



NEWS RELEASE

Quest Diagnostics Launches Three New Combined COVID-19 and Respiratory Virus Tests

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Nearly 20 Viral and Bacterial Infections Can Be Identified from a Single Swab, Reducing Time to Diagnose and Treat
SECAUCUS, N.J., Sept. 30, 2020 /PRNewswire/ -- Healthcare providers across the United States can now access three different test options from Quest Diagnostics (NYSE: DGX) to aid the diagnosis of COVID-19 and differentiate it from other seasonal respiratory infections, including influenza (flu).

Each test is designed to use a single specimen, promoting faster test ordering, reporting and diagnosis, as compared to ordering multiple tests, for potentially improved patient care. The tests may also help reduce demand for specimen collection devices amid supply constraints.

According to the Centers for Disease Control and Prevention, this fall and winter could be one of the most complicated times in the history of public health due to the potential spread of seasonal respiratory viruses with the SARS-CoV-2 virus that causes COVID-19. Some symptoms of COVID-19 and seasonal respiratory viruses, including flu, are similar, and diagnostic testing can help determine the virus causing this illness. Because of the COVID-19 pandemic, reducing the spread of respiratory illnesses, like flu, this fall and winter is more important than ever.

The new test options include the cobas® SARS-CoV-2 & Influenza A/B*, an automated high throughput multiplex real-time RT-PCR assay from Roche. The U.S. Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the test earlier this month. The test is intended for simultaneous qualitative detection and differentiation of SARSCoV-2, the virus that causes COVID-19, and/or influenza A or B virus RNA from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

The test may be performed on healthcare provider-collected nasal and nasopharyngeal swab specimens and self-



collected nasal swab specimens (collected in a healthcare setting with instruction by a healthcare provider). Nasal swabs include anterior nares swabs, which involve collecting a specimen from the lower nostril.

Two additional test panels from Quest Diagnostics, the **Respiratory Viral Panel (RVP) test** and the **Respiratory Pathogen Panel (RPP)**, now include testing for SARS-CoV-2 using the company's SARS-CoV-2 RT-PCR test**, which was granted FDA EUA in March 2020 to aid the diagnosis of SARS-CoV-2*. With the addition of SARS-CoV-2, the RVP panel can aid the identification of up to a dozen viruses and subtypes and the RPP panel can aid the identification of 18 viral targets and two bacterial targets. Each respiratory panel test also only requires a single nasopharyngeal specimen.

"With a perfect storm of COVID-19, influenza and seasonal respiratory viruses circulating over the Fall and Winter months, laboratory testing that can reliably identify the virus causing disease will be critical to mobilizing effective patient care and public health response," said Jay G. Wohlgemuth, M.D., Senior Vice President and Chief Medical Officer, Quest Diagnostics. "Our goal is to give providers multiple tools to care for patients as quickly and effectively as possible, using a minimum of specimen collection materials amid continuing supply constraints."

Patients suspected of having or confirmed to have active SARS-CoV-2 infection or COVID-19 disease may not visit Quest patient service centers, which are not equipped to collect the necessary respiratory specimens for molecular SARS-CoV-2 diagnostic testing. Patients who believe they may have COVID-19, Influenza or other respiratory virus infections are strongly encouraged to contact their healthcare provider.

*The cobas ® SARS-CoV-2 & Influenza A/B Test and the Quest SARS-CoV-2 RT-PCR test ("Tests") have not been FDA cleared or approved. The Tests have been authorized by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests. The Roche test has been authorized only for the detection of RNA from SARS-CoV-2 virus, Influenza A virus, and Influenza B virus and not any other viruses or pathogens. The Roche test is only authorized for the duration of the declaration that circumstances exist justifying the authorized of the emergency use of in vitro diagnostics for detection and differentiation of SARS-CoV-2 virus, Influenza A, and Influenza B under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorized is terminated or revoked sooner.

**The Quest SARS-CoV-2 RT-PCR test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens. The Quest test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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 Our COVID-19 Testing

Quest Diagnostics is at the forefront of the response to the COVID-19 pandemic, working to broaden access to laboratory insights to help us all lead healthier lives. We provide both molecular diagnostic and antibody serology tests to aid in the diagnosis of COVID-19 and the immune response to the virus. Our COVID-19 test services are based on tests that have received FDA emergency use authorization and which also meet our high standards for quality. We are providing these test services under the Public Readiness and Emergency Preparedness Act. We provide data on COVID-19 testing to various federal and state public health authorities, including the Centers for Disease Control and Prevention, and participate in studies with government and private institutions, aiding COVID-19 public health response and research. Through our team of dedicated phlebotomists, air fleet team, couriers and laboratory professionals, Quest Diagnostics works hard every day to help patients and communities across the United States access quality COVID-19 testing.

For Media Statements about our COVID-19 Testing:

newsroom.questdiagnostics.com/COVIDTestingUpdates

For High Resolution Photos and B-Roll on COVID-19 Testing:

<https://app.box.com/s/djpwi9bt8bwnaptdvvtxkgotszvw0hp>

About Quest Diagnostics

Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our 47,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com

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