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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 \[CDC\]](#), 06/13/20):

- **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, collection source, and competent collection technique.

Antigen ([FDA Coronavirus Testing Basics](#), 06/10/20):

- Used for rapid diagnostic testing for active coronavirus infection.
- Antigen tests are more likely to miss an active coronavirus infection compared with molecular tests. Positive results are usually highly accurate, but negative results may need to be confirmed with molecular test.

Serology (Antibody) ([CDC](#), 05/23/20; [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. 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.
- The accuracy of antibody tests are varied and uncertain. Antibody tests **without FDA Emergency Use Authorization (EUA) approval** are not recommended for use in physician offices or clinics unless a laboratory-developed test validation can be performed and high-complexity testing personnel are available.
- 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, antigen, and serology tests, please refer to [FDA Coronavirus Testing Basics](#).

Point of Care (POC)

Molecular and serological tests that have received FDA 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 \(FDA, 06/12/20\)](#). **[Appropriate biosafety controls must be implemented for POC testing that can result in aerosols or microdroplet dispersal.](#)**

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 personal protective equipment (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 June 14, 2020, FDA has issued an EUA for a saliva test for COVID-19 to clinics affiliated with [Rutgers University](#), using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device either for samples collected in health care settings or for at-home collection with a prescription. An EUA has also been issued for a saliva test kit manufactured by [Phosphorus Diagnostics LLC](#). Individuals can receive an at-home collection kit if determined eligible by the company's questionnaire, or saliva specimens can be collected in a health care setting using the Oragene Dx OGD-510 collection device.

At Home

In addition to the saliva test kit offered by Phosphorus Diagnostics LLC, FDA has issued an EUA for the [Everlywell COVID-19 Test Home Collection Kit](#) and extended its [EUA to the LabCorp COVID-19 RT-PCR Test](#) to permit testing of self-collected samples by patients at home using the [Pixel by LabCorp](#) home collection kit. Both are available to consumers after deemed appropriate from an online screening. Both kits contain nasal swabs and saline.

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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