Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

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

1. What is coronavirus (COVID-19)?

Coronavirus disease 2019 (COVID-19), formally known as 2019-nCoV, is the name for the respiratory syndrome caused by the virus SARS-CoV-2 (severe acute respiratory syndrome coronavirus 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 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 through respiratory transmission. Transmission typically occurs from being in close contact (within about 6 feet) with an infected individual, who may cough or sneeze producing respiratory droplets. . 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 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 state of Arizona in this time of crisis, Sonora Quest Laboratories is focusing on this prioritization with offerings and testing availability.

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

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

5. What is the Sonora Quest Laboratories COVID-19 virology test?

The virology test for SARS-CoV-2 (COVID-19) from Sonora Quest is a reverse transcription polymerase chain reaction (RT-PCR) 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 emergency use authorization (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 Sonora Quest Roche and Hologic and testing?

For PCR we are using the Roche and Hologic systems.

The FDA EUA site has manufacturing information for the PCR test. 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.

- Roche IFU: https://www.fda.gov/media/136049/download
- Hologic IFU: https://www.fda.gov/media/136156/download

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

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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 Sonora Quest performs, visit the following:

- Sonora Quest Laboratories website: https://www.sonoraquest.com/coronavirus
- Roche: https://www.fda.gov/media/136049/download
- Hologic: https://www.fda.gov/media/136156/download

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

The COVID-19 PCR test in use at Sonora Quest Laboratories under an EUA from the FDA include the Roche and Hologic assays. FDA has not required that assays be clinically validated for this emergency use; the RT-PCR testing in use at Sonora Quest has 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 Sonora Quest. To read about the analytical performance of the COVID-19 PCR tests in use at Sonora Quest, see the publicly available information located on the FDA website.

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

No. PSCs will not be collecting specimens for RT-PCR tests. Anyone with active COVID-19 symptoms should not go to a PSC. All RT-PCR testing should be completed through monitored self-collection or by a healthcare provider.

11. Can an employee receive a false positive result?

The Sonora Quest SARS-CoV-2 RT-PCR 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.

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

The average turnaround time to report SARS-CoV-2 (COVID-19) RT-PCR test results is 3-5 days after Sonora Quest Laboratories receives the specimen.

13. How will my employees receive their COVID-19 RT-PCR test results?

Individuals will be able to receive their COVID-19 RT-PCR test results online at SonoraQuest.com/results.

14. Will participants receive a printed copy of their COVID-19 PCR test results?

No. At this time, individuals will not receive a physical copy of their COVID-19 PCR test results. Results will only be available online.

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

The invalids process is determined by the employer in conjunction with Sonora Quest Laboratories. If applicable, per employer direction, employees who receive an invalid are able to complete another monitored COVID-19 nasal swab.

16. Where does Sonora Quest Laboratories conduct SARS-CoV-2 RT-PCR specimen testing?

Sonora Quest is performing RT-PCR testing at its main laboratory located in Phoenix.

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

Sonora Quest Laboratories 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. Sonora Quest cannot make the determination about whether an individual can return to work. Sonora Quest can only provide clinical information regarding the employee's COVID-19 status.

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

18. 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 do not 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.

19. What is the Sonora Quest Laboratories COVID-19 antibody test?

The Sonora Quest Laboratories antibody test is a venipuncture blood draw that can be completed at a Sonora Quest Patient Service Centers (PSCs). The Sonora 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 SARS-CoV-2 has not yet been firmly established. During the SARS (SARs-CoV-1) outbreak, it was shown that presence of IgG is an indicator for immunity for up to 2 years.

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 SARS-CoV-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.

- 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 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.

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

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

Sonora Quest Laboratories will be requiring all individuals who visit a PSC (for antibody testing or other reasons) to wear a face covering.

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

A negative PCR test (no current infection) and a test that is 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. Sonora Quest Laboratories cannot make the determination if an individual can return to work. Sonora Quest can only provide clinical information regarding the employee's antibody status.

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

The average turnaround time to report antibody test results is 3-5 days after the completed blood draw.

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

Individuals will be able to receive their antibody test results online at SonoraQuest.com/results.

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

No. At this time individuals will not receive a physical copy of their COVID-19 PCR test results. Results will only be available online.

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25. What does it mean to have a detectable SARS-CoV-2 IgG result?

A positive IgG antibody test result 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.

26. 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.

27. Which assays is Sonora Quest Laboratories using to conduct antibody testing for COVID-19?

The testing that Sonora Quest Laboratories is utilizing to perform antibody testing for COVID-19, was developed by EUROIMMUN. The test developed by EUROIMMUN has received FDA EUA for processing in clinical laboratories.

28. 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. The SARS-CoV-2 serology test used by Sonora Quest Laboratories has been analytically validated by the manufacturers and analytically verified by Sonora Quest to ensure quality.

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29. What is the sensitivity and specificity for SARS-CoV-2 (COVID-19) IgG antibody testing from Sonora 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. Sonora Quest Laboratories ensures that testing offered for SARS-CoV-2 IgG are extensively validated by manufacturers to be highly specific. Sonora 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.

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. The test is 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%.

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