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Testing Employees for COVID-19

Responses to FAQs From Employers

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As the United States and other countries around the world plan to start sending more people back to work, questions abound about how employers can protect their employees and prevent transmission of the virus in the workplace. Screening for infection and symptoms as well as contact tracing will play critical roles in reducing the chance of a resurgence of cases, and many employers have raised questions about what screening methods are available, how different methods work, and individual rights and privacy considerations associated with testing. This guide answers a number of questions we have received from our clients and colleagues.

Important Disclaimer: The information provided below is based on news reports, scientific publications, and advice from public health authorities and other regulatory agencies which has been collated, reviewed, and summarized by Faegre Drinker scientists. It is introductory, summary, and generalized in nature. It is not a substitute for medical or legal advice about your employees, workplace, or obligations.

COVID-19 is a new disease. Many questions remain and understanding of the virus, its transmission, when infected individuals are contagious, and whether infection confers lasting immunity is continually evolving. The information provided here is based on a growing body of scientific knowledge and will be updated as more information becomes available.

For more return-to-work issues and action items for employers to consider as they contemplate reopening physical work locations, read our Question & Answer Employer Guide: Return to Work in the Time of COVID-19.

Frequently Asked Questions

1. I've read that testing employees can be an important part of preventing an outbreak of infections or a rebound in cases as people come back to work. What kind of COVID-19 tests are available?

Screening approaches for COVID-19 are evolving, and include diagnostic tests for active infection with SARS-CoV-2 (the virus that causes COVID-19), serological assays for screening past infection and other less precise screening methods to identify potential cases of COVID-19 and minimize risk.

Diagnostic Tests to Detect Current or Past Infection

While not yet widely commercially available, there are hundreds of diagnostic tests being developed around the world. As of mid-April 2020, over three dozen commercially available tests had been authorized by the U.S. Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA).[1]

Additionally, FDA has stated that they will not object to the use of tests that have not received EUA, as long as they have been validated and authorized under processes established by the state in which they are conducted. Commercial developers may also supply their tests after they have been validated according to FDA's recommendations and while they are preparing their request for EUA. However, commercial developers that intend to supply their tests before receiving EUA should provide instructions for use and post data about the test's performance characteristics on their website.

All of these tests, FDA authorized or not, can be grouped into two broad categories based on what the test detects and what information about an individual's infection status the results provide.

Nucleic Acid Diagnostic Tests: These account for the majority of FDA-authorized tests and work by detecting viral genetic material from swabs taken from the back of the nasal cavity or from saliva. Administration of these tests involves the insertion of a long swab into the back of the nose or throat. For many of these tests, samples must be analyzed at CLIA-certified laboratories, where technicians use RT-PCR (reverse transcription polymerase chain reaction) to amplify copies of viral genetic material. Typical processing time can range from 24 hours to a couple of days, but may be longer depending on location and lab availability. A positive test is a reliable indicator of the presence of the virus in the person tested and also suggests that individual is infectious. Likewise, a negative test in someone that has previously tested positive for COVID-19 is a reliable indicator that the individual is no longer infectious.

Recently, the FDA has also authorized point-of-care tests. These rely on similar technology, but utilize specialized, automated equipment to process and analyze specimens in a single machine, delivering onsite results in under 45 minutes.[2] These tests may be performed in a patient care setting by appropriately trained staff, such as hospitals, physician's offices, urgent care and temporary patient care settings that are operating under a CLIA Certificate of Waiver or Certificate of compliance[3]. Recent experiences, however, have indicated that certain methods of collection and processing may impact the reliability of these tests, leading to false negatives (i.e., negative results when the person is actually infected), and directions on their administration are being updated.

In addition to point-of-care tests, the first coronavirus testing kit that allows for at-home sampling received EUA approval by FDA on April 21. Other suppliers had begun marketing at-home testing kits in March, but the FDA has since confirmed these other tests were unauthorized. For these at-home sampling kits, individuals use a sterile cotton swab (similar to a Q-tip) to collect a sample from a shallow part of their own nasal cavity. The swab is then sent to a commercial lab for testing. Currently, these kits are available only to health care workers and first responders following completion of a health screening questionnaire. However, these kits and other at-home sampling tests may be made more broadly available in the coming weeks, though a health care provider will still have to order the test based on the results of a questionnaire.

