Which patients should physicians test for COVID-19?

Although Centers for Disease Control and Prevention (CDC) guidance has expanded testing to a wider group of patients (CDC 04/27/2020), clinicians should be aware of reports of national shortages of viral transport media, testing reagents, and other testing supplies, which are significantly impacting the testing capacity of commercial, hospital, and public health laboratories in the U.S.

Because of these resource limitations, recommendations have been developed for prioritization of diagnostic testing for certain patients, to help physicians test wisely. Testing guidelines likely will change as testing and new information becomes available. In deciding whether to order a test, clinicians should consider clinical features, results of other tests, and how the COVID-19 results will change clinical management and infection control measures.

Physicians should use their judgment to determine if a patient has signs and symptoms consistent with COVID-19 (e.g., fever, cough, shortness of breath) and whether the patient should be tested. However, the following patients should be prioritized for testing (CDC 04/27/2020; IDSA, 03/17/2020):

**High Priority**

- **Hospitalized patients**, particularly critically ill patients receiving ICU-level care with unexplained viral pneumonia or respiratory failure regardless of travel history or close contact with suspected or confirmed COVID-19 patients, to inform decisions about infection control and investigational therapeutics.

- **Symptomatic physicians, health care personnel, first responders, and workers in a congregate living setting:** Testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed health care personnel, given their extensive and close contact with vulnerable patients in health care settings.

- **Symptomatic residents in long-term care facilities or other congregate living settings, including prisons and shelters.**

- **Persons identified through public health cluster and selected contact investigations.**
Priority

- Persons 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.

- Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

CDC recommends that mildly ill patients should be encouraged to stay home and contact their physician by phone for guidance about clinical management. If you have the capability to use telemedicine in your practice and determine the patient’s symptoms are mild, refer the patient to a mobile testing site if available or test the patient at the end of the day in your office away from other patients. This can protect staff and other patients and preserves the use of personal protective equipment.

What infection prevention measures are necessary if I want to collect specimens for COVID-19 testing from my patient in my outpatient setting, and how do I collect them?

- See CDC’s Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.

- For outpatient-setting FAQs, see TMA’s COVID-10 Infection Prevention and Control for Outpatient Clinics.

- For initial diagnostic testing for COVID-19, CDC recommends collecting and testing one of the following upper respiratory specimens (CDC, 04/29/2020):
  - A nasopharyngeal (NP) specimen collected by a health care professional
    - Use only a synthetic fiber swab with a plastic or wire shaft. Do not use a calcium alginate swab or a swab with a wooden shaft, as it may contain substances that inactivate some viruses and inhibit PCR testing.
    - Insert the swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions.
  - An oropharyngeal (OP) specimen collected by a health care professional
    - Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
  - An anterior nares (nasal swab) specimen collected by a health care professional or by onsite or home self-collection (using a flocked or spun polyester swab)
    - Using a flocked or spun polyester swab, insert the swab at least 1 cm (0.5 inch) inside the nostril (naris) and firmly sample the nasal membrane by rotating the swab and leaving in place for 10 to 15 seconds. Sample both nostrils with same swab.
  - Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a health care professional
    - Attach catheter to suction apparatus. Have the patient sit with head tilted slightly backward. Instill 1 mL-1.5 mL of non-bacteriostatic saline (pH 7.0) into one nostril. Insert the tubing into the nostril parallel to the palate (not upwards). Catheter should reach depth equal to distance from nostrils to outer opening of ear. Begin gentle suction/aspiration and remove catheter while rotating it gently. Place specimen in a sterile viral transport media tube.
    - The NW specimen and the non-bacteriostatic saline used to collect the specimen should be placed immediately into a sterile transport tube.
Swabs should be placed immediately into a sterile transport tube containing 2-3mL of either viral transport medium (VTM), Amies transport medium, or sterile saline, unless using a test designed to analyze a specimen directly, (i.e., without placement in VTM), such as some point-of-care tests. If VTM is not available, see the standard operating procedure for public health labs to create viral transport medium in accordance with CDC’s protocol.

Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

**If I am not able to implement the recommended infection prevention measures to collect specimens for COVID-19 testing in my outpatient setting, what other options are available for collection of specimens from my patient?**

- Some outpatient networks, urgent care networks, hospitals, and federal government initiatives are setting up ancillary specimen-collection facilities, such as “drive-thru” collection sites. You can inquire about the availability of such options within your referral network or area.
- For a list of current drive-thru testing sites, please visit DSHS’ Drive-Thru Screening Locations page.
- Do **not** physically send patients to the commercial laboratory or local health department for testing.
- Do **not** physically send mildly ill patients who do not meet testing guidelines to the emergency department simply for testing, to minimize exposures to other vulnerable patients and to health care workers.

**Is testing for COVID-19 available through commercial laboratories?**

Whenever feasible, physicians should send specimens for COVID-19 testing to commercial laboratories. Many large commercial reference labs offer COVID-19 testing to physicians in Texas. Additionally, multiple hospital-based laboratories are in the process of validating their testing assays for use within their hospitals per institution-specific guidelines.

A list of private and hospital labs offering testing can be found on the DSHS website. However, it is recommended to consult each laboratory’s test menu for their specimen collection instructions, submission forms, and shipping requirements.

**Is testing for COVID-19 available through public health laboratories?**

Specimens from patients (not patients themselves) who meet Texas DSHS criteria can be sent to public health laboratories in Texas. See CDC’s Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for COVID-19.

Prior consultation with and approval from the local or regional state health department serving the patient’s county of residence is required for these specimens. For testing at public health laboratories, call your local health department with your patient’s name, date of birth, address, and phone number to discuss the case. If possible, please call during business hours. See details on DSHS guidance.
What molecular tests for COVID-19 have been authorized for emergency use by the FDA?

All in vitro diagnostic tests that have received an Emergency Use Authorization (EUA) are listed here.

The FDA also has stated they will not object to a commercial manufacturer’s development and distribution to clinical laboratories of test kits to perform assays to detect SARS-CoV-2 for a reasonable period of time after the manufacturer’s validation of the test and while the manufacturer is preparing its EUA. Considering the validation of these tests have not been fully vetted, it is advised to proceed with caution in ordering any test kit that does not have an EUA (FDA, 04/30/20).

Are serological tests recommend for use in testing for COVID-19?

Although there are several uses for serology in SARS-CoV-2, including epidemiologic surveillance, identification of convalescent plasma donors, and future verification of vaccine response, the CDC does not currently support the use of serology testing for sole diagnosis or exclusion of SARS-CoV-2 infections or to inform infection status. Negative results from serology testing do not rule out SARS-CoV-2 infections, particularly for those individuals who have been exposed to the virus and are still within the estimated incubation period. Until the performance characteristics of serologic tests have been evaluated, it is possible that positive results from such testing may be due to past or present infections with a coronavirus other than SARS-CoV-2.

- The FDA recommends health care providers:
  - Continue to use serological (antibody) tests, as appropriate, and be aware of their limitations.
  - Do not use serological (antibody) tests as the sole basis to diagnose COVID-19 but instead as information about whether a person may have been exposed.
  - Be aware that not all marketed serological tests have been evaluated by the FDA. The FDA’s authorized tests, including serological tests, are listed on the Emergency Use Authorization (EUA) page. Tests being offered under a policy outlined in the FDA’s COVID-19 Diagnostic Policy Guidance are listed on our FAQ page. Such tests have not been reviewed by the FDA, unless an EUA has also been submitted and reviewed by FDA.

How accurate are serological tests? (IDSA COVID-19 Antibody Testing Primer, 04/22/2020)

There are a multitude of different antibody tests for COVID-19 with variable performance. Tests vary in the viral antigen(s) they target, e.g., nucleoprotein (N protein) or spike protein (S protein). It is not yet clear which antibody responses, if any, are protective or sustained. A “positive” test is exceptionally difficult to interpret because the performance of these tests is not well known. For some assays both sensitivity and specificity may be poor, or at the very least undefined.

