



PUBLIC HEALTH CONSIDERATIONS FOR COVID-19 HOME-BASED/ SELF-TESTS

Date: February 3, 2022

Overview

Several types of tests for current infection are available, including laboratory-based tests, tests offered at the point-of-care (POC) by a healthcare provider, and home-based tests. There are also different types of home-based tests. While all involve self-collection of specimens, some home-based test kits require a prescription and others are over-the-counter (OTC), also referred to as [self-tests](#). Some collections/tests are observed by a telehealth provider, some involve self-collection but are sent to a laboratory for processing, and others use self-collection and self-testing without any involvement of a healthcare provider.

While home-based tests offer accessible and affordable testing options, test results may not be reported to public health authorities, thereby placing the onus on the individual to self-isolate for the recommended period of time and to notify contacts of possible exposure. Most home-based tests, including self-tests, are antigen tests and have the same considerations as healthcare provider performed antigen tests in terms of sensitivity, specificity and recommendations for confirmatory testing.

Self-tests can be taken anywhere, are easy to use, and produce rapid results. They can be used regardless of vaccination status, or whether symptomatic or asymptomatic. Because of the lower sensitivity of self-tests and the fact that testing may be negative early in infection, it is often recommended that testing be repeated (serial testing). Some self-tests include instructions for performing serial testing, including the number of days between tests, and may include more than one test in the package. If the first test is positive, there is generally no need for the same person to take the second test. If, however, the first test is negative, to reduce the chance of a false negative result, the same person should take the second test at least 24 hours after the first test (follow manufacturer's instructions). If both tests are negative, this increases the confidence that the person is not infectious.

Acknowledging the increasingly important role of home-based testing and self-tests in particular, this document provides updated guidance for local health departments (LHDs) and public health partners for reporting and interpreting self-test results for the purpose of determining public health actions.

Reporting Test Results

Home-based tests that involve healthcare oversight or that are sent for testing in a laboratory must be reported to public health authorities (positive and negative results). Self-tests are not CLIA-waived tests and are authorized for self-collection, self-testing, and self-reading of test results. Individuals are not required to report the results of at-home-self tests to public health authorities.

Persons who test positive for COVID-19 on