COVID-19

Testing: Answers to Frequently Asked Questions

Testing is an option for employers seeking to monitor the health of employees who have remained on the job during the COVID-19 pandemic or are returning to work as restrictions are lifted and businesses ramp up.

The following are answers to frequently asked questions about COVID-19 testing:

Q: *What types of tests can be provided in the workplace?*

A: There are two basic types of COVID-19 tests: molecular (PCR)-viral (antigen) tests to confirm current infection and serology (antibody) tests to identify whether someone has been infected by SARS-CoV-2. Both types may be provided by onsite clinical staff.

Q: *What factors are important to consider when deciding whether to provide tests?*

A: When evaluating test options, factors for employers to consider include reasons for testing; test sensitivity and specificity; populations for testing; current community infection rates; and frequency and delivery of tests.

Q: *What is the difference between test sensitivity and specificity?*

A: Several factors affect the sensitivity and specificity of test results. These include the instruments and chemical reagents used to perform the test, timing and quality of specimen collection, and each test subject's biological profile. Laboratory tests are characterized by their ability to accurately detect a positive result (sensitivity) and identify a negative result (specificity). In other words, a sensitive test is less likely to provide a false-negative result and a specific test is less likely to produce a false-positive result. When evaluating test options, it is important to check validation data provided by the manufacturer and/or CLIA-certified laboratory. Refer to Clinical Laboratory Improvement Amendments (CLIA) to learn more about regulations governing lab operations. Optimally, sensitivity is at least 95 percent and specificity is 98-100 percent.

Q: *What do we learn from tests beyond positive or negative results?*

A: With viral testing, an employee may have symptoms but not know whether they have COVID-19 or another type of illness or condition, such as a cold or seasonal allergy. In some cases, an employee may be an asymptomatic disease carrier, which means he or she has the virus but no symptoms and is unaware of being contagious. Antibody tests help detect those who have COVID-19 and are in the process of

developing immunity, or who are presumed to be immune after recovering from COVID-19. Antibody testing is not recommended for diagnosing acute infections.

Q: What is the expected return on an investment in workplace testing?

A: Testing supports a process to keep healthy employees on the job and workers with exposure risk or illness at home until a physician determines it is safe to clear them for return to work. Test results give employees information to make informed decisions about their personal health and preventive steps they can take to protect their co-workers and family members. This helps reduce anxiety and ensure appropriate care is received, if needed. Testing also demonstrates a company has done all it can to protect its employees, customers, visitors and the community at large from potential exposure. In addition, test results collectively offer insights for staffing, production and service delivery decisions, and when implementing pandemic response plans. Testing can be particularly effective when combined with protection measures including daily screening, social distancing and good hygiene practices.

Q: Which tests are approved for use in the U.S.?

A: In response to the pandemic, the U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for more than 100 tests – and the list continues to grow. It's advisable to check the FDA's website for the current EUA list. EUA is not the same as an FDA-approved or FDA-cleared product. Under Section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act), the FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions. Some tests on the market have not obtained EUA and their quality cannot be verified.

Q: What are molecular tests?

A: Molecular tests, also called nucleic acid amplification (NAAT) tests or polymerase chain reaction (PCR) and quantitative reverse transcriptase PCR (qRT-PCR) tests, are used to identify the presence of virus.

Q: What is PCR?

A: PCR tests detect the presence of viral ribonucleic acid (RNA) in the body's cells. PCR is a technique used to amplify or copy small segments of DNA for molecular and genetic analyses. DNA, or deoxyribonucleic acid, is the genetic code that occupies nearly every cell in a person's body. These tests are based on the unique genetic sequence of SARS-CoV-2. A PCR reaction requires reagents, which are ingredients used to isolate and purify nucleic acids from starting material. The accuracy of these tests may vary depending on the laboratory process.

Q: What is a qRT-PCR test?

A: This is a PCR test that allows measurement of gene expression in real time.

Q: What is diagnostic testing?

