SARS-CoV-2 (COVID-19) Return-to-work testing: General FAQs

1. What is SARS-CoV-2 (COVID-19)?

COVID-19 (formally known as 2019-nCoV) is the name for the respiratory syndrome caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organization has declared COVID-19 an international public health emergency.

2. What are the symptoms of COVID-19?

Reported illnesses have ranged from mild symptoms to severe illness and death for confirmed coronavirus disease 2019 (COVID-19) cases. These symptoms may appear 2-14 days after exposure, and include fever, new or worsening cough, and/or shortness of breath. If you develop emergency warning signs for COVID-19, including trouble breathing, persistent pain or pressure in the chest, confusion, and/or bluish lips or face, get medical attention immediately. Please reference the Centers for Disease Control and Prevention (CDC) for the most updated list of symptoms.

3. How is COVID-19 spread?

The virus is thought to spread mainly from person to person, between people who are in close contact with one another (within about 6 feet), and through respiratory droplets produced when an infected person coughs or sneezes. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs. There is currently no vaccine to prevent coronavirus disease 2019 (COVID-19). The best way to prevent illness is to avoid being exposed to this virus.

4. Who should be tested for COVID-19?

The CDC has guidance for who should be tested, but decisions about testing are at the discretion of state and local health departments and/or individual clinicians. Please note that when it comes to helping the nation in this time of crisis, Quest Diagnostics is focusing on this prioritization with offerings and testing availability.

For more information on priority levels, please visit the CDC's website.

COVID-19 Return-to-work testing: Molecular testing FAQs

5. What is the Quest Diagnostics COVID-19 molecular (NAAT) test?

The molecular test for SARS-CoV-2 (COVID-19) from Quest Diagnostics is a reverse Nucleic Acid Amplification Test (NAAT) test that looks for the presence of viral RNA in a respiratory specimen.

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and,
- This 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.

6. What is sensitivity and specificity?

In medical diagnosis, test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate).

7. What is the sensitivity/specificity of the Quest LDT, Hologic, and Roche assays?

For molecular tests we are using the Quest LDT, Roche, and Hologic tests.

The FDA EUA site has manufacturing information for all 4 of the molecular tests. The sensitivity and specificity for the tests are listed in the Instructions For Use (IFU) documents that are linked to under each record. The manufacturers are responsible for providing this information for their tests. Below are links to the IFU documents.

- Quest LDT IFU: https://www.fda.gov/media/136231/download
- Roche IFU: https://www.fda.gov/media/136049/download
- Hologic Panther Fusion IFU: https://www.fda.gov/media/136156/download
- Hologic Panther COVID-19 molecular assay IFU: https://www.fda.gov/media/138096/download

The assays listed on the FDA website as authorized by the FDA as an Emergency Use Authorized (EUA) method for molecular COVID-19 testing for ALL assay systems are ANALYTICALLY Validated. FDA EUA authorized assays have NOT been clinically validated.

8. Can a person test negative and later test positive for COVID-19?

A negative result means that the virus that causes COVID-19 was not found in the person's sample. In the early stages of infection, it is possible the virus will not be detected. For COVID-19, a negative test result for a sample collected while a person has symptoms likely means that the SARS-CoV-2 (COVID-19) virus is not causing their current illness.

For more information on each virology test Quest Diagnostics performs, visit the following:

- Quest LDT: https://www.fda.gov/media/136231/download
- Roche: https://www.fda.gov/media/136049/download
- Hologic Panther Fusion: https://www.fda.gov/media/136156/download
- Hologic Panther COVID-19 molecular assay: https://www.fda.gov/media/136153/download

9. What is the likelihood of an employee receiving a false negative result?

The COVID-19 molecular tests in use at Quest Diagnostics under an Emergency Use Authorization (EUA) from the FDA include our lab-developed test (LDT) and the Roche assay. FDA has not required that assays be clinically validated for this emergency use; all assays in use at Quest have been analytically validated. Formal studies of "false negative" rates are not FDA-required for any EUA tests and therefore no studies have been performed on the assays used at Quest. To read about the analytical performance of the COVID-19 molecular tests in use at Quest, see the publicly available information located on the FDA website.

