



**FOR IMMEDIATE RELEASE**

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**LABCORP RECEIVES EMERGENCY USE AUTHORIZATION FOR AT HOME COLLECTION KIT FOR COMBINED COVID-19 AND FLU DETECTION**

Kit Authorized for Ages 2 and Over and Available at Zero Upfront Cost to Those Who Meet Clinical Guidelines

**BURLINGTON, N.C., October 1, 2021** — Labcorp (NYSE: LH), a leading global life sciences company, today announced that it received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a combined home collection kit that detects COVID-19 and influenza A/B simultaneously in individuals as young as 2 years of age. The kit will be available at no upfront cost to those who meet clinical guidelines, which may include experiencing symptoms, being exposed to someone with COVID-19 or if asked to be tested by a health care provider.

“Our newest home collection kit makes it convenient for individuals, including children over the age of 2, to take the test in the safety of their homes,” said Dr. Brian Caveney, chief medical officer and president, Labcorp Diagnostics. “In time for flu season, the single test helps doctors and individuals make more informed treatment decisions given that symptoms of COVID-19 and flu are similar.”

Individuals infected with COVID-19 and flu may experience similar symptoms such as fever, runny and/or stuffy nose and cough. The kit helps people test for both flu and COVID-19 in the safety of their home and avoid the risk of spreading the virus to others. The kit uses a short nasal swab that is inserted into the lower nostril, making it more comfortable and easier for individuals and parents to collect samples at home.

Starting in early October, adults 18 and over, as well as parents and guardians of children 2-17 years of age, can request the combined collection kit online through [Pixel by Labcorp](#). In addition, physicians can order the collection kit for children as young as 2 years old directly from their electronic medical record system. The home collection kit is shipped via FedEx Priority Overnight and will include a prepaid return envelope. Test results are available on average between 1-2 days after Labcorp receives the completed collection kit. In most cases, results are available in one day after the kit is received. Results can be accessed conveniently through an individual’s Pixel by Labcorp account, and results from physician ordered tests will be available online through the patient portal and the Labcorp Patient™ app.

Labcorp offers a suite of readily accessible prevention-to-detection solutions for COVID-19 that doctors, health care providers, individuals, employers and students can access. For more information, visit [Labcorp's COVID-19 website](#). Labcorp has performed more than 50 million COVID-19 PCR tests since March 2020 and is able to process up to 300,000 COVID-19 PCR tests per day.

The home collection kit uses the Roche cobas® SARS-CoV-2 & influenza A/B Test for use on the cobas® 6800/8800 Systems. This PCR test simultaneously identifies and differentiates SARS-CoV-2, influenza A, and B and enables labs to provide reliable, consolidated, and accurate answers by leveraging the high-volume cobas® 6800/8800 Systems.

The cobas SARS-CoV-2 & influenza A/B Test is a multiplex reverse transcription polymerase chain reaction (RT-PCR) assay intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and influenza B virus in nasal or nasopharyngeal swab samples collected from individuals suspected of a respiratory infection, and is not intended for the detection of influenza C virus. Under FDA EUA, the test can be taken by individuals suspected of a respiratory viral infection like COVID-19 by their health care provider. The test has a full-process negative control, positive control and internal control. Multiplexing will increase lab efficiency and save resources in the labs.

Negative results do not preclude infection from SARS-CoV-2 or influenza virus and should not be used as the sole basis of treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history and epidemiological information.

The cobas SARS-CoV-2 & influenza A/B Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. In the United States, the cobas SARS-CoV-2 & influenza A/B Test for use on the cobas® 6800 and cobas® 8800 Systems is only for use under the FDA's Emergency Use Authorization. More information about the test is available at: <https://diagnostics.roche.com/us/en/products/params/cobas-sars-cov-2-influenza-a-b-test.html>

Labcorp's combined home collection kit for COVID-19 and influenza A/B has not been FDA cleared or approved and has been authorized by the FDA under an emergency use authorization only for the detection of nucleic acid from SARS-CoV-2, influenza A and/or influenza B, 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 COVID-19 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 is a leading global life sciences company that provides vital information to help doctors, hospitals, pharmaceutical companies, researchers, and patients make clear and confident decisions. Through our unparalleled diagnostics and drug development capabilities, we provide insights and accelerate innovations to improve health and improve lives. With more than 70,000 employees, we serve clients in more than 100 countries. Labcorp (NYSE: LH) reported revenue of \$14 billion in 2020. Learn more about us at [www.Labcorp.com](http://www.Labcorp.com) or follow us on [LinkedIn](#) and Twitter [@Labcorp](#).

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