Immunoassays: Immunoassays detect antibodies that individuals produce when infected with SARS-CoV-2. Thus they detect the body's immune response to the virus, rather than the virus itself. The most common of these tests use structural components of

the virus to capture and detect two types of antibodies: IgM (immunoglobulin M) and IgG (immunoglobulin G). IgM antibodies are produced early on and persist throughout infection. IgG antibodies, on the other hand, are produced only after an individual has mounted an immune response, which can occur between 1-4 weeks after initial infection.

These tests require blood samples from the patient, and the amount of blood needed varies with the type of test. Some tests require a blood draw from a vein and others only need a finger prick. Currently, these tests must be processed in a CLIA-certified facility and ordered by a physician,[4] but can generate results in 20-60 minutes.

At present, the FDA does not recommend the use of these tests as the sole basis for diagnosing COVID-19[5] and a negative test should not be interpreted to mean that an individual is not currently infected with the virus. Because these tests rely on antibodies that need time to accumulate, they are not effective in identifying the early stages of infection, and when COVID-19 is suspected, a nucleic acid test should be used to rule out active infection. However, when used in combination with clinical data and other test results, these tests may help detect recent infections.

The other main application of serological assays is research on disease surveillance (i.e., to better understand how widespread the infection is), but the accuracy and reliability of these tests are still being evaluated. These tests may eventually be useful for assessing if an individual has developed protective immunity, but until these tests have been validated for this purpose, current FDA-authorized tests should not be used to determine whether someone is immune to COVID-19.

FDA has also advised health care providers using these test to understand their limitations and to be aware that FDA is permitting distribution of these tests prior to FDA review and authorization.

Importantly, the sensitivity (the likelihood of correctly diagnosing an infected individual) and specificity (the likelihood of correctly diagnosing an uninfected individual) of both kinds of tests can be affected by a number of factors, such as the status of the person's infection at the point of sample collection and testing protocol compliance. Accordingly, a negative result from any of the tests described above may require interpretation from a licensed medical professional in light of other diagnostic criteria.

Other Screening Methods

Because many employers may not be able to implement diagnostic testing in the near-term or may not be able to implement on-site testing, they may turn to other methods to screen their employees for possible COVID-19 infection.

Temperature Screening: Perhaps one of the easiest diagnostic tests to administer, temperature screening allows employers to identify possible symptomatic cases, as fever is one of the symptoms of an active COVID-19 infection. Since other types of diseases, such as influenzas and colds, also commonly present with a fever, a temperature screening protocol may also reduce the spread of other diseases in the work place.

Questionnaires: Another simple screening method is to have employees complete a questionnaire about recent symptoms (i.e., within the prior two weeks) that could indicate infection, exposure to known cases, and activities that increase risk, such as travel to areas with higher numbers of cases.[6] Known signs and symptoms for COVID-19 range from mild to severe and can include:[7]

- Fever
- Shortness of breath or difficulty breathing
- Cough
- Repeated shaking with chills
- Sore throat
- Muscle pain
- Headache
- New loss of taste or smell
- Chills

Because many COVID-19 cases are asymptomatic and employees may have been exposed to the virus without knowing it, these methods are not as effective at identifying infections as diagnostic testing. However, they are practical risk stratification methods, and may help to reduce the spread of the virus.

Regardless of the screening methods used, employers should develop policies and procedures for how to respond if possible or confirmed exposure or infection is identified.

2. Currently, we're planning to take everyone's temperature when they arrive on site and send anyone home who is running a fever. But I'm reading more about asymptomatic transmission in the press. Can the virus be spread by employees who don't have a fever? What other measures can I take to reduce the risk of transmission in our workplace?

Current studies indicate that infected individuals who do not run a fever do transmit the virus. Some individuals test positive for the virus but never experience any symptoms (asymptomatic); others may be infected but show up for work prior to exhibiting symptoms (pre-symptomatic); and others may only experience mild symptoms (mildly symptomatic). Asymptomatic, pre-symptomatic, and mildly symptomatic individuals all can transmit the virus to others without a fever.

Transmission by these individuals without a fever likely contributes significantly to the spread of the disease. The Centers for Disease Control and Prevention (CDC) recently indicated that up to 25% of infected individuals remain asymptomatic.[8] In others, symptoms may take 2 to 14 days to develop, and clinical studies have shown that infected individuals may start shedding large amounts of virus that are capable of infecting others 1-2 days before they experience symptoms.

