

COVID-19 questions and answers for U.S. employers:

Coronavirus testing

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Please note: For the most up-to-date information and resources, visit the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH). The CDC should be your primary source for emergency preparedness and response to the coronavirus. The below information is designed to guide businesses to known, credible online resources covering the coronavirus and does not constitute medical advice.

Employers with offices outside the U.S. should review their statutory obligations for reporting suspected cases and paid time off policies with employment counsel to ensure compliance with local and national legislation.



Coronavirus testing

For an overview of COVID-19 testing, refer to <u>CDC guidance</u>.

For additional testing information, refer to Lockton's testing guide for employers.

What strategies should employers consider for the use of testing for the SARS-CoV-2 virus?

Testing is a process and should be part of a comprehensive approach to reducing transmission of the virus. In non-healthcare workplaces, this approach consists of four key areas: (1) daily screening for COVID-19 related symptoms and potential exposure, (2) testing in certain circumstances, (3) contact tracing to identify those potentially exposed based on close contact (within 6 feet for more than 15 cumulative minutes), and (4) clinical and return to the workplace management.

Employers should develop a plan for managing employees who are exposed to the virus in the workplace with respect to testing. This may include:

- Deferring to the employee's healthcare provider for guidance.
- Referring to local test sites such as CVS, Walmart, Walgreens or local urgent care facilities; a doctor's order is not needed.
- Providing a home test kit.
- Offering on-site testing through a vendor. In some cases, there can be delays of 2-3 weeks to coordinate, which render testing ineffective. Availability for rapid testing outside of urgent care facilities and healthcare providers is limited.
- Partnering with a local urgent care facility that will provide rapid testing on-site. This will require pre-work to identify options for testing asymptomatic people. <u>Castlight provides a COVID-19 test site finder</u>.

Ideally, the timing of the test should occur five to seven days after exposure to ensure anyone who has the disease has developed a viral load for an accurate result. In some cases, these tests (especially the home test) may need to be repeated for more accurate results.

Employers seeking to test employees or executives prior to a group meeting should plan at least three weeks prior to ensure a provider can be identified. Employers should collaborate with their <u>state and local public health departments</u> when considering implementing a testing process as part of their overall COVID-19 response strategy.

Who should get tested?

The timing of viral tests (also called molecular or PCR tests) is important and is why broad-based testing of asymptomatic employees presents challenges and potentially flawed results. Viral tests check samples from the respiratory system for the presence of the infection and are a point-in-time test, which means they do not capture results of future exposure. Additionally, in the early days of the infection, the viral load may not be high enough and give a false negative result whereas the sample collected in days 5-7 of the infection may test positive. There is a risk that the employee who is tested at work early in their infection will think they are negative and not attribute new symptoms to the virus, even though they could be contagious. If the test is performed in the later stages of the infection (i.e., 10-14 days), the person could test positive but no longer be contagious. To ensure accuracy of broad-based testing, employees would need to be tested 1-2 times per week.

The CDC describes strategies for viral testing.

We would like to coordinate rapid testing on-site when we have a COVID-19 outbreak.

A proactive approach is to partner with local test centers that offer the rapid test. There are several ways to identify the test center and look for "rapid testing":

- Use of the Castlight test finder
- CVS, Walgreens, CareNow clinics and Walmart offer rapid testing
- Local urgent care centers- if not found on the Castlight app, perform a local search (some local UC centers may even come on-site); these sites list whether they provide rapid or standard PCR testing
- Many public health departments list testing centers available in local areas

Another option is to consider home test kits while those exposed are in self-quarantine.

Timing of testing is important to avoid testing too early and risking a false negative test. If a person in the workplace is diagnosed with the virus, those who were exposed/in close contact with that person should have the test performed between 5-7 days from first exposure (defined as up to 48 hours prior to the infected person developing symptoms).



There are antigen rapid tests being developed that will not require a healthcare provider. They will be self-administered like a pregnancy test. It's expected they'll be much less costly, and timing is unknown.

Can employers require COVID-19 testing for an employee who initially tested positive for the virus to return to work?

