



NEWS RELEASE

# FDA Authorizes Quest Diagnostics COVID-19 Nasal Specimen Self-Collection Kit for Emergency Use

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Company to make the device available through broad range of healthcare, state, employer and consumer-initiated channels

More than a half-million self-collection kits to be available by end of June

SECAUCUS, N.J., May 28, 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) for the Quest Diagnostics Self-collection Kit for COVID-19 (self-collection kit). The self-collection kit is for individuals to self-collect a nasal specimen at home or in a healthcare setting when determined to be appropriate by a healthcare provider.

The self-collection kit allows an individual to swab the front part of the nostril and may be used on children (supervised by an adult) as well as adults. Specimens are shipped overnight via FedEx at room temperature (without a frozen cold pack).

Specimens collected using the kit may be tested with the Quest Diagnostics SARS-CoV-2 RT-PCR test that received an Emergency Use Authorization in March. RT-PCR testing aids in diagnosing infection with SARS-CoV-2, the virus that causes COVID-19.

"COVID-19 molecular diagnostic testing has been constrained partly by limited supplies of swabs and trained healthcare professionals to do the specimen collection," said Steve Rusckowski, Chairman, CEO and President. "The self-collection kit enables an individual to self-collect at home, and the process is far less invasive and uncomfortable than many traditional methods."

"We plan to utilize this device with a range of populations, from state-run programs and employers to healthcare



providers and individuals," said Jay G. Wohlgemuth, M.D., Senior Vice President and Chief Medical Officer. "Our scientists at our advanced diagnostics laboratory in San Juan Capistrano, California developed the technology, which has been validated in real-world studies."

Quest shared data with FDA that indicate that the self-collection kit offers a consumer-friendly approach to high quality diagnostic testing for COVID-19. Quest Diagnostics already tested specimens using a similar collection method in real-world settings in drive-thru and other onsite COVID-19 testing sites across the United States.

The self-collection kit was developed to be very consumer friendly, with the specimen collected at home and without the need to directly involve a healthcare professional to perform or observe the collection.

Key features of the new kit include:

- Self-collection by individuals, at home, with a consumer-friendly nasal swab approach
- Overnight shipping to the individual and back to Quest Diagnostics with FedEx, leveraging their extensive logistics network
- Specimens shipped at room temperature, which eliminates the need for ice packs
- Availability for children less than 18 years of age (with adult supervision)
- Results reporting through the **myQuest** patient portal and mobile app
- Test data reported by Quest Diagnostics to the relevant departments of health as required

The company plans to make the self-collection kits available through several channels, including for healthcare providers for patient care and healthcare workers as well as for states and organizations for return-to-work testing programs. Over time, the kits may also be made available to other employers as well as for individual users of the company's **QuestDirect** consumer-initiated platform. The company will prioritize healthcare workers, first responders, law enforcement personnel and others critical to pandemic response to ensure they have timely access to the kit.

The company expects to have more than a half-million kits available by the end of June, with plans to make additional kits available on an ongoing basis.

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.

The antibody tests and the molecular tests (together "all tests") have not been FDA cleared or approved; all tests have been authorized by FDA under EUAs for use by authorized laboratories; the antibody tests have been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; the molecular tests have been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and, all tests are 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.

For more information about the latest developments with our COVID-19 testing, visit:

**[newsroom.questdiagnostics.com/COVIDTestingUpdates](https://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](http://www.QuestDiagnostics.com)**

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## SOURCE Quest Diagnostics

