



INTERIM GUIDANCE FOR USE AND INTERPRETATION OF SARS-CoV-2 (COVID-19) POINT OF CARE TESTS

As SARS-CoV-2 (COVID-19) testing becomes more widespread, including the use of rapid antigen tests and other point of care tests, the Maryland Department of Health (MDH) continues to update its guidance regarding use of these tests for diagnostic or screening purposes and the interpretation of results. Facilities and providers using rapid antigen COVID tests should be aware of the following:

- CLIA-waived facilities are required to notify the Office of Health Care Quality to add testing
- Tests must be ordered by an authorized practitioner
- The tests must follow the emergency use authorization (EUA) manufacturer’s instructions; CDC and FDA have specific discussions regarding “off-label” uses such as screening of asymptomatic individuals (see references below)
- All results (positive and negative) must be reported to MDH

According to the CDC, “There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19, or to determine whether a previously confirmed case is still infectious.” Clinical correlation, and assessment of the situation of the patient (e.g., work, school, childcare, health care setting) should be considered when making administrative recommendations based on test results. See table footnotes for additional important details.

Reason for Visit/ Question	Has the Person had Symptoms? ¹	Type of COVID-19 Test ²	Recommendations ³
Recent (within 14 days) known exposure/ close contact	No	Not Tested	<ul style="list-style-type: none"> • Self-quarantine for 14 days from last exposure date⁴ • Recommend COVID-19 test
	Yes	Not Tested	<ul style="list-style-type: none"> • Isolate for at least 10 days after symptom onset • Recommend COVID-19 test and clinical evaluation
Symptoms of COVID-19 with unknown or no known exposure/ contact	Yes	Not Tested	<ul style="list-style-type: none"> • Isolate pending test and/or clinical evaluation/ decision • Recommend COVID-19 test • If tested positive within the previous 90 days, obtain clinical evaluation/decision

Reason for Visit/ Question	Has the Person had Symptoms? ¹	Type of COVID-19 Test ²	Recommendations ³
Positive COVID-19 Test Result	No	RT-PCR	<ul style="list-style-type: none"> Isolate for at least 10 days after date the test taken Release from isolation if remains symptom-free for 10 days after date the test taken Inform person about contact tracing process
	No	Rapid Antigen Test	<ul style="list-style-type: none"> Isolate for at least 10 days after date the test taken Obtain confirmatory RT-PCR test regardless of community prevalence or reason for test Inform person about contact tracing process
	Yes	RT-PCR	<ul style="list-style-type: none"> Isolate for at least 10 days after symptom onset, fever-free for at least 24 hours and symptoms improved Inform person about contact tracing process If symptoms persist, follow up with provider
	Yes	Rapid Antigen Test	<ul style="list-style-type: none"> Isolate for at least 10 days after symptom onset, fever-free for at least 24 hours, and symptoms improved Inform person about contact tracing process If symptoms persist, follow up with a health care provider.
Negative COVID-19 Test Result	No	RT-PCR	<ul style="list-style-type: none"> If tested because of contact/exposure, continue to quarantine for 14 days⁵ If tested as a part of a facility setting or population testing strategy, continue current activity unless symptoms develop If tested because of a recent prior positive antigen test, interpret as negative for COVID-19, resume normal activity unless symptoms develop or testing is related to contact/exposure, and release close contacts from quarantine⁶
	No	Rapid Antigen Test	<ul style="list-style-type: none"> If tested because of contact/exposure, continue to quarantine for 14 days⁵ Consider referral for RT-PCR test If tested for routine surveillance, continue current activity unless symptoms develop
	Yes	RT-PCR	<ul style="list-style-type: none"> Clinical referral to determine if there is an alternative diagnosis for the symptoms Consider repeat testing if clinically indicated
	Yes	Rapid Antigen Test	<ul style="list-style-type: none"> Obtain RT-PCR test Recommend isolation pending RT-PCR results See Note 7 regarding management of close contacts in different settings

Notes:

- [Symptoms of COVID-19](#) include: fever or chills, cough (either new or different than usual), shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea. Consider influenza and other respiratory virus testing as well.

2. RT-PCR= reverse transcriptase polymerase chain reaction.
3. If the person has had a laboratory-confirmed COVID-19 within 90 days, repeat testing is not recommended unless clinically indicated. If a person develops COVID-19 symptoms within the 90 day period, CDC recommends an evaluation for other potential causes of symptoms, and consideration of reinfection in consultation with an infectious disease expert if no alternative explanation is found for the symptoms. More information is available on the CDC website on [Overview of Testing for SARS-CoV-2 \(COVID-19\)](#) and [Duration of Isolation and Precautions for Adults with COVID-19](#).
4. If the exposure occurred over multiple days, the COVID-19 test should generally be as soon as possible (but not generally sooner than 3 days from day first exposed). If the exposure occurred on a single date, and symptoms have not developed, the test should generally be at least 3 days after exposure due to the high probability of a negative test if performed sooner.
5. [Critical infrastructure employers](#) for whom a particular worker is considered [essential](#) should contact the local health department for [guidance](#) on whether to permit the worker to continue working with close monitoring and appropriate personal protective equipment.
6. Close contacts are elicited when someone tests positive for COVID-19, regardless of whether that is a PCR or antigen test. In a case where a recent (specimen collections within 48 hours of each other) prior Rapid Antigen test was positive, close contacts may have been elicited and advised to quarantine, prior to the confirmatory RT-PCR test.
7. If a person with COVID-19 symptoms has a negative Rapid Antigen Test, and is in isolation awaiting test results from a confirmatory RT-PCR, close contacts do not need to quarantine but should self-monitor for possible symptoms. In higher exposure risk settings when larger groups of persons may have been exposed, consider quarantine of contacts pending test results.

References

Association of Public Health Laboratories. *Considerations for Implementation of SARS-CoV-Rapid Antigen Testing, Version 4*. September 24, 2020: <https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf>

U.S. Centers for Disease Control and Prevention (CDC). *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2*. Updated September 4, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

U.S. Centers for Disease Control and Prevention (CDC). *COVID-19 Critical Infrastructure Sector Response Planning*. Updated May 6, 2020: <https://www.cdc.gov/coronavirus/2019-ncov/community/critical-infrastructure-sectors.html>

U.S. Food and Drug Administration (FDA). *FAQs on Testing for SARS-CoV-2*: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

U.S. Food and Drug Administration (FDA). *Pooled Sample Testing and Screening Testing for COVID-19*. <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19>