No. According to the CDC, a person testing positive for COVID-19 who has symptoms can return to work after:

- At least 10 days elapsed since symptoms first appeared **and**
- At least 24 hours have passed with no fever without fever-reducing medication **and**
- Other symptoms of COVID-19 are improving

Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation. If the employee was asymptomatic, they can return to work 10 days following a positive test result.

Currently, the CDC advises that once an individual recovers from the symptoms associated with COVID-19 after testing positive for the virus, they may continue to test positive for three months or more without being contagious to others. For this reason, testing should only be used if new symptoms develop and then testing should only occur after guidance from a healthcare provider.

Click <u>here</u> to read more about ending home isolation for persons not in healthcare settings.

What information should employees be provided about testing?

The FDA requires tests which have received <u>emergency use authorization</u> (EUA- current COVID-19 test authorization) provide a patient fact sheet. Employee's undergoing testing should receive information on:

- The manufacturer and name of the test, type and purpose of the test, reliability and any limitations associated with the test
- Who will pay for the test and how it will be performed



• How to understand what the results mean, actions to take, particularly if the test is positive, who will receive the results and how they will remain confidential, and any consequences for declining the test

Can a person test negative but later test positive for the coronavirus?

The short answer is yes. Using an FDA EUA diagnostic PCR test, a negative result means the virus that causes the coronavirus was not found in the person's sample. In the early stages of infection, it is possible the virus will not be detected, resulting in a false negative, but the person is able to transmit the disease. A negative PCR test result for a sample collected while a person has symptoms likely means the coronavirus is not causing their current illness.

Rapid point-of-care antigen tests, which look for the protein of the virus, may be used at mobile test locations. These tests are not sent to the lab and results are provided during the visit. These tests are between 85-98% sensitive in identifying the SARS-CoV-2 virus. If an individual has symptoms and the antigen test is negative, they should have a viral (PCR) test which is sent to the lab to confirm results.

As more employees return to work, may an employer administer a COVID-19 test (a test to detect the presence of the COVID-19 virus) when evaluating an employee's presence in the workplace?

The ADA requires that any mandatory medical test of employees be "job related and consistent with business necessity." Applying this standard to the current circumstances of the COVID-19 pandemic, employers may take screening steps to determine if employees entering the workplace have COVID-19 because an individual with the virus will pose a direct threat to the health of others. Therefore, an employer may choose to administer COVID-19 testing to employees before initially permitting them to enter the workplace and/or periodically to determine if their presence in the workplace poses a direct threat to others. The ADA does not interfere with employers following recommendations by the CDC or other public health authorities regarding whether, when, and for whom testing or other screening is appropriate. Testing administered by employers consistent with current CDC guidance will meet the ADA's "business necessity" standard.

Employers do need to ensure that the tests are considered accurate and reliable. Employers may wish to consider the incidence of false-positives or false-negatives associated with a particular test. Note that a positive test result reveals that an individual most likely has a current infection and may be able to transmit the virus to others. A



negative test does not guarantee someone does not have COVID-19, especially in screening individuals that are asymptomatic or may be early in the infection. A negative test result means that the individual did not have detectable COVID-19 at the time of testing. A negative test does not mean the employee will not acquire the virus later. Based on guidance from medical and public health authorities, employers should still require – to the greatest extent possible – that employees observe infection control practices (such as social distancing, regular handwashing, wearing masks in public places and other measures) in the workplace to prevent transmission of COVID-19.

Workplace-based testing should not be conducted without the employee's informed consent. Employees undergoing testing should receive clear information on:

- The manufacturer and name of the test, the type of test, the purpose of the test, the performance specifications of the test, any limitations associated with the test, who will pay for the test, how the test will be performed, how and when they will receive test results, and;
- How to understand what the results mean, actions associated with negative or positive results, the difference between testing for workplace screening versus for medical diagnosis, who will receive the results, how the results may be used, and any consequences for declining to be tested.

The <u>CDC</u> emphasizes the necessity that an employee have the ability to make a free decision on testing according to their values, goals and preferences and provides guidance for employers developing a program.

