SAFE
RETURN TO WORK PROGRAM

Comprehensive Testing Details

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Comprehensive testing is a key component of successful return-to-work strategies. However, as organizations have begun adopting these tools, it is apparent that many misconceptions remain. Below, we address common questions with the goal of improving employers' and employees' confidence in preparing to return to work. We use our epidemiologic and clinical expertise alongside the most recent recommendations from the Centers for Disease Control and Prevention to explain the strengths and limitations of current testing strategies. The information provided here reflects our current understanding of the SARS-CoV-2 virus, availability and reliability of testing, and federal recommendations; as additional research is performed and regulations are updated, so will the SAFE program.

1. What are the different types of tests?

Testing is directed at answering 2 questions: 1) Am I infected now? or 2) Was I infected in the past?

Viral Testing: identifies the presence of the SARS-CoV-2 virus. There are two categories of viral tests on the market to measure the presence of virus- molecular and antigen testing.

Molecular testing identifies the genetic material of the SARS-CoV-2 virus and uses a technique called Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). To perform this test, a swab is used to collect a sample of mucous from either the nose or mouth (depending on the test manufacturer). This is sent to a laboratory (either on site or to a different location), where a lab technician safely handles and processes the specimen, obtains the result, and sends the test result information back to relevant parties by paper, fax, or electronically.

Antigen testing identifies the presence of a viral protein- either a "nucleocapsid", which is located inside the viral cell, or the spike protein, which is located on the outside surface of the virus. These tests can typically be collected using the same methods as molecular tests or using a saliva sample. The processing of these samples is different and is often quicker than molecular testing, though their sensitivities are typically lower.

Antibody (i.e. serological) Test: blood test that identifies the presence of a specific antibody to the SARS-CoV-2 virus. A positive test indicates that your body has had some level of response to the SARS-CoV-2 virus. Historically, if antibodies are present, it indicates that you were infected with a pathogen - it also implies that you now have improved resistance to future infections of that pathogen. Current research suggests that immunity to SARS-CoV-2 can last at least 3 months, but more research is needed to confirm and extend these findings.

2. What are the cost of tests?

Tests costs related to geographic region and service providers. Currently available viral tests and pricing include:

- Nasal Swab viral testing using a lab run PCR test is between $130 - $150 per test
- Salvia collection method, viral testing using a lab run PCR test is between $115 - $150 depending on dispensing and selected shipping options
- Rapid tests (in select regions, with more sites becoming available). These tests are completed and resulted within less than 20 minutes. Prices range from $55 - $160 for these tests based on market and supply availability
- New advancements are happening weekly and new tests are being added regularly

The antibody test (i.e. serologic) cost $79 per test. Currently antibody tests require a complete blood draw. New tests are under development and review from the FDA that will bring to market improved antibody testing options.

3. Test Collection Options

STC has partnerships with national nursing, pharmacies and lab options across the country to provide the right test solution for your organization. In many cases, employers are using all three options depending on industry and current regional COVID-19 community spread. Our testing concierge service works directly with the employer to ensure the right option is employed at the right time for your business.

4. What is the availability of the tests?

Availability varies widely by location. Broadly, in the United States, test quality and quantity still need to be improved. However, there appears to be progress on both fronts and there is merit that widely available, high quality tests will be developed with additional research.

Viral Testing: As of August 25, 2020, nearly 150 individual emergency use authorizations for molecular tests and 3 for antigen diagnostic tests. The SAFE program utilizes several tests depending on the location and needs of the employer, including individual testing strategies. The landscape of testing is changing rapidly; STChealth and the SAFE program continuously monitor developments in the field and provide real-time access to testing for clients.

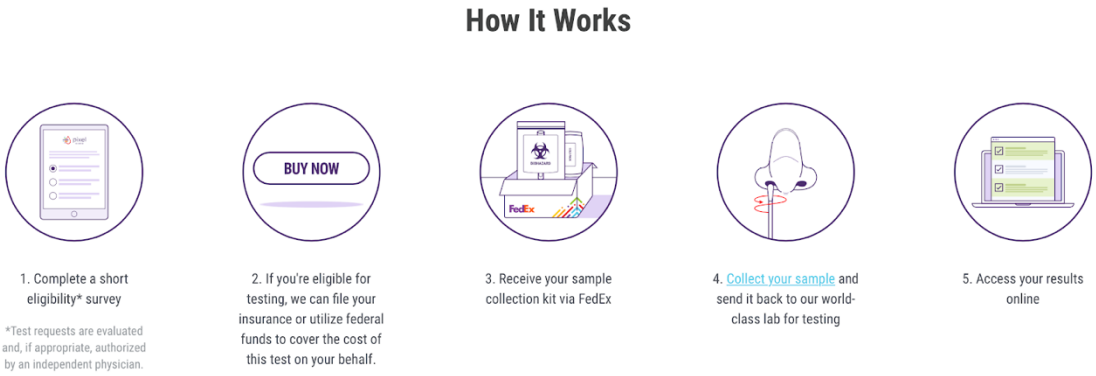
Antibody (i.e. serological) Testing: As of August 25, 2020, the FDA has granted authorization for 39 individual serologic tests. STChealth and the SAFE program collaborates with individual manufacturers and pharmacy partners to determine the availability of the most appropriate test so that clients have ready access to this technology.

