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LabCorp Contacts:
Media: Pattie Kushner — 336-436-8263
Media@LabCorp.com

Investors: Clarissa Willett — 336-436-5076
Investor@LabCorp.com

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

BURLINGTON, N.C., March 5, 2020 — LabCorp® (NYSE: LH), 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 today, 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 bronchoalveolar 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.


About LabCorp
LabCorp (NYSE: LH), an S&P 500 company, is a leading global life sciences company that is deeply integrated in guiding patient care, providing comprehensive clinical laboratory and end-to-end drug development services. With a mission to improve health and improve lives, LabCorp delivers world-class diagnostic solutions, brings innovative medicines to patients faster, and uses technology to improve the delivery of care. LabCorp reported revenue of more than $11 billion in 2019. To learn more about LabCorp, visit www.LabCorp.com, and to learn more about Covance Drug Development, visit www.Covance.com.
Forward-Looking Statements

This press release contains forward-looking statements, including but not limited to statements with respect to clinical laboratory testing. Each of the forward-looking statements is subject to change based on various important factors, many of which are beyond the Company’s control, including without limitation, competitive actions and other unforeseen changes and general uncertainties in the marketplace, changes in government regulations, including healthcare reform, customer purchasing decisions, including changes in payer regulations or policies, other adverse actions of governmental and third-party payers, the Company’s satisfaction of regulatory and other requirements, patient safety issues, changes in testing guidelines or recommendations, adverse results in material litigation matters, failure to maintain or develop customer relationships, our ability to develop or acquire new products and adapt to technological changes, failure in information technology, systems or data security, and employee relations. These factors, in some cases, have affected and in the future (together with other factors) could affect the Company’s ability to implement the Company’s business strategy and actual results could differ materially from those suggested by these forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. The Company has no obligation to provide any updates to these forward-looking statements even if its expectations change. All forward-looking statements are expressly qualified in their entirety by this cautionary statement. Further information on potential factors, risks and uncertainties that could affect operating and financial results is included in the Company’s most recent Annual Report on Form 10-K and subsequent Forms 10-Q, including in each case under the heading RISK FACTORS, and in the Company’s other filings with the SEC.

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