Regardless of whether an employer relies on in-house medical staff, a third-party service provider, or employees themselves to collect the specimen for COVID-19 testing, most employers will have no choice but to rely on a third-party lab to test the specimen for the presence of COVID-19. Many testing labs are "covered entities" subject to HIPPA. When a HIPAA-covered lab conducts the COVID-19 test, the test results and all related health and demographic information are protected health information (PHI) that must be handled in compliance with HIPPA.

HIPAA generally prohibits a covered entity from disclosing PHI without the subjects first executing a HIPAA-compliant authorization. Labs subject to HIPAA cannot disclose COIVD-19 test results to the employer without a HIPAA-compliant authorization executed by the employee. Employers should include in their employee-testing packet a HIPAA compliant authorization form that employees must sign and provide to the testing lab when the testing lab is subject to HIPAA. If using a testing lab that is not



subject to HIPAA, the employer would avoid the need for this authorization; however, that benefit does not necessarily outweigh the advantages of using a HIPAA-covered testing lab because HIPAA-covered labs are required to implement the extensive information security safeguards required by the HIPAA Security Rule, which reduces the risk of a security breach involving COVID-19 test results. Additionally, an employee may have a greater level of trust in a HIPAA-covered testing lab and be less likely to refuse to participate in the testing program.

The ADA requires employers to maintain the confidentiality of the results of employee medical examinations. Test results must be maintained in a confidential medical file separate from the general personnel file. Only those employees who need the test outcome to protect the workplace from COVID-19 infection should be granted access to the information. Those employees authorized to review test results should be trained not to disclose them to third parties with one important exception – employers may disclose positive COVID-19 test results to relevant public health authorities.

Employers who mandate workplace testing should discuss further with employees who do not consent to testing and consider providing alternatives as feasible and appropriate. If an employee requests a reasonable accommodation with respect to the employer's COVID-19 testing program, the employer would be well advised to follow an ADA-compliant reasonable accommodation process. An employer should consider including a provision regarding reasonable accommodations for employees unable to submit to COVID-19 testing due to a disability or a sincerely held religious belief.

Can we require routine testing for unvaccinated employees?

Some private companies already require routine COVID-19 tests for unvaccinated employees. The protocol for paying for these tests ranges from the company bearing the full cost, to employees paying a copay, to requiring employees bear the full expense. Some states may require employers to cover the cost of mandatory testing, so be sure to check state and local statues.

Do we have to compensate employees for routine COVID-19 testing if they don't want the vaccine?

At this time, the informal guidance from the Department of Labor is that employees should be compensated for the time spent being tested for COVID-19.



Can testing be a requirement for an employee who receives a vaccine exemption if the employer pays for testing?

Yes. Testing would be a reasonable accommodation

Do private employers need to have an alternative testing program?

If a private employer is mandating the vaccination, they are not required to have an alternative testing program for unvaccinated persons. Regular COVID-19 testing would potentially be a reasonable accommodation under the ADA and/or Title VII for employees with a medical reason for not being vaccinated or a religious objection to the vaccine.

What else should an employer consider when thinking about implementing a testing procedure as employees begin to return to work?

When contracting with a testing lab, employers may want to consider options for exiting the arrangement by including language regarding their right to terminate the agreement without cause or penalty within a reasonable notice period to allow for completion of scheduled testing and find another vendor, if needed. The agreement can also allow for immediate termination by the employer upon a reasonable determination that the vendor poses a threat to the health or safety of employees or the vendor loses its license or authorization to perform the testing.

An employer may also want to include indemnification language in the lab agreement as protection should they fail to comply with applicable laws, regulations or guidance or engage in gross negligence or willful misconduct. Employers can seek to require testing vendors to carry insurance and minimum coverage amounts, including professional and cyber liability, covering the testing services furnished and any liability arising from testing.

Can an employer exclude fully vaccinated employees from a testing program?

Yes. CDC guidance says fully vaccinated people with no COVID-like symptoms and no known exposure should be exempted from routine screening testing programs, if feasible.



Are there certain businesses or industries that are requiring regular testing of all employees?

