated for use with respiratory samples, including nasopharyngeal (NP) or oropharyngeal (OP) aspirates or washes, NP or OP swabs, and broncheoalveolar lavage (BAL). The test is a qualitative assay using PCR technology, which LabCorp played a central role in commercializing when PCR was introduced nearly 30 years ago.

LabCorp does not currently collect specimens for the test. Patients for whom testing has been ordered should not be sent to a LabCorp location to have a specimen collected. Instead, an appropriate specimen should be collected at the healthcare facility where the patient was seen and the test was ordered. The specimen should be sent to LabCorp using standard procedures. Test results will be available in 3-4 days. More information about the test, including specimen collection and packaging requirements, is available here: https://www.labcorp.com/tests/139900/2019-novel-coronavirus-covid-19-naa

“As COVID-19 continues to spread in the U.S., having high-quality, reliable, scalable laboratory tests available is a critically important part of the response,” said Marcia Eisenberg, Ph.D., chief scientific officer for LabCorp Diagnostics. “Identifying people who are infected is necessary to make sure that patients receive the appropriate care, to better manage the use of

healthcare resources, and to help contain the spread of the virus. We will continue to stay closely involved in the ongoing response, and we are prepared to expand our testing capacity to help meet demand."

The LabCorp 2019 Novel Coronavirus (COVID-19), NAA test is made available pursuant to "Immediately in Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff" issued by the FDA on February 29, 2020. Pursuant to the policy set forth in that guidance, LabCorp is certified to perform high-complexity testing under CLIA in compliance with CLIA requirements. The LabCorp 2019 Novel Coronavirus (COVID-19), NAA test has been developed and validated, and is being performed by LabCorp, but FDA's independent review of the validation is pending. LabCorp is pursuing an EUA for the test.

Yesterday, LabCorp joined with colleagues from the American Clinical Laboratory Association (ACLA) for a meeting with Vice President Pence and members of the White House's Coronavirus Task Force. As an industry, clinical labs have taken steps to meet the growing demand for national testing and are part of a newly-formed consortium working together with the Administration, the CDC and FDA as well as state and local public health labs, hospitals and academic medical centers.

In addition to its test for COVID-19, LabCorp is also able to perform the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel if needed to meet testing demand. The CDC test is for the presumptive detection of 2019-nCoV RNA in upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate), and other authorized specimens collected from individuals who meet CDC criteria for COVID-19 testing. The CDC test has not been FDA cleared or approved, has been authorized by FDA under an EUA for use by authorized laboratories, and has been authorized only for the detection of nucleic acid from 2019-nCoV, not for any other viruses or pathogens. The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of 2019-nCoV under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.