



NEWS RELEASE

FDA Authorizes New Quest Diagnostics Lab Method Designed to Increase COVID-19 Molecular Diagnostics Capacity

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Technique to increase COVID-19 molecular diagnostic testing capacity and provide faster test results reporting
SECAUCUS, N.J., July 29, 2020 /PRNewswire/ -- **Quest Diagnostics** (NYSE:DGX) today announced that the U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for a new laboratory technique that speeds the process of extracting viral RNA from specimens* and will enable the company to expand its daily capacity of COVID-19 molecular diagnostic tests on behalf of patients in the United States.

"Laboratory innovation is key to optimizing testing capacity for COVID-19," said Steve Rusckowski, Chairman, Chief Executive and President, Quest Diagnostics. "We appreciate the collaboration of the FDA to bring this technique to several of our labs spanning the U.S. With more testing capacity, we expect to improve turnaround times for our customers and patients."

With the new FDA EUA, five of the company's laboratories in the U.S. may now run this new RNA extraction method, including on pooled specimens. Those laboratories are well situated geographically to address high testing demand in states where the virus has been surging. The labs are in San Juan Capistrano and Valencia, California; Lewisville, Texas; Lenexa, Kansas; Chantilly, Virginia; and Marlborough, Massachusetts.

[Optimizing Capacity for Faster Testing](#)

In its submission to the FDA, the company explained that "the method is needed to address availability of extraction supplies and increase testing capacity."

The company currently has the capacity to perform 135,000 COVID-19 molecular diagnostic tests a day. The new

method is expected to add an additional 35,000 tests a day in overall capacity over the next several weeks. In addition, the company will be able to use specimen pooling with the new method to increase capacity even further.

Consequently, Quest now expects to have the capacity to perform 150,000 tests per day by next week and to continue to build additional capacity beyond that to 185,000 tests per day by Labor Day. Quest expects this innovation will help it to achieve average turnaround times of 1 day for "Priority 1" patients and 2-3 days for all other patients in coming weeks.**

The new extraction technique may be used with the Quest Diagnostics SARS-CoV-2 RNA, Qualitative Real Time RT-PCR (Quest SARS-CoV-2 rRT-PCR), a proprietary test developed and validated by Quest Diagnostics for use on respiratory specimens from individuals suspected of COVID-19 by their healthcare provider. **On July 17**, the FDA granted an EUA for the test to be used with pooled specimens.***

Quest Diagnostics is a leader in infectious disease testing services, with a broad menu of molecular, antibody, and other test services to aid diagnosis, treatment and monitoring. The new FDA EUA follows several others received by the company for its COVID-19 test innovations.

*The method extracts RNA with the Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek) and the Hamilton MagEx STAR.

**Turnaround time for molecular diagnostic and antibody testing includes the time to transport a specimen to a Quest Diagnostics laboratory after collecting it at a patient service center or provider site to reporting results. Turnaround time can fluctuate with demand and vary by region. Priority 1 patients include hospital patients, pre-operative patients in acute care settings and symptomatic healthcare workers. We rely on the healthcare provider to indicate the level of priority of each patient specimen referred to us for testing.

***The Quest Diagnostics molecular test and self-collection kit have not been FDA cleared or approved, have been authorized by FDA under an EUA, and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The test and self-collection kit are 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 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 immune response. 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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