

# COVID-19

## CORONAVIRUS DISEASE

**VISION:** To improve the health of all Texans.

**MISSION:** TMA supports Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients.



Physicians Caring for Texans

# COVID-19 Testing Information

## Frequently Asked Questions (FAQs)

### TMA COVID-19 Task Force

JUNE 18, 2020

#### **Which patients should physicians test for COVID-19?** ([Centers for Disease Control and Prevention 06/16/2020](#))

The Centers for Disease Control and Prevention (CDC) has five categories for testing individuals suspected of SARS-CoV-2 with viral tests (i.e., nucleic acid or antigen tests):

1. Testing individuals with signs or symptoms consistent with COVID-19:
  - CDC recommends using [authorized nucleic acid or antigen detection assays](#) that have received a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) to test individuals with symptoms when there is a concern of potential COVID-19.
  - Clinicians should use their judgment to determine if a patient has signs or symptoms compatible with COVID-19 and whether the patient should be tested.
  - Among individuals with extensive and close contact to vulnerable populations, such as health care personnel (HCP), even mild signs and symptoms (e.g., sore throat) of possible COVID-19 should prompt consideration for testing.
2. Testing asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission:
  - Testing is recommended for all close contacts of people with SARS-CoV-2 infection, especially initial testing during an outbreak or pandemic due to the high likelihood of exposure.
  - CDC specifically recommends testing for all neonates born to women with COVID-19, regardless of whether there are signs of infection in the neonate.
3. Testing asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings:
  - For settings that house vulnerable populations in close quarters for extended periods, such as [long-term care facilities](#), homeless shelters, and correctional and detention facilities, and settings where critical infrastructure (e.g., health care personnel, first responders) may be disproportionately affected by an outbreak of SARS-CoV-2, widespread testing may help prevent the spread of disease.

- Facilities are encouraged to work with local, territorial, and state health departments to help inform decisionmaking about broad-based testing. Before testing large numbers of asymptomatic individuals without known or suspected exposure, the facility should have a plan in place for how it will modify operations based on test results.
4. Testing to determine resolution of infection (i.e., test-based strategy for [Discontinuation of Transmission-Based Precautions](#), [HCP Return to Work](#), and [Discontinuation of Home Isolation](#)): A test-based strategy, which requires serial tests, can be used as an alternative to a symptom-based or time-based strategy to determine when a person with SARS-CoV-2 infection no longer requires isolation or work exclusion. This strategy could be considered in three situations: disposition of patients in health care settings, discontinuation of isolation of people not in health care settings, and return-to-work criteria for health care personal with confirmed or suspected infection.
  5. Public health surveillance for SARS-CoV-2: Viral tests are used in community, outpatient, and hospital-based surveillance systems to identify cases of SARS-CoV-2 infection. These data help identify areas of ongoing circulation (hot spots), determine trends in disease by location, provide insight into the impact of the disease over time and by location, and inform disease forecasts.

Generally, viral testing for SARS-CoV-2 is considered to be diagnostic when conducted among individuals with symptoms consistent with COVID-19 or among asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2 to control transmission or to determine resolution of infection. Testing is considered to be surveillance when conducted among asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification or to detect transmission hot spots or characterize disease trends.

CDC does not currently recommend using antibody testing as the sole basis for diagnosis of acute infection, and antibody tests are not authorized by FDA for such diagnostic purposes. In certain situations, serologic assays may be used to support clinical assessment of individuals who present late in their illnesses when used in conjunction with viral detection tests. In addition, if a person is suspected to have post-infectious syndrome (e.g., multisystem inflammatory syndrome in children) caused by SARS-CoV-2 infection, serologic assays may be used.

### **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 SARS-CoV-2, CDC recommends collecting and testing one of the following upper respiratory specimens:
  - A nasopharyngeal (NP) specimen collected by a health care professional,
  - An oropharyngeal (OP) specimen collected by a health care professional,
  - A nasal midturbinate swab collected by a health care professional or by supervised on-site self-collection (using a flocked tapered swab),
  - An anterior nares (nasal swab) specimen collected by a health care professional or by on-site or home self-collection (using a flocked or spun polyester swab), or

- A nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a health care professional.
- 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 a viral transport medium is not available, the [Food and Drug Administration](#) recommends using liquid Amies medium or a dry swab in a sterile glass or plastic vial containing 1mL to 3mL of phosphate-buffered saline. For both of these alternatives, specimens should be stored at 4°C or frozen if not shipped and received within 72 hours of collection.

### **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 have set 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 Texas Department of State Health Services’ (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, including but not limited to ARUP, Clinical Pathology Laboratories, LabCorp, Quest, and Viracor.

A list of private and hospital labs offering testing can be found on the [DSHS website](#). Please see each laboratory’s test menu for its 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. DSHS’ [Interim Criteria to Guide Testing of Persons Under Investigation \(PUIs\) for Coronavirus Disease](#). **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 EUA are listed [here](#).

[FDA](#) also has stated it 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, [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.

[FDA](#) recommends physicians and 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 FDA. FDA's authorized tests, including serological tests, are listed on its [EUA page](#). Tests being offered under a policy outlined in FDA's [COVID-19 Diagnostic Policy Guidance](#) are listed on its [FAQ page](#). Such tests have not been reviewed by 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 FDA?

Similar to the molecular tests available to test for SARS-CoV-2, few serological tests 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, 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 SARS-CoV-2 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](#) 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 adopted by 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 **2-1-1 Option 6**, Monday-Friday, 7 am-8 pm
- DSHS email: [coronavirus@dshs.texas.gov](mailto:coronavirus@dshs.texas.gov)
- TMA Knowledge Center (800) 880-7955 or [knowledge@texmed.org](mailto:knowledge@texmed.org)

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