To reduce risk of transmission, employers can implement a range of measures. These include screening — discussed in the response to Question 1 — as well as social distancing, increased cleaning and disinfecting of frequently used surfaces, requiring that employees wash hands often, staggering work schedules, and providing employees with personal protective equipment (such as cloth coverings for the mouth and nose).

These measures are important because the virus is predominantly transmitted through moist droplets that travel short distances in the air (when a person coughs, sneezes, or even strongly exhales). The primary modes of virus transmission are thought to include close contact with an infected person and touching both contaminated surfaces and one's mouth, eyes, or nose. Studies have shown that the virus can remain viable on surfaces such as plastic and stainless steel for up to three days,[9] although these timeframes depend on environmental conditions such as temperature and humidity.[10]

In addition to these general measures, the CDC has issued guidance on specific measures for certain communities, schools, and workplaces to adopt.[11] OSHA has also issued similar guidance for particular industries.[12]

Employers should implement policies for how to react when an employee has a fever. A common approach is to restrict the employee from coming onsite until the individual no longer presents with a fever (without the aid of fever-reducing drugs) for an appropriate period of time. A more stringent approach would be to require a diagnostic test to confirm that the employee is not positive for COVID-19 infection.

3. Some of my employees tested positive for COVID-19, but some weren't able to be tested although they were symptomatic. Can I invite my recovered employees back to work? What about the ones who have not been tested?

The decision of when to allow employees who have recovered from COVID-19-like symptoms, whether or not they tested positive for the virus, to return to the workplace should be based on the time since resolution of symptoms and, if available, a negative test confirming that the individual is no longer infectious (i.e., actively shedding live virus). Additionally, all patients should consult with their healthcare provider for guidance on when it's safe for them to return to work.

The CDC has issued minimum criteria that recovered individuals should meet before they discontinue self-isolation, although the CDC acknowledges that meeting these criteria will not prevent all instances of secondary transmission.[13] Consequently, the CDC guidance is a good starting point for employers to consider as they develop their own policies, but in workplaces where there is a greater need to prevent transmission, employers may want to apply more stringent requirements. Employers should consult counsel regarding whether proposed measures satisfy legal requirements (taking into account the current pandemic circumstances) such as the Americans with Disabilities Act's (ADA) restrictions on medical examinations and inquiries.

In general, the CDC suggests that individuals who have recovered from COVID-19-like symptoms can discontinue self-isolation after:

- at least three days have passed since the individual's body temperature was 100.4 degrees or higher, without the use of fever-reducing medication.
- respiratory symptoms such as cough and shortness of breath have improved.
- two consecutive nucleic-acid test results from specimens collected at least 24 hours apart have come

back negative. In the event that testing is unavailable, individuals should wait until at least seven days have passed since they last experienced COVID-19-like symptoms, in addition to meeting the other criteria.

These recommendations may be subject to change as more information on transmission and potential reinfections are better understood, so employers should actively monitor the CDC guidance for changes.

4. I've heard that recovered patients might have immunity from the virus – does this mean that I don't have to screen them for COVID-19 when they return to work?

As of April 24, 2020, the World Health Organization has stated there is thus far no evidence that individuals who have recovered have immunity.[14] So, for the time being, employees that have recovered from COVID-19 and are cleared to return to work should be considered susceptible to reinfection and adhere to the same risk mitigation strategies as other employees (e.g., screening, hygiene, social distancing).

Very little is known yet about the immune response to the virus, including whether or not previously infected individuals develop a potent and broadly protective response, and how long after recovery protection is conferred. When exposed to viruses through natural infection, the human immune system mounts a multi-staged response. Initially, the body responds with a non-specific attack on the virus to slow its progress and trigger the second adaptive phase, during which the body developing immune cells that recognize and eliminate infected cells and produce antibodies that bind to the virus and prevent it from further infecting other cells.

