|  |  |  |
| --- | --- | --- |
|  | The Commonwealth of MassachusettsExecutive Office of Health and Human ServicesDepartment of Public HealthBureau of Infectious Disease and Laboratory Sciences305 South Street, Jamaica Plain, MA 02130 |  |
| CHARLES D. BAKERGovernorKARYN E. POLITOLieutenant Governor | Tel: (617) 983-6550 Fax: (617) 983-6925 [www.mass.gov/dph](http://www.mass.gov/dph) | MARYLOU SUDDERSSecretaryMONICA BHAREL, MD, MPH Commissioner |

**To:** Healthcare Providers, Clinical Laboratories and Local Boards of Health

**From:** Catherine M. Brown, DVM, MSc, MPH, State Epidemiologist

 Larry Madoff, MD, Medical Director, BIDLS

 Sandra Smole, PhD, Director, State Public Health Laboratory

**Date:** June 14, 2021

**RE:** Testing of Persons with Suspect COVID-19

This document includes guidance about appropriate use of laboratory testing for COVID-19. This guidance is not intended to replace or supersede clinical judgment; clinicians concerned that their patient has COVID-19 or has been exposed to COVID-19 should utilize testing as they deem appropriate.

**RECOMMENDATIONS for DIAGNOSTIC COVID-19 Testing:**

To evaluate individuals for current infection, a molecular diagnostic test to detect the presence of the virus by polymerase chain reaction (PCR) or other nucleic acid amplification test (NAAT) methodology is the gold standard. These assays can detect even a small amount of viral genetic material, such as may be present during asymptomatic, pre-symptomatic or minimally symptomatic infection.

Rapid antigen tests are most useful in diagnosing COVID-19 in symptomatic individuals within the first few days of symptom onset. These tests detect the presence of viral proteins and are most likely to be positive when individuals have a high level of virus in respiratory secretions. They are faster to perform but less sensitive and less specific than NAATs. When using an antigen test to diagnose whether an individual has COVID-19, results are considered presumptive and may need to be confirmed by a NAAT. Situations in which a confirmatory NAAT should be considered include a negative antigen test in a symptomatic person or a positive antigen test in an asymptomatic person without a known exposure. Individuals with a clinical syndrome consistent with COVID-19 and who test positive via the antigen assay do not require a confirmatory NAAT.

Serologic antibody tests check for SARS-CoV-2 antibodies. These tests are often part of a diagnostic testing algorithm for suspect cases of multisystem inflammatory syndrome but are otherwise rarely indicated for diagnostic purposes. If an antibody test is performed, it is recommended that healthcare providers order a NAAT at the same time. At this time, antibody testing should not be used to guide release from isolation or for return-to-work purposes.

Performance characteristics for specific tests vary between manufacturers and real-world performance may or may not match data from controlled settings used to obtain an FDA Emergency Use Authorization (EUA). Providers should assess available data when choosing a test.

* <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2>
* <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>
* <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2>

Additional data on the performance of the Abbott BinaxNOW antigen test at a Massachusetts testing site is available online at <https://journals.asm.org/doi/full/10.1128/JCM.00083-21>.

***Symptomatic individuals***:

All symptomatic individuals in Massachusetts, even those with mild symptoms, should be tested with either NAAT or an antigen test. Symptoms of COVID-19 include:

* Fever or chills;
* Signs of a lower respiratory illness (e.g., cough, shortness of breath, lowered oxygen saturation);
* Fatigue, sore throat, runny nose or congestion, headache, body aches/myalgia, or new loss of sense of taste or smell;
* Other less common symptoms can include gastrointestinal symptoms (e.g. nausea, vomiting, diarrhea), rash, inflammatory conditions such as “COVID toes”, and thromboembolic events;
* Subtle signs or symptoms of COVID-19 such as alterations in mental status or blood glucose control in elderly, chronically ill, or debilitated individuals (e.g., residents of a long-term care facility);
* Children with multisystem inflammatory syndrome.

Note that symptoms of COVID-19 in children and adolescents are often mild and overlap with symptoms of other infections and noninfectious processes, making it impossible to distinguish COVID-19 infections without testing. In order to protect children and staff at school and daycare from COVID-19, testing of symptomatic individuals should be the default practice. Unvaccinated children with acute onset of new symptoms (especially respiratory symptoms such as cough, shortness of breath, sore throat) or fever should almost always receive a negative NAAT before returning to school.

***Close contacts of confirmed or clinically diagnosed COVID-19 cases***:

Most individuals in Massachusetts identified as a close contact should be tested with a diagnostic test (NAAT or antigen). A local Board of Health, the Massachusetts Department of Public Health, the Community Tracing Collaborative, or a healthcare provider can recommend testing of a close contact.

Close contact is defined as:

* 1. Being less than 6 feet from a person with confirmed or clinically diagnosed COVID-19 for at least 15 minutes while indoors, while the case was symptomatic or within the 48 hours before symptom onset. Additionally, the definition of close contact includes exposure to a person diagnosed with COVID-19 in the period 48 hours before their diagnosis through 10 days after diagnosis.
	2. Having direct contact with infectious secretions of a confirmed or clinically diagnosed COVID-19 case (e.g., being coughed on) while not wearing recommended personal protective equipment or PPE (e.g., gown, gloves, facemask, eye protection).