We have seen in the past, especially in high prevalence and high exposure areas, testing required in industries where there is high exposure to the virus, such as hospitals, or vulnerable groups in an effort to bring their employees back to work, and occasionally testing on a regular basis thereafter (such as monthly), although the cadence is more anecdotal than evidence based. These industries have included:

- Hospitals, surgery centers, emergency centers and other healthcare facilities
- Nursing homes, long-term care facilities and group homes
- Emergency responders
- Correctional facilities
- Homeless centers
- People that travel frequently for work (e.g., sales)
- Casinos
- Critical infrastructure

I'm seeing offers from companies to send a coronavirus test kit to my home. Is this an approved test method?

The FDA has given EUA to several home test kits, and continues to evaluate others submitted for authorization, since it "sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection." The sample methods include nasal swab and sputum. A doctor's order is not needed as a medical order is included with the test. Home test providers vary in terms of allowing testing for asymptomatic people and should be verified. To stay up to date on the latest FDA approvals for coronavirus testing, please visit the <u>FDA website</u>.

Two of the three home-kits most commonly seen and available in pharmacies require two tests, 36-hours apart. This improves the accuracy of the results.

Employers will be invoiced for at-home testing for workplace COVID-19 surveillance as these are not covered by health plans.

COVID-19 tests intended for at-home testing (including tests where the individual performs self-collection of a specimen at home) must be covered when the test is



ordered by an attending HCP who has determined that the test is medically appropriate for the individual based on current accepted standards of medical practice and the test otherwise meets the statutory criteria of the FFCRA. This coverage must be provided without imposing any cost-sharing requirements, prior authorization or other medical management requirements.

If I do purchase a home test kit, can the results be used by my healthcare provider or public health authority to clear me from self-home isolation or public healthordered quarantine?

Yes, the results may be used by an HCP to diagnose the infection and need for home isolation. If an individual tests negative with a home test kit and has symptoms of COVID-19, an HCP may request a second viral (PCR) test be performed at a test site and sent to the lab for confirmation, or decide to follow the CDC symptom-based approach to release the individual from home isolation. There are circumstances, such as ineffective self-sample collection or testing too early in the infection, which result in a false negative test.

The public health department is not using home test kits for clinical diagnosis.

Where can we locate mobile testing locations?

The two resources below have developed local mobile testing lists and are continually adding new sites and appear to be comprehensive. Because this is a fluid process, Lockton is not confirming the testing locations but providing as free available resources.

- <u>Castlight</u>
- <u>GoodRx</u>

Additionally, testing is being offered in certain locations by CVS pharmacies, Walgreens and Walmart.

Castlight provides additional information:

- <u>COVID-19 Cost Analysis</u>: shows the approximate cost people can expect to see when seeking care for COVID-19 based on geographic location.
- <u>COVID-19 Risk Analysis</u>: Castlight has leveraged their data set of 7 million members to identify individuals who would be at the most risk for serious outcomes from COVID-19 and are living in areas where they may face limited capacity of intensive care beds.



How does the COVID-19 blood test (serology/antibody) work and what should we consider in promoting and providing this test to our employees?

A blood test (serology/antibody test) measures the presence of antibodies in the blood when the body is responding to, or has responded to, a specific infection like COVID-19. They measure the body's immune response to an infection (even for those without symptoms), rather than detecting the presence of a virus itself. These COVID-19 antibody tests should NOT be used to determine someone is immune to COVID-19.

The CDC recommends only considering FDA EUA-approved serology tests, and they should be used only in special circumstances by a healthcare provider.

The CARES Act stipulates that the health plan is to cover these tests as long as they are part of a diagnostic process and the labs are required to post their pricing online. States may have additional provisions for testing.

