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.

COVID-19 Quick How-To Testing Guide for Outpatient Clinics

TMA COVID-19 Task Force

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STEP 1

Understand the difference between the types of tests available, including purposes, limitations, restrictions for use, and potential associated risks.

Here is a quick reference:

PCR (Molecular) (Centers for Disease Control and Prevention [CDC], 04/20/20):

• Currently the most accurate test authorized by the Food and Drug Administration (FDA) to diagnose the presence of SARS-CoV-2 infection

• Depending on the test, the specificity and sensitivity of PCR-based tests vary. However, most PCR tests that use 2+ targets are likely to have high specificity (few false positives). Sensitivity varies, as it is dependent on the state of the disease.

Serology (Antibody) (CDC, 04/20/20; Texas Department of State Health Services [DSHS], 04/24/20):

• Should not be used as the sole basis to diagnose SARS-CoV-2. If a serology test is performed, whether negative or positive, CDC recommends following up with a molecular diagnostic test.

• Serological, or antibody, tests can detect IgG, IgA, and IgM antibodies from an immune response to SARS-CoV-2.

• The accuracy of antibody tests are varied and uncertain. Negative results do not rule out infections in individuals who have been recently exposed to the virus and are still in the incubation period. Positive results may reflect either past or present infections with a coronavirus OTHER than SARS-CoV-2.

• For more information on serology testing, please refer to the Infectious Diseases Society of America COVID-19 Antibody Testing Primer and the New York City Health Alert, Current Status of SARS-CoV-2 Serologic Testing.

For further comparison between PCR and serology tests, please refer to DSHS, COVID-19 Testing: PCR Versus Serology Testing, Explained.

Point of Care (POC)

Molecular and serological tests that have received FDA Emergency Use Authorization (EUA) approval for the POC setting can be used in a Clinical Laboratory Improvement Amendments (CLIA)-waived facility. Although many serological tests may be marketed as a POC test, this might not be reflected in the test's EUA. As such,
these tests may still require performance by a facility with a CLIA authorization for high- and moderate-complexity tests. The authorized settings for the test will be specified in the manufacturer’s EUA (FDA, 04/28/20).

Be careful to thoroughly read through protocols and take precautions when conducting POC tests within your clinic. Some POC tests, e.g., Abbott Labs ID NOW, contain an open well and are subject to generation of aerosol and splash/splatter. A risk assessment is necessary to ensure safety of the personnel performing the test, and testing should be conducted in a biosafety cabinet (i.e., under a venting hood), or else while donning full PPE. If the clinical scenario necessary to safely conduct the POC test is not compatible with what is feasible within your clinic, seek a safer test (Association of Public Health Laboratories, 04/16/20).

For POC tests, due to uncertain sensitivity, if test results are incompatible with your clinical judgment and suspicion, a more reliable PCR test should be pursued.

**Saliva**

As of April 26, 2020, the one saliva test for COVID-19 that has received an FDA EUA is currently available only to clinics affiliated with Rutgers University. Collection of saliva specimens is limited to patients with symptoms of COVID-19 and should be performed in a health care setting under the supervision of a trained health care professional using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.

**At Home**

On April 21, 2020, FDA authorized its first COVID-19 test for patient at-home sample collection, which permits testing of a sample collected from the patient’s nose using a designated self-collection kit that contains nasal swabs and saline. The home collection kits will be made available to consumers in most states, with a doctor's order, in the coming weeks.

For more information on testing, please refer to TMA’s COVID-19 Testing Information Frequently Asked Questions (FAQs).

**STEP 2**

Check the FDA Emergency Use Authorization list to make sure the test of interest is authorized. Proceed with caution when ordering any test kit that does not have an EUA, as these tests have not been fully vetted.

**STEP 3**

Access the testing via these routes:

- For POC tests, contact the vendor of interest and consult with it to see how best to access the desired testing.
  
  Abbott Labs ID NOW HOTLINE: (877) 441-7440; EMAIL: COVIDService@abbott.com
- Consult with the laboratories that routinely perform your diagnostic services. Here is a list of private and hospital laboratories.
- Refer your patient to a drive-thru screening location.
- Refer your patient to a public health laboratory (make sure you meet the public health lab's testing criteria).
STEP 4

Make sure you get paid for the test.

• See the American Medical Association COVID-19 coding and guidance (CPT codes are still being adopted by both payers and laboratories, and may not be consistent).

• Many large insurance companies are waiving copays, deductibles, and cost-shares for certain tests and visits.

• Public health lab tests are free.

• For more information on payer and payment issues, please visit TMA's Practice Viability page.

ALSO, take into consideration for your clinic:

• PPE availability

• Infection prevention and control precautions (e.g., do you have the necessary equipment to collect the specimen and/or conduct POC testing safely in your clinic?)

Due to high demand, these test kits, or key components of the tests, may be in limited supply, which can limit or delay access.

Note also: Many tests that have not been validated are being marketed aggressively to physicians and patients.

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