10. Can an employee have a specimen collected for SARS-CoV-2 molecular testing at a Patient Service Center (PSC)?

No. PSCs will not be collecting specimens for molecular tests. Anyone with active COVID-19 symptoms should not go to a PSC. All molecular specimen collection should be completed through self-collection (observed or unobserved) or by a healthcare provider.

11. Previously you mentioned you were using a mid-turbinate nasal swab. Why did you switch to an anterior nares nasal swab?

The FDA required the switch to the anterior nares swab to make the self-collection process easier and less invasive for participants. In addition to the easier collection method, Quest Diagnostics has also added additional testing on each self-collected specimen to ensure the collection was completed. More information on this additional test is presented in question 12 on the following page.

12. Can an employee receive a false positive result?

The Quest SARS-CoV-2 RT-molecular test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other patients potentially infected with COVID-19, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

13. How long will it take for my employees to get their SARS-CoV-2 (COVID-19) molecular test results?

Turnaround times may vary due to high demand. For current estimates, visit https://newsroom.questdiagnostics.com/COVIDTestingUpdates.

14. How will my employees receive their molecular test results?

Individuals will be able to receive their molecular test results online at My.QuestForHealth.com. In addition, if a test is positive, employees will receive a phone call from PWNHealth, the medical oversight provider, to provide guidance on appropriate medical follow-up care.

15. Will participants receive a printed copy of their molecular test results?

No. At this time individuals will not receive a physical copy of their molecular test results. Results will only be available online.

16. What if a specimen is unable to be processed?

The invalids process is determined by the employer in conjunction with Quest Diagnostics. If applicable, per employer direction, employees who receive an invalid are able to complete another nasal swab.

17. Where does Quest Diagnostics conduct SARS-CoV-2 molecular specimen testing?

Quest is performing molecular testing at 12 laboratories in its national network. Three of these laboratories perform both the company's lab-developed Quest SARS-CoV-2 molecular test (which was granted FDA emergency use authorization on March 17) and the highly automated Roche cobas® SARS-CoV-2 Test. These labs are in San Juan Capistrano, CA; Chantilly, VA; and Marlborough, MA.

18. How long does Quest store molecular specimens before discarding them?

Generally, molecular test specimens are discarded 3 days following testing, with positive samples retained for approximately 5-7 days depending on demand and storage capacity.

19. Who developed the qualifying questionnaire that Quest is using? Is this questionnaire customizable?

PWNHealth, the organization providing medical oversight, developed the questionnaire and question logic based on CDC guidelines. The questionnaire is not customizable.

20. If an employee tests negative for the virus, can they return to work?

Quest Diagnostics provides results to the individual and does not make the determination if employees should or should not be eligible to return to work. Employers must set policies for whether or not an employee may return to work in accordance with their disaster relief policies and business needs. Quest Diagnostics cannot make the determination about whether an individual can return to work. Quest can only provide clinical information regarding the employee's COVID-19 status.

21. Why are race and ethnicity required on an eligibility file for molecular testing?

Many state and local public health departments are requiring race and ethnicity information to be reported along with positive and negative COVID-19 test results. In order to comply with these regulations, PWNHealth, the organization that orders medical testing and provides medical oversight for molecular testing through Quest Diagnostics, is requiring this information be present on all eligibility files for molecular testing programs they are overseeing.

22. Why are state and local health departments requiring race and ethnicity to be reported?

Having access to data such as race, age, ethnicity, etc. helps researches and public health officials learn how diseases may impact different groups of individuals in our communities. With this information, policymakers and public health administrators can then make informed decisions on how to best allocate public health resources and promote health equity. For more information on why demographic reporting is necessary during the COVID-19 pandemic, visit the John's Hopkins Coronavirus Resource Center.