5. How are the tests administered?

Depending on the test manufacturer and the route of collection, samples can be collected by a healthcare professional (e.g. nasopharyngeal swab) or overseen by a clinician as the individual collects the sample (e.g. nasal swab or saliva collection). The SAFE program utilizes both strategies depending on the testing needs of the individual client and availability of resources.

Nasopharyngeal (NP) Swab Tests:

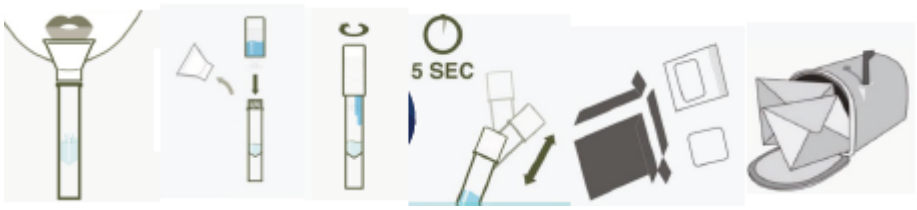
Obtaining a valid NP swab is not a simple task even for professionals. It is not something that you can easily do satisfactorily to yourself or a family member, and done incorrectly may cause bleeding or tissue damage. Beware - there are fraudulent non-FDA approved home tests being marketed.



Note: Specifically, the FDA is allowing the Burlington, N.C.-based diagnostics maker to test consumers' self-collected nasal samples using the company's at-home test kit. Initially, LabCorp will make the kits available to frontline healthcare workers and first responders who have been exposed to COVID-19 or have symptoms of the illness.) LabCorp intends to make its home collection kits available to consumers, in most states, with a doctor's order in the coming weeks.

Oropharyngeal (Throat): Take a swab, insert into mouth, and swab the posterior pharynx and tonsillar areas. (Avoid the tongue.) Place tip of swab into the viral transport medium tube and cut off the applicator tip. This method does not require cold chain shipping.

Salvia Collection: Kits can be administered at the worksite, dispensed to be conducted at home, or mailed directly to the employee home. A simple process of filling the tube with salvia, sealing the tube, shaking to ensure the sample remains stable and mailing the sample per the instructions.



Antibody (i.e. serological) Testing: Currently all approved antibody tests are performed by a licensed healthcare professional. Since the antibody test is from blood, it may become possible in the future to do an antibody test at home using a small drop of blood from a fingerstick. However, there is no FDA approved home antibody test.

6. What are the testing turnaround times?

For both the viral and antibody (i.e. serological) tests, this can vary. For viral testing, the SAFE program is contracted with laboratory partners around the country to ensure that once the sample arrives at the facility, there is a 48-hour service level agreement with most test options , which is crucial for a timely public health response in the event of a positive test result. Most of our lab results are available in around 24 hours after being received by the lab. This is exceedingly important where the broader testing environment across the U.S. has been characterized by testing delays. In multiple regions, rapid tests are available. These results are provided within 10 – 20 minutes depending on the test.

7. Interpreting test results

The Centers for Disease Control and Prevention published guidance on interpreting COVID-19 test results for both, viral and antibody testing. As this guidance is updated, STC's plan is subject to change.

8. Which employees should be tested?

Testing is part of a comprehensive strategy that includes prevention, surveillance, screening, and response. In other words, testing should not be the sole factor used to make decisions about returning persons to the workplace. The SAFE program is designed to provide personalized testing solutions to individual clients based on their workplace, workforce, resources available, and testing strategies available based on geography. The basic architecture of testing is as follows:

Viral Testing: Employees with positive screening questionnaire, elevated body temperature, or who report a potential exposure should be tested. If an employee tests positive, employers should consider providing testing for all employees in the same department who share common areas, are served by the same HVAC system, or have other close contact with the employee who tested positive.

Antibody (i.e. serological) Testing: Interim guidelines from the Centers for Disease Control and Prevention note the current limitations in the available antibody tests. Because the prevalence of SARS-CoV-2 antibodies is likely low in the population at this time, individual serological tests have a low positive predictive value (i.e. the probability that individuals with positive test results truly have antibodies to this SARS-CoV-2 virus). To overcome this limitation, there are 2 recommended, alternative strategies. First, only test those persons with a "high pre-test probability of having SARS-CoV-2 antibodies, such as persons with a history of COVID-19 like illness. If the employer wishes to gain a better understanding of the overall seroprevalence within their workforce (i.e. what percent might have developed antibodies), an alternative strategy is to provide a second test (different design characteristics) to those who test positive on the first test, also called an orthogonal testing algorithm. The table below, from the Centers for Disease Control and Prevention, shows how this strategy can greatly increase the positive predictive value.

