NEWS RELEASE

FDA Authorizes Quest Diagnostics COVID-19 Diagnostic Testing for Specimen Pooling for Emergency Use

7/18/2020

First FDA authorization of laboratory technique for use in COVID-19 diagnostic testing
Company also receives new FDA emergency use authorizations for use of self-collection molecular diagnostic kit on the Hologic and Roche platforms, expanding use with healthcare provider supervision via telemedicine

SECAUCUS, N.J., July 18, 2020 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), the world's leading provider of diagnostic information services, today announced that it has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) to use specimen pooling with its proprietary molecular diagnostic test for COVID-19. Quest is the first lab provider to receive FDA authorization for the technique for COVID-19 testing in the United States.

In pooling, specimens must still be collected into individual vials, but then are combined into small batches or pools by the laboratory. A negative result for a batch means that all patients in that pool are considered negative (If a positive result occurs for the batch, each specimen is retested individually). The technique is an efficient way to evaluate patients in regions or populations with low rates of disease. Pooling is used routinely in blood banking to screen donated blood for a variety of viruses, among other applications.

With the new pooling EUA, the Quest Diagnostics SARS-CoV-2 RNA ("Quest SARS-CoV-2 rRT-PCR") test* may be used with pooled upper respiratory specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs). **In clinical data presented by Quest to the FDA, none of 3,091 total specimens from a population with a prevalence rate of 1-10 percent, if pooled, would have been incorrectly determined to be negative (95%CI 0.0-0.1%).

The company expects to deploy the technique at its laboratories in Chantilly, VA and Marlborough, Mass., by the end of next week with additional laboratories to follow.

"As COVID-19 continues to spread around the country, access to timely, quality laboratory testing is critical to patients and an effective public health response," said Steve Rusckowski, Chairman, CEO and President, Quest Diagnostics. "Pooled specimen testing is a proven technique that will help us to optimize testing capacity at this critical time for our country."

"We applaud FDA for taking this important step to empower Quest to increase capacity across our national laboratory network," said Jay G. Wohlgemuth, M.D., Senior Vice President and Chief Medical Officer, Quest Diagnostics. "Pooling will help expand testing capacity but it is not a magic bullet, and testing times will continue to be strained as long as soaring COVID-19 test demand outpaces capacity. Each of us can practice behaviors that will reduce COVID-19 infections in our communities, so our national healthcare system can better respond to this crisis."

On July 13, 2020, Quest issued a **statement** that soaring demand for COVID-19 molecular diagnostics is slowing turnaround times to report results.

FDA EUAs for Telemedicine Self-Collection

Yesterday, the FDA also granted three emergency use authorizations to Quest Diagnostics for the use of its Quest Diagnostics Self-Collection Kit with the Hologic Panther Fusion, Hologic Aptima and Roche cobas molecular platforms. The new EUAs expand the use of the self-collection kit beyond the EUA, granted on May 27th, for the use of the kit on the Quest SARS-CoV-2 rRT-PCR test. The company expects the new EUAs will allow it to use self-collection more broadly on behalf of clients and patients in the United States. Self-collected specimens that were not observed by a healthcare professional are not eligible for pooling.

New FDA EUAs Follows EUAs for Other Quest Innovations

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 EUAs follow several others received by the company for its COVID-19 test innovations.

In March 2020, Quest received FDA EUA for The Quest Diagnostics SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR ("Quest SARS-CoV-2 rRT-PCR"), a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper and lower respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider. In May 2020, the company received an FDA EUA to use the test nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit when determined to be appropriate by a healthcare provider.

*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.

**The Quest Diagnostics molecular test is also for use with pooled samples containing up to four individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) collected under observation in individual vials containing transport media from individuals suspected of COVID-19 by their healthcare provider. Negative results from pooled testing should not be treated as definitive. If patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive, inconclusive, or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

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 more information about the latest developments with our COVID-19 testing, visit:
newsroom.questdiagnostics.com/COVIDTestingUpdates

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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