COVID-19 Return-to-work testing: semiquantitative IgG Antibody testing FAQs

23. What is an antibody?

An antibody (also known as an immunoglobulin) is part of our body's response to a foreign molecule or pathogen (also known as an antigen) such as a virus or bacterium. This is valuable to fight off infection. Protective antibodies can provide immunity, so we do not become reinfected with the same viruses or bacteria. Antibodies are vital for our health. The protection antibodies provide may last a lifetime, or only a matter of months. And we don't always develop antibodies—or the right antibodies in sufficient quantity—to fight off all infectious diseases. It is not yet known how much protection the SARS-CoV-2 antibodies may provide, or for how long.

24. What is the Quest Diagnostics COVID-19 antibody test?

The Quest Diagnostics antibody test is a venipuncture blood draw that can be completed at a Quest Diagnostics Patient Service Centers (PSCs). The Quest antibody test detects the presence of IgG antibodies in the blood. It usually takes at least 10 days after symptom onset for IgG antibodies to reach detectable levels. An IgG positive result may suggest immunity after resolution of primary infection, but the relationship between IgG positivity and immunity to SARSCoV-2 has not yet been firmly established. During the SARS (SARs-CoV) outbreak, it was shown that presence of IgG is an indicator for immunity for up to 2 years.

IgG antibody test results are reported as positive at an index of ≥1.00. This positive result indicates that an individual has developed an immune response to a SARS-CoV-2 infection or a SARS-CoV-2 spike vaccine within the limits of the assay.

Conversely, a negative result is reported at an index3 of <1.00. A negative semi-quantitative antibody result means that the patient serum specimen had no SARS-CoV-2 spike IgG antibodies, or that the relative level of antibodies in the patient specimen was below the index cutoff.

The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARSCoV-2 is necessary. The test should not be used to diagnose acute SARS-CoV-2 infection. False positive results for the test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

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- This test has been authorized by FDA under an EUA for use by authorized laboratories;·
- This test has been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and, · This 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.

25. Why can antibody specimens be collected at PSCs, but not COVID-19 molecular specimens?

COVID-19 molecular tests are looking for an active viral infection, and individuals who may need a molecular test are likely to be symptomatic and can infect others. In order to prevent the spread of the disease, PSCs will not be collecting molecular specimens. Individuals who may need antibody testing are those who are asymptomatic, have not had the disease, and/or have already recovered from the disease. They are less likely to infect others.

Quest Diagnostics will be requiring all individuals who visit a PSC (for antibody testing or other reasons) to wear a face covering and have their temperature taken upon arrival. Anyone who has a fever of 100.3 degrees or higher or exhibits symptoms of COVID-19 will have to reschedule their appointment.

26. If an employee tests positive for SARS-CoV-2 IgG antibodies, can they return to work?

A negative molecular test (no current infection) and a test that is considered positive for IgG antibodies suggest prior exposure and/or a prior infection which may be resolved or resolving. With other coronaviruses, the presence of antibodies indicated some protection against reinfection (“protective immunity”). Whether this is true of the SARS-CoV-2 antibodies is not yet proven. Employers must set policies for whether or not an employee may return to work in accordance with their disaster relief policies and business needs. Quest Diagnostics cannot make the determination if an individual can return to work. Quest can only provide clinical information regarding the employee’s antibody status.

27. How long will it take for my employees to get their antibody test results?

Turnaround times may vary due to high demand. For current estimates, visit https://newsroom.questdiagnostics.com/COVIDTestingUpdates.

28. How will my employees receive their antibody test results?

Individuals will be able to receive their antibody test results online at My.QuestForHealth.com.

29. Will participants receive a printed copy of their antibody test results?

Yes. Individuals will be able to see their antibody testing results online and will also receive a paper results report in the mail approximately 10-15 days after their appointment.