Some FDA-authorized COVID-19 antibody tests are estimated to have 96 to 98% specificity, which would mean that a positive test result is more likely a false positive result than a true positive result if the prevalence or pretest probability is 5% or less.

What serological tests have received an EUA from the FDA?

Similar to the molecular tests available to test for SARS-CoV-2, there are a few serological tests that have received an EUA, and several that have not yet been validated.
For a detailed comparison between polymerase chain reaction (PCR) and serology testing, please see DSHS' COVID-19 Testing: PCR Versus Serology Testing, Explained.

**Are there any point of care (POC) tests available?**

There are a few POC molecular tests for SARS-CoV-2 that have received an EUA, however physicians should be sure to check the FDA EUA site to assess test accuracy (FDA, 04/29/20). To use a POC test, the requesting facility needs to be CLIA waived. For all other types of molecular tests, the facility needs to be CLIA authorized to perform high and/or moderate complexity tests. For the currently available serological tests with an EUA, the FDA indicates that they all must be performed by a facility with a CLIA authorization for high and moderate complexity tests (FDA, 04/09/20). Authorized settings for acquired tests can be determined from the FDA list of In Vitro Diagnostics EUAs.

For a quick resource on the various COVID-19 tests available, please see the TMA COVID-19 Quick How-To Testing Guide for Outpatient Clinics.

**How is COVID-19 testing paid?**

CDC covers testing conducted at public health labs, and patients will not be billed at this time. For commercial lab testing, many large insurance companies are waiving copays, deductibles, and cost-shares for both the cost of certain tests and the office visit.

To ensure proper tracking of testing, make sure to use the appropriate billing codes. The Centers for Medicare & Medicaid Services (CMS) has created two new Healthcare Common Procedure Coding System (HCPCS) codes for labs for testing patients for coronavirus.

- HCPCS code U0001 is used specifically for CDC testing laboratories to test patients for the coronavirus.
- HCPCS code U0002 allows laboratories to bill for non-CDC laboratory tests for the virus.

For non-Medicare or Medicaid patients, be sure to check with your payer for proper billing procedures. Current Procedural Terminology (CPT)* codes are still being adopted by both payers and laboratories and may not be consistent.

**Do I report a positive test result for COVID-19?**

All positive COVID-19 test results should be reported to your local health department immediately.

**For questions not addressed by this FAQ, please refer to the following resources:**

- CDC Coronavirus COVID-19 website
- TMA COVID-19 Resource Center
- DSHS Coronavirus Disease (COVID-19) website
- DSHS COVID-19 Call Center at (877) 570-9779, Sun.-Sat., 8 am-5 pm
- DSHS 24/7 Hotline at (888) 963-7111
- DSHS email: coronavirus@dshs.texas.gov
- TMA Knowledge Center (800) 880-7955 or knowledge@texmed.org
NOTICE: The information and opinions presented as part of this publication should not be used or referred to as primary legal sources, nor construed as establishing medical standards of care for the purposes of litigation, including expert testimony. The standard of care is dependent upon the particular facts and circumstances of each individual case and no generalization can be made that would apply to all cases. This information should NOT be considered legal advice and receipt of it does not create an attorney-client relationship. This is not a substitute for the advice of an attorney. The Texas Medical Association (TMA) provides this information with the express understanding that 1) no attorney-client relationship exists, 2) neither TMA nor its attorneys are engaged in providing legal advice and 3) the information is of a general character. Although TMA has attempted to present materials that are accurate and useful, some material may be outdated and TMA shall not be liable to anyone for any inaccuracy, error or omission, regardless of cause, or for any damages resulting therefrom.

Certain links provided with this information connect to websites maintained by third parties. TMA has no control over these websites or the information, goods or services provided by third parties. TMA shall have no liability for any use or reliance by a user on these third-party websites or information provided by third parties.

*CPT copyright American Medical Association. All rights reserved.