COVID-19 Diagnostics

10 THINGS TO KNOW

For additional details on these tests, consult ASHP's COVID-19 Diagnostic Testing Chart.

1. FEDERAL GUIDELINES SAY WHEN TO GET TESTED

The Centers for Disease Control and Prevention (CDC) recommends testing for people who have symptoms of COVID-19, people who have had close contact with someone with confirmed COVID-19, and anyone who has been asked by a healthcare provider or local or state health department to get tested.

The agency advises people who are tested to self-quarantine or isolate at home until the test results are available and to follow the advice of their healthcare provider or public health professional.

2. TESTING TOO SOON AFTER EXPOSURE MAY PRODUCE A FALSE NEGATIVE RESULT

Establishment of infection with SARS-CoV-2 requires exposure to the virus, transmission to a susceptible host, and sustained replication in that host.

Because COVID-19 diagnostic tests vary in sensitivity, specimens collected very early during the course of infection may not contain enough virus material to be detected. ASHP's COVID-19 Diagnostic Testing Chart cites studies indicating that tests can begin to detect the virus about 3–7 days after exposure.

According to CDC, SARS-CoV-2 RNA levels in the upper respiratory system decline after symptom onset. The agency states that people who have recovered from COVID-19 may have detectable amounts of viral RNA in their upper respiratory tract for up to three months after the onset of illness but are unlikely to be infectious.

3. THERE ARE A LOT OF COVID-19 DIAGNOSTIC TESTS ON THE MARKET

The Food and Drug Administration (FDA) has cleared more than 200 in vitro COVID-19 diagnostic test products for use under Emergency Use Authorization (EUA) provisions. Initial tests required laboratory processing but as the pandemic has progressed, manufacturers have increasingly offered products for point-of-care testing.

FDA has released results of a comparative analysis of COVID-19 diagnostic tests that the agency evaluated using a standardized SARS-CoV-2 reference panel.

4. BUT THERE ARE JUST TWO DISTINCT TYPES OF COVID-19 DIAGNOSTIC TESTS

FDA classifies COVID-19 diagnostics as molecular tests, which detect SARS-CoV-2 RNA, and antigen tests, which detect viral proteins. Both types of test are used to diagnose active infection in symptomatic and asymptomatic people.

According to FDA, antigen tests can quickly deliver results, but negative results in a symptomatic patient may need to be confirmed by more a more sensitive molecular diagnostic test.

Molecular diagnostics include reverse transcriptase-polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP), and clustered regularly interspaced short palindromic repeats (CRISPR) tests. According to FDA, molecular diagnostics typically detect acute SARS-CoV-2 infection with high sensitivity, and test results usually don't need to be confirmed.

Some molecular diagnostics using LAMP and CRISPR technology are authorized for point-of-care testing and provide results in 30 minutes or less. The availability of test results from molecular diagnostics that require laboratory processing may be affected by issues such as equipment and technician availability and capacity.

5. ANTIBODY TESTS DON'T DIAGNOSE ACTIVE INFECTION

FDA's website lists more than 50 authorized tests to detect SARS-CoV-2 antibodies in patient blood samples. A positive result indicates a past infection but cannot be used to diagnose or confirm active infection with the virus.

6. TESTS ARE AVAILABLE TO DETECT VIRUS IN DIFFERENT SPECIMEN TYPES

Most COVID-19 tests require a specimen obtained by nasopharyngeal, oropharyngeal, or nasal swab; some tests use a saliva sample. Collection of nasopharyngeal and oropharyngeal specimens requires special training and is performed by a healthcare provider or other person.

Specimens must be placed into the appropriate transport medium and may need to be maintained at refrigerated temperature during transport and storage before processing. For additional details about the specimen collection and testing process, review ASHP's October 21 webinar and supporting documents.

Patients may be able to collect their own specimen for tests that require a nasal swab or a saliva sample. Although some COVID-19 test kits are designed for patients to collect samples at home, most kits require that specimens be sent to a laboratory for processing. FDA on Nov. 17 cleared the first point-of-care COVID-19 diagnostic test (available by prescription) that allows patients to collect a nasal specimen and process it at home.

7. PHARMACISTS CAN COLLECT PATIENT SPECIMENS FOR COVID-19 TESTING

Federal guidance issued in accordance with the Public Readiness and Emergency Preparedness (PREP) Act authorizes licensed pharmacists — and, in some states, pharmacy technicians and pharmacy interns — to order and administer COVID-19 tests as part of the nation's response to the pandemic. The PREP Act also confers liability protection to licensed pharmacists and authorized pharmacy technicians and pharmacy interns who engage in these activities.

Pharmacists have been on the front lines of testing since early in the pandemic.

8. FEDERAL GUIDANCE DOESN'T REQUIRE THAT PHARMACISTS BE DIRECTLY REIMBURSED FOR ORDERING OR ADMINISTERING COVID-19 TESTS

Medical practices can use conventional incident-to billing to be reimbursed for pharmacists' COVID-19 diagnostic testing services. ASHP's Government Relations Office is advocating for mandatory direct reimbursement of pharmacists' testing services and for ordering and administering COVID-19 vaccines when they are available.

9. INSURERS MUST COVER COVID-19 TESTING — BUT WITH CAVEATS

Federal law requires insurers to cover COVID-19 testing to patients at no cost to them, but regulatory guidance appears to permit insurers to limit coverage on the basis of medical necessity. Specific questions about coverage for individual patients should be directed to their insurer.

Federal resources, such as the Health Resources and Services Administration's COVID-19 Claims Reimbursement Portal, are available to cover costs incurred when testing uninsured patients.

10. COVID-19 TESTS ARE AVAILABLE IN MANY SETTINGS

The Department of Health and Human Services maintains a list, organized by state, of health centers and pharmacies in the community where patients can be tested for SARS-CoV-2 infection. The list includes links to state public health departments. State and local health departments may have additional options for testing, including drive-up clinics.

Medical offices, urgent care facilities, and hospital outpatient clinics may also offer testing services in their communities.