Recommended timing of testing for close contacts:

* Close contacts without symptoms should be tested after exposure to COVID-19. The contact is required to quarantine for ten days. If the contact tests negative after day five from contact (NAAT or antigen test), quarantine can be discontinued after seven days. Close contacts should continue to monitor themselves for symptoms for a full 14 days after their last exposure.
* Close contacts that develop any symptom at any time in the 14 days following their last exposure should be tested promptly (NAAT or antigen). Testing should occur even if the person previously had a negative test result during their quarantine period.
* Close contacts that are fully vaccinated do not need to be tested following exposure and are not required to quarantine unless they develop symptoms. Testing of close contacts who are fully vaccinated but immunocompromised should be considered given the potential for incomplete immunity.

***Admission to a healthcare facility:***

Unvaccinated individuals should be tested (NAAT or antigen) upon inpatient admission to a healthcare facility, including but not limited to hospitals operated or licensed by the Department of Public Health or Mental Health, long-term acute care hospitals, or skilled nursing facilities. Additionally, unvaccinated individuals undergoing aerosol generating procedures (AGP) in the ambulatory setting should be tested prior to the procedure.

Vaccinated individuals, who do not have symptoms of COVID-19 AND have not had a known exposure to COVID-19 in the last 14 days, do not require testing upon inpatient admission or prior to ambulatory AGPs.

***Asymptomatic individuals***:

Asymptomatic individuals not identified as close contacts can be recommended for diagnostic testing (NAAT or antigen) at the direction of their healthcare provider, the Department of Public Health, or a local Board of Health. Testing generally requires a clinician’s order and asymptomatic individuals are strongly encouraged to contact their insurer to confirm coverage.

***Screening:***

In certain situations, screening testing may be helpful in identifying people with COVID-19. Examples include testing of asymptomatic individuals not identified as close contacts in the workplace, schools and universities, and prior to travel. Symptom-based screening has a low sensitivity and low specificity for detecting individuals with COVID-19. Pooled sample testing increases the number of individuals that can be tested but has a greater likelihood of false negative results. Clinicians should use discretion when selecting or recommending home-based rapid antigen tests for screening testing as the performance characteristics may vary between tests. While any positive results from a home-based rapid antigen test should be considered evidence of infection, only medically attended home-based tests will be used for epidemiologic reporting purposes.

***Previously positive individuals cleared from isolation:***

Individuals previously diagnosed with COVID-19 infection confirmed by molecular diagnostic testing may continue to have PCR detection of viral RNA for several weeks. This persistence of viral RNA does not correlate with the presence or transmissibility of live virus. Those who have been cleared from isolation are not recommended for re-testing within 90 days of their original positive test. These individuals are also not subject to quarantine during this period.

Individuals previously diagnosed with COVID-19 who develop new symptoms or findings consistent with COVID-19 during the 90 days after the date of initial symptom onset or original positive test should undergo evaluation for alternative etiologies. If an alternative etiology cannot be identified by a provider, then the person ***may*** warrant retesting for COVID-19. Consultation with infectious disease or infection control experts is recommended since positive tests in this setting may not represent active viral infection. Isolation maybe considered during this evaluation, especially in the event that no more likely alternative diagnosis is identified or symptoms developed within 14 days after close contact with an infected person.

Individuals who were previously diagnosed with COVID-19 and are more than 90 days from the date of initial symptom onset or original positive test **are** subject to isolation in the event they test positive again and are subject to quarantine if they are identified as a close contact of a confirmed case.

***Vaccinated individuals:***

Individuals who have been fully vaccinated for COVID-19 should undergo testing for COVID-19 if they develop a compatible clinical syndrome. Prior immunization will not affect the results of a viral test for SARS CoV-2 (NAAT or antigen) but some serologic tests (those that measure antibodies to the SARS-CoV-2 spike protein) don’t differentiate between antibodies from natural infection or immunization. Testing is also available for nucleocapsid antibodies, which will not detect antibodies elicited by currently available SARS-CoV-2 vaccines. The presence of detectable antibody may not necessarily indicate immunity.

**RECOMMENDATIONS for COVID-19 Test resulting:**

COVID-19 testing providers should always follow their clinical judgement regarding the most appropriate way to contact and relay test results to their patients. Quickly communicating results of COVID-19 laboratory tests is a critical part of reducing the spread of the disease and is a required part of providing testing services. It is not appropriate to direct patients to contact the state or local health department for their results. The following recommendation outline best practices for communicating test results with patients.

***Positive test results:***

All individuals whose COVID-19 test results are positive must be contacted by a clinician and provided with clear instructions to self-isolate. Patients should also be informed that they will be contacted by the Department of Public Health and be urged to answer the phone.

***Negative test results:***

All individuals whose COVID-19 test results are negative must be informed promptly of their results, but do not need to be contacted by a clinician. Phone calls are not required for every patient, testing site providers may utilize HIPAA compliant messages (e.g., online portals, secure emails) to inform patients of negative test results. In the case that testing site providers decide to utilize HIPAA compliant electronic communications to inform patients of negative COVID-19 test results, patients must be clearly informed of this policy prior to receiving a COVID-19 test and should be provided contact information if they do not receive their result.

**This guidance is not intended to cover every possible situation. To discuss specific scenarios, please call the Massachusetts Department of Public Health Epidemiology line at 617-983-6800 available 24/7.**