30. What does it mean to have a SARS-CoV-2 IgG result that is considered positive?

A result considered positive for IgG antibodies suggests recent or prior infection with SARS-CoV-2. It usually takes at least 10 days after symptom onset for IgG detectable levels to be reached. Patients tested prior to this time may be negative for SARS-CoV-2 IgG antibodies. An IgG positive result may suggest an immune response to a primary infection with SARS-CoV-2, but the relationship between IgG positivity and immunity to SARS-CoV-2 has not yet been firmly established.

31. If an employee has been diagnosed with COVID-19 disease, when should they get an antibody test performed?

If an individual was suspected of having (or diagnosed with) COVID-19 disease, they should wait to obtain an IgG antibody test until they are both symptom free and at least 10 days since symptoms began in order to allow enough time for IgG antibodies to develop to detectable levels.

32. Which assays is Quest Diagnostics using to conduct antibody testing for COVID-19?

In order to maximize our capacity and flexibility for testing in this time of need, Quest Diagnostics is utilizing several technologies to perform antibody testing for COVID-19. Quest may add more manufacturers in the future to adjust the supply situation.

33. Is it true that serology tests for COVID-19 have a high false-positive rate?

There are many point of care (POC) tests out in the market that have not been validated and/or have no EUA from the FDA. Many of these fingerstick tests show false positives or false negatives. This has resulted in the FDA being more restrictive with those testing options. All SARS-CoV-2 serology tests used by Quest Diagnostics have been analytically validated by the manufacturers and analytically verified by Quest to ensure quality.

34. What is the sensitivity and specificity for SARS-CoV-2 (COVID-19) IgG antibody testing from Quest?

Sensitivity is normally used in the context of measuring sensitivity to detect the disease, however, in the context of serology, you are only measuring sensitivity to antibodies, not SARS-CoV-2. Because antibody testing is not used for diagnosis, sensitivity is less important than specificity. The focus is on maximizing specificity for IgG so that we have no false positives. Quest Diagnostics ensures that tests offered for SARS-CoV-2 IgG are extensively validated by manufacturers to be highly specific. Quest is also performing our own supplementary validation using stringent acceptability criteria for precision, reproducibility, accuracy, method comparison, cross reactivity and clinical performance before starting patient testing.

Quest is using 3 antibody tests manufactured by Ortho Clinical, Abbott, and EUROIMMUN. As stated in literature provided by Ortho Clinical, the snalytical specificity is 100%. As stated in literature provided by Abbott, analytical specificity of the Abbott IgG antibody test is 99.4%. As stated in literature provided by EUROIMMUN AG, analytical specificity of the EUROIMMUN Anti-SARS-CoV-2 ELISA IgG antibody test is 98.5-99%.

The FDA does not consider SARS-CoV-2 IgG antibody tests to be diagnostic for COVID-19. Diagnostic testing for COVID-19 disease relies on RNA detection. Therefore, the importance of IgG "sensitivity" is not paramount. FDA and other experts are emphasizing specificity over sensitivity. Both tests are highly accurate. Specificity in banked sera was around 98-100% in several populations. Sensitivity in patients at least 14 days after symptom onset was reported as 100%.

Estimated assay sensitivity is >99.9% for specimens collected at least 15 days post–symptom onset, based on positive percent agreement (PPA) of SARS-CoV-2 IgG serology results among SARS-CoV-2 RNA−positive patients.

Estimated assay specificity is approximately 99.9% based on negative percent agreement (NPA) assessed by performing cross-reactivity studies utilizing serum specimens positive for antibodies to other respiratory viruses pre– and post–COVID-19 time periods.

Sources:
Centers for Disease Control and Prevention. 2020. Coronavirus Disease 2019 (COVID-19). Accessed April 15, 2020 https://www.cdc.gov/coronavirus/2019-ncov/index.html

Li-Ping Wu, et.al. Duration of antibody responses after Severe Acute Respiratory Syndrome. *Emerg Infect Dis*. 2007: 13(10);1562-1564. doi: 10.3201/eid1310.070576