A: Diagnostic, viral, molecular and antigen are all terms that refer to tests that confirm a SARS-CoV-2 infection. These tests involve the collection of secretions, such as those obtained using nasal or throat swabs or a saliva (spit) test. Some tests are performed at the point of care with rapid results (within 30 minutes). Test specimens collected at other locations, such as hospitals, doctors' offices, onsite clinics or at home using a self-administered kit, are sent to a laboratory for analysis. With shipping, turnaround time for results is several days.

Q: What are antigen tests?

A: Antigen tests detect the presence of viral proteins that are part of the SARS-CoV-2 virus. These tests are often faster and easier to do. However, they're

not as sensitive as molecular tests. A positive result is highly accurate, but there is a higher chance for a false-negative result. Negative results from an antigen test may need to be confirmed with a molecular test before making treatment decisions and to prevent spread of disease due to a false-negative result. Immunoassays involve a biochemical process that can be used to test for the presence of a specific antibody or antigen in body fluids.

Q: What are antibody tests?

A: Antibody tests involve checking blood samples acquired with a blood draw or finger prick for immune-proteins that help fight infection. Antibody tests reveal the presence of IgG and IgM, two molecules in the blood which are antibodies produced by the immune system ***(Table 1)***. IgM starts to be produced with the onset of symptoms and becomes detectable after five to seven days of illness. IgG is typically measured starting two to three weeks after symptoms occur.

Q: How do saliva tests work?

A: The test detects an active SARS-CoV-2 infection. The donor spits into a sterile tube that is sealed for shipping to a lab. Laboratory testing detects unique genetic markers in saliva that are specific to the virus. The home/work test kit offered as a testing solution by WorkCare has a high degree of sensitivity and specificity.

Q: How can we be sure if someone is immune to COVID-19?

A: Based on experience with other viruses, a person with a positive antibody test has had COVID-19 and is presumed to be immune for an undetermined length of time. According to the FDA, the duration of time antibodies can be detected is not yet well-characterized. The Centers for Disease Control and Prevention (CDC) reports that the extent to which antibodies provide short- or long-term immunity against COVID-19 also is unclear.

Q: Who should be tested, and how often?

A: Employers may elect to test employees with exposure risk, those who have had symptoms, a representative sample or an entire working population. Testing 100 percent of a workforce for the virus and antibodies is a best-practice recommendation for surveillance programs because it establishes baselines for future comparisons and a more accurate way to predict case rates and presumed immunity in the test population over time. Testing frequency typically depends on business objectives, the industry type and likely exposure risk.

TABLE 1: COVID-19 ANTIBODY TESTING

Test Results			Clinical Significance
RT-qPCR	IgM	IgG	
+	–	–	Patient may be in the early asymptomatic window of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stages of infection or PCR result may be false-negative.
–	–	+	Patient may have had a past infection and has recovered.
–	+	+	Patient may be in the recovery stages of infection or PCR results may be false-negative.

The CDC has issued guidance on who should be tested. For example:

High Priority

- Hospitalized patients ***with*** symptoms
- Health care facility workers, workers in congregate living settings and first responders ***with*** symptoms
- Residents in long-term care facilities or other congregate living settings, including prisons and shelters, ***with*** symptoms

Priority

- People ***with*** symptoms of potential COVID-19 infection, including fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.
- People ***without*** symptoms who are prioritized by health departments or clinicians for any reason, including public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

Clinicians are advised to use their judgment to determine whether a person should be tested. Initially, with widespread test shortages in the U.S., patients with high exposure risk and obvious symptoms were not tested. Instead, available tests were saved for cases with less clear indicators. Other considerations that may guide the selection of test subjects are epidemiologic factors, such as the occurrence of local transmission in a workplace or community.

Q: What is the government's guidance on testing protocols for specimen collectors?

A: Refer to the CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens. For home test kits, refer to the FDA's COVID-19 Test Home Collection Kit instruction sheet.

If you have additional questions about COVID-19 testing, please send them to communications@workcare and our occupational health physicians will answer them.