Prevalence of SARS-CoV-2 antibodies in population	Positive predictive value for one test	Positive predictive value for two orthogonal tests
2%	27%	87%
5%	49%	95%
10%	67%	97%
30%	89%	99%

*Estimates based on an antibody test with 90% sensitivity and 95% specificity

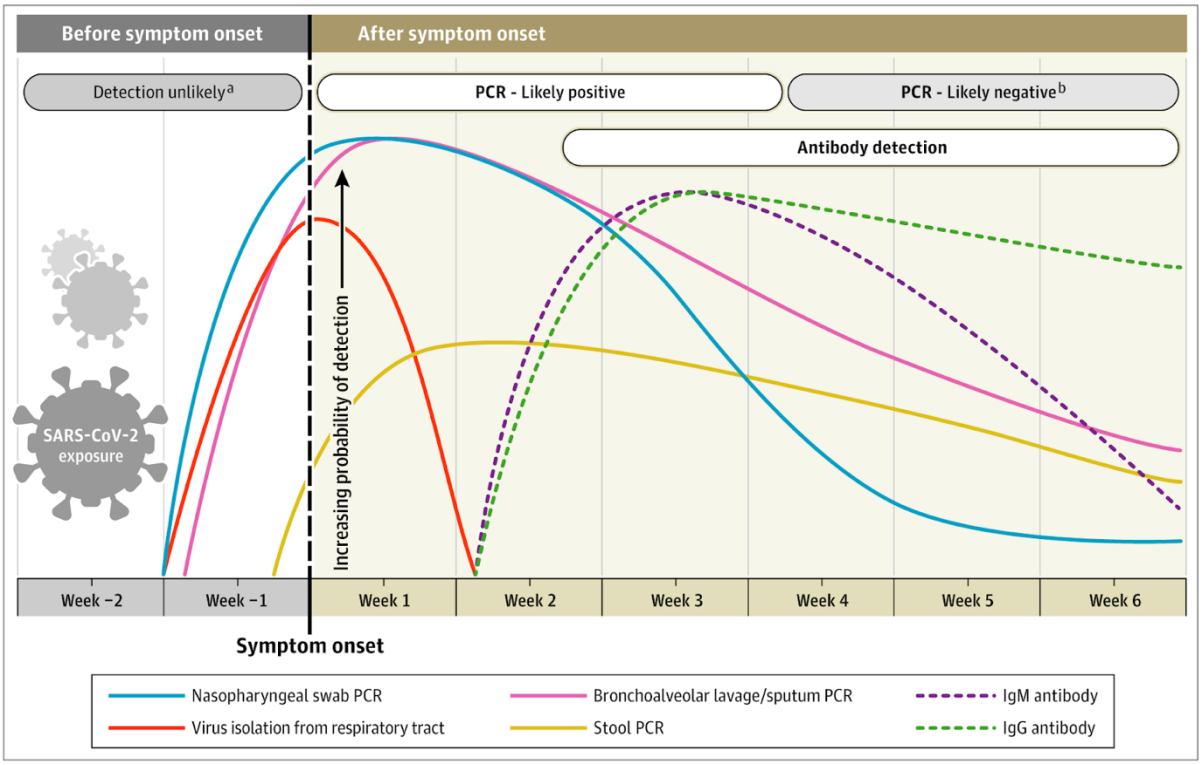
9. How often should someone be tested?

The figure below illustrates the time periods in which each type of test is likely to detect the intended target.

Viral Testing: Current guidelines from the Centers for Disease Control and Prevention gives priority to testing persons with symptoms (fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat). If an employee tests positive, develops symptoms, and recovers from the illness, most likely would not ever need this test again. If the test is negative when ill with symptoms, it implies another cause for the illness. However, there is a possibility for false negatives (i.e. the individual actually is infected with the SARS-CoV-2 virus).

If an employee has no symptoms and tests negative, it is likely that they are not infected at the time of testing and remain at risk for contracting the virus. For most people, they will not need to be retested unless they become ill or are aware that they have been exposed to someone who is ill with COVID-19. There are some people who, because of their work situation, may need to be retested at some interval (regardless of symptoms) to ensure they have not contracted the virus and pose a risk of spreading to others. Nursing home personnel likely to be in this situation.

Antibody (i.e. serological) Testing: As discussed above, current limitations of the antibody tests warrants careful consideration of these test results. Assuming a high positive predictive value of the antibody test, if one tests negative, it suggests that there is no immune response to the SARS-CoV-2 virus and the individual remains at risk of infection. If the test is positive (again, using the strategies discussed above), it suggests a previous infection with SARS-CoV-2 and that the immune system has mounted some response.



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