There are several considerations with these tests:

- Antibody testing should not be used to determine immune status in individuals until the presence, durability and duration of immunity are established.
- Any advertisement that a test is FDA approved is illegal and can be reported to the FDA for investigation and consumer protection. Note that no COVID-19 test has received FDA approval and the FDA has been fast-tracking COVID-19 testing and providing emergency use authorization (EUA), which includes submission of limited test validation. This is the first step of authorization. At a later date, labs will still need to follow the FDA approval process. Labs that have submitted and received authorization for EUA can be found <u>here</u>.
- In the early days of an infection, antibodies may not yet be detectable, even though the virus itself may be detected, so timing is key for the proper use and interpretation of a serological test. There can be false negatives and positives that give people a false sense of security with the possibility of ignoring subsequent symptoms that develop. Antibody testing may be appropriate for population community prevalence studies (i.e., nursing homes or long-term care facilities) or for antibody donations for immune therapy trials.
- Antibody tests may be useful as part of the diagnostic assessment for the virus late in the infectious process (9-14 days) as the PCR sensitivity is lessening and antibodies are developing.



- Antibody tests may also be used to identify healthcare personnel (and first responders) who have overcome an infection or have developed an immune response to the disease and could return to work, although they would still use PPE even if they were positive for the presence of antibodies, per CDC guidance.
- Studies are underway with the FDA in partnership with NIH, the CDC and other academia to address questions that will better inform the appropriate use of these tests, such as whether the presence of antibodies conveys a level of immunity that would prevent or reduce the severity of reinfection as well as the duration for which immunity lasts.
- In the future, serological tests may be used to help determine, together with other clinical data, that individual patients may no longer be susceptible to infection and could possibly return to work.

The World Health Organization <u>recommends</u> the use of these new point-of-care immunodiagnostic serology tests only in research settings. They should not be used in any other setting, including for clinical decision-making, until evidence supporting use for specific indications is available.

The <u>CDC</u> stipulates antibody test results should not be used to determine if someone can return to work and should not be used to group people together in settings such as schools, dormitories and correctional facilities.

Lockton recommends the employer passively cover these through the claims process but not actively promote these tests or bring them on-site, due to the potential risk and liability. When labs are marketing their testing programs, confirming if they have submitted for FDA EUA and where they are in the process will provide insight into their validity measures.

I'm hearing about vendors who will send a healthcare provider to the home to collect my sample for coronavirus testing. Is this authorized testing?

If an HCP has performed a risk assessment and determined that an individual meets the criteria for coronavirus testing, and an HCP makes a house call to collect the sample, it is authorized – as long as the test is being performed by an approved clinical laboratory.



What should we consider when several members of the family test positive for the virus in bringing our employee back to work, given ongoing exposure in the home?

Persons who test positive for SARS-CoV-2 may discontinue home isolation after meeting criteria for the symptom-based approach. Click <u>here</u> for CDC guidance on when to end home isolation. The employee should take precautions at home in terms of sanitizing and disinfecting commonly touched surfaces daily, having their family members wear a mask and not sharing a bathroom. A fully vaccinated person should get tested three to five days following a known exposure to someone with suspected or confirmed COVID-19 and wear a mask in public indoor settings for 14 days after exposure or until a negative test result.

We do not know the degree to which previous COVID-19 illness protects against a subsequent infection or for how long individuals are protected.

Experience from other respiratory viral infections, in particular influenza, suggests that people with COVID-19 may shed detectable viral materials of unknown infectious potential for an extended period after recovery. The best available evidence suggests that most persons recovered from illness with detectable viral RNA (either persistent or recurrent) are likely no longer infectious, but conclusive evidence is not currently available.

The employee's HCP may be able to provide guidance. If the employee cannot telework, and they can wear PPE and isolate from other workers, maintaining 6 feet distancing, etc. while their family is recovering, they should be able to return to the workplace. This employee's previous infection is a known entity which might be able to be carefully managed versus the unknown exposures that are potentially occurring in the workplace from all employee's engagement in the community.

What is the current turnaround time (TAT) for test results?

Coronavirus testing is complex, and TAT depends on the testing methodology and the level of community spread. Readily available rapid tests for symptomatic individuals can deliver results within 15-20 minutes. With specialized, more accurate PCR FDA EUA nasopharyngeal swabs, the usual TAT for results once the sample is received in the laboratory is generally between 24-72 hours. We've seen higher costs for the rapid test versus the standard PCR test by some test sites.



References

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