

Considerations for Physicians Ordering SARS-CoV-2 PCR Diagnostic Testing

Diagnostic Testing for SARS-CoV-2 in the United States

Polymerase chain reaction (PCR) diagnostic testing for SARS-CoV-2, the virus that causes COVID-19, has been fraught with challenges since the current pandemic reached the United States. Supply chain issues have persisted in various degrees of severity since March 2020 and continue to impact the ability to increase testing capacity. While shortages of items such as swabs have improved, laboratories nationwide continue to struggle with shortages of reagents, viral transport media, and are seeing increased issues accessing plastic components such as pipette tips. These shortages are unlikely to improve throughout the remainder of this year. In addition to continued shortages of critical testing components, demand for testing services has significantly increased, driven by a surge in cases of COVID-19 nationwide, and by asymptomatic individuals wishing to resume certain activities. Testing services are now in high demand for those seeking to return to work, return to school, and engage in social gatherings and non-essential travel.

Exceptionally high demand coupled with a struggling supply chain, shortages of personal protective equipment (PPE), and laboratory staffing shortages has resulted in significant delays for the return of PCR testing results. It has also hampered the ability of laboratories at hospitals and academic centers to meet the needs of patients, both COVID-19 patients and those requiring non-COVID treatment and procedures. Additionally, the demand for SARS-CoV-2 testing and the accompanying shortage issues are beginning to impact the availability of other testing services, such as testing for other infectious diseases running on the same platforms and other molecular testing services. Laboratories nationwide are reporting that without supply chain improvements, our current testing capacity will not be able to continue to meet all demands.

PCR diagnostic testing is the most widely available and highest performing type of diagnostic testing for the presence of SARS-CoV-2. Other tests, such as rapid antigen testing, have been authorized for use by the Food and Drug Administration (FDA), but are not widely available and do not share the same performance characteristics as many of the available PCR tests. Until some form of rapid point-of-care or home-based screening tests with acceptable performance characteristics become available, demand for PCR testing is expected to be exceptionally high.

Considerations for Ordering Physicians

As demand for PCR diagnostic testing services continues to outpace capacity, the AMA recommends ordering physicians carefully consider when to recommend PCR diagnostic testing for SARS-CoV-2. At this time, the AMA recommends that physicians consider prioritizing testing services for those individuals with a medically indicated need for diagnostic testing. These individuals include those exhibiting COVID-19 symptoms, those with a known exposure

to SARS-CoV-2, those requiring a negative SARS-CoV-2 test to pursue medical treatment or procedures, and healthcare workers¹. For other individuals not at an immediate-risk of illness or other medically indicated need for testing, at-home quarantine would likely serve the purpose of limiting risk of transmission to others while easing demand on the testing capacity. Individuals not at immediate-risk of illness or other medically indicated need may include those wishing to engage in social gatherings, those who have previously participated in social gatherings but do not have a known exposure, those wishing to engage in non-essential travel, and those returning to work or school. Where there is no medically indicated need for testing, we encourage physicians to consider recommending at-home quarantine in lieu of testing. As the demand for testing services is dynamic, these recommended considerations may change should demand for testing ease, availability of testing supplies improve, or if new tests with acceptable performance become widely available.

We further encourage physicians to provide certain counseling to patients seeking testing for SARS-SoV-2. If a patient presents with symptoms of COVID-19 or a known exposure to COVID-19, it is critical that providers counsel patients on the importance of at-home quarantine until test results are received. Potentially infected patients choosing not to quarantine during this time risk transmission to others and clear counseling to this effect is critical to help limit spread of this disease. The Centers for Medicare and Medicaid Services and the Centers for Disease Control have announced their intent to reimburse physicians for these counseling services².

Physicians should further counsel their patients about what a negative SARS-CoV-2 test result means. It should be made clear to patients that a negative test result means only that patients were SARS-CoV-2 negative at the moment in time when the sample was collected and that they will not necessarily continue to be negative in to the future. It is possible that patients could be infected in the hours or days after receiving the test result or were tested too early during the course of illness. Those with negative test results <u>must</u> continue to follow all public health protocols, including physical distancing, employing good hand hygiene practice and wearing face masks in public and/or where physical distancing is not possible.

The AMA recognizes that there is likely need for testing of asymptomatic individuals as part of public health surveillance efforts. The AMA continues to advocate for the development of a well-defined surveillance strategy for COVID-19 infections. Patients participating in such efforts should be included as those with a prioritized need for testing services.

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¹ This list is not exhaustive and other individuals may have legitimate medically indicated needs for testing services. These requests should be considered on a case-by-case basis.

² <u>https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19</u>