While studies of the immune response to SARS-CoV-2 infection have demonstrated the presence of antibodies in recovered individuals, some people have low levels and there is not yet evidence that the presence of antibodies provides immunity to subsequent infection.[15,16,17] Studies in larger, more diverse populations are needed to better understand immune responses, and — if immunity is conferred — how long it might last. Studies aimed at answering these questions are underway but results may take weeks to months.[18,19] In addition, the accuracy and reliability of tests to detect antibodies to SARS-CoV-2 is still being evaluated, and current FDA-authorized tests cannot be used at this time to determine whether an individual has developed protective immunity to COVID-19.[20,21]

Another important factor in the development of immunity is the genetic evolution of the virus. Researchers tracking the evolution of the virus as COVID-19 cases have moved across the world found a limited number of mutations, suggesting a slow mutation rate. However, if the virus continues to spread, it is possible that it could acquire mutations that render previously recovered individuals vulnerable to reinfection.[22]

5. Once I start testing my employees, how often will I need to retest them to make sure there aren't active cases in my workplace? Should I test everyone every day? Once a week?

To have the best chance of identifying all cases of COVID-19 among your employees, daily testing of all employees who are in contact with others in and outside of the workplace would be needed. However, rapid and reliable on-site tests are not yet widely available.

Screening for symptoms such as elevated temperatures or coughs will help identify symptomatic cases, but will not identify all infected persons, as many individuals who are infected never develop symptoms. Additionally, the progression and severity of the disease varies amongst individuals. In some cases, the progression is very rapid (e.g., from mild discomfort to critical condition within a week or two), and in some cases the symptoms may linger for weeks. Transmission may start within hours of infection.

Until tests that can rapidly detect infection are widely available and affordable, employers may consider implementing other practices to reduce risk. Public health authorities are recommending frequent cleaning and providing all employees easy access to handwashing stations — which are more effective than hand sanitizer — and encouraging fastidious hygiene practices.[23] Limiting in-person interactions between employees also reduces transmission risk. This can be done by restricting "live" meetings and establishing rotating teams to complete necessary onsite work. By creating rotating teams, employers can increase the likelihood that if one team is exposed and or infected, the employees on other teams may remain unexposed and can continue operations. Employers will need to conduct customized risk assessments for their organization and implement testing and other preventative measures in a manner appropriate to their circumstances. Employers may also consider whether special measures are appropriate to protect persons at higher risk of serious illness, such as the elderly or people with compromised immune systems.[24]

6. Am I allowed to require my employees to be tested for either COVID-19 or antibodies before coming to work?

On April 23, 2020, the Equal Employment Opportunity Commission (EEOC) updated its Technical Assistance Questions and Answers about COVID-19 to state that, given the current pandemic status, employers may test employees before they enter the workplace to determine if they are infected with the virus. However, to comply with ADA standards, employers have a responsibility to ensure that any tests administered are accurate and reliable. To help employers in this evaluation, the EEOC cites FDA guidance on what may be considered safe and accurate testing. The new EEOC guidance also refers employers to CDC and public health authority guidance, with a reminder to monitor these resources for updates. The agency suggests that employers consider whether the test to be used has a high incidence of either false negative or positive results, and reminds employers that testing provides a result at the moment of testing only.

The agency goes on to say that, consistent with public health and other medical authority guidance, employers should still supplement any testing with good infection control practices, including social distancing and regular handwashing.

This guidance follows ADA requirements that mandatory employee medical testing must be "job related and consistent with business necessity," and recognizes that any employee infected with COVID-19 who enters the workplace poses a direct threat to others' health. Employers should keep in mind that this guidance is specific to current pandemic conditions, and if (as we all hope) more effective COVID-19 prevention and treatment options are discovered and the level of threat to the general population abates, it may change.

Employers who conduct testing should take into consideration how potential requests to be excused from a testing requirement for medical or faith-based reasons will be handled, as well as how the confidentiality of data collected during the testing process will be maintained. Also, employees will need to determine whether non-exempt personnel who are required to undergo testing will be compensated for time spent waiting to be tested, taking the test and, if applicable, waiting for a test result before entering the workplace and commencing work.

From a logistical and administrative standpoint, it is important to consider where the testing will be conducted, and if it is done onsite, how to maintain social distancing for employees waiting to be tested as well as for those who may be required to leave the testing site without entering the workplace based on the testing or screening result. Visitor and vendor screening is a further consideration if such third parties will be needed onsite to support the regular workforce's return to the workplace.

7. If I hire someone to administer the test, do I have to comply with HIPAA?

If you retain a licensed medical provider to provide your employees with tests, the provider might be a covered entity under HIPAA. Merely hiring such an entity, however, does not make you a covered entity. HIPAA permits covered entities to disclose information to employers for the purpose of workplace health monitoring and such information is not regulated by HIPAA once received by an employer, but a notice about such disclosures must be posted prominently or provided to each patient.

8. What should I do with the results of this testing? Can I tell other employees that one of their colleagues has been sick? Can I tell that employee's supervisor?

The ADA requires that results of employee medical exams be kept confidential. Taking an employee's temperature, testing for COVID-19 or related antibodies, or even asking an employee about any history of symptoms would all be types of medical exams. You should keep records of this information in a secure location, separate from your other employee files, and disclose it only on a strict need-to-know basis.

If an employee tests positive or has symptoms, you may tell that employee's supervisor that the individual is unable to work or will be working from home. But you should not disclose the employee's symptoms, test results, or health status to co-workers or other colleagues absent the employee's consent. Any such consent must be given in a truly voluntary manner and should be documented in writing. If others in your workplace have been exposed to the employee and should begin following the CDC's recommendations for self-isolation, you should inform them that they may have been exposed at a particular time

and location or during a particular event, and ask them to begin self-isolation. You should not identify the colleague or co-worker who tested positive absent that person's voluntary consent to do so.

There may be further limits on what you can and cannot do with employee information, depending on applicable state law. California, for example, limits the use of employee medical information under its Confidentiality of Medical Information Act.

9. What are public health authorities requiring in terms of employee testing? Can a public health authority force me to test my employees or require me to limit the employees who can enter my facility based on exposure risk? I know in some countries, authorities are requiring or encouraging the use of a mobile app that tracks exposure risk – could I be required to screen my employees based on an app?

In the United States, no public health authority has yet begun a mandatory mass-testing regime or announced intention to begin generally testing certain populations. This has occurred outside the United States in some jurisdictions, however. And although public health authorities may have the power to take action in specific cases, no public health authority has decreed a generally-applicable testing requirement for all employers. Some public health authorities have, however, mandated temperature checks for essential employees and directed employers to send home any employees with a fever. Public health authorities may also have the authority to demand information from you related to the pandemic, including contact-tracing information if you have affected employees.

Some states are restricting entry into particular locations based on screening and questionnaires.[25] However, no public health authority in the United States has decreed a general screening requirement or mandated the use of a particular technology for tracking exposure. Although app-based exposure tracking has begun outside the United States in some jurisdictions, in the U.S., no public authority is requiring tracking or screening based on an app. Some authorities have endorsed or encouraged use of a specific app (e.g., the North Dakota Department of Public Health - https://ndresponse.gov/COVID-19-resources/care19), but none have indicated an intention to make app use mandatory.

We hope these FAQs will be helpful as you navigate the range of issues relating to a return to work. We will continue to expand and update this document in the coming weeks.

As the number of cases around the world grows, Faegre Drinker's Coronavirus Resource Center is available as a resource to help you understand and assess the legal, regulatory and commercial implications of COVID-19. Visit the Coronavirus Resource Center.

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[2]https://www.statnews.com/2020/03/21/coronavirus-test-returns-results-in-45-minutes

[3]https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

[4]https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2

[5]https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

[6]https://my.clevelandclinic.org/landing/preparing-for-coronavirus

[7]https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

[8]https://www.npr.org/sections/health-shots/2020/03/31/824155179/cdc-director-on-models-for-the-months-to-come-this-virus-is-going-to-be-with-us

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[12]https://www.osha.gov/SLTC/COVID-19/news_updates.html.

[13]https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.

[14]https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19

[15]https://www.nature.com/articles/s41586-020-2196-x

[16]https://www.biorxiv.org/content/10.1101/2020.03.21.990770v2.full.pdf

[17]Ibid. (WHO)

[18]https://www.nih.gov/news-events/news-releases/nih-begins-study-quantify-undetected-cases-coronavirus-infection

[19]https://www.sciencemag.org/news/2020/04/these-are-answers-we-need-who-plans-global-study-discover-true-extent-coronavirus

[20]https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests.

[21]https://jamanetwork.com/journals/jama/fullarticle/2764954

[22]https://hub.jhu.edu/2020/03/30/covid-19-gene-sequencing

[23]https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html

[24]https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html

[25]e.g., https://dbm.maryland.gov/employees/Documents/COVID-19%20Building%20Entry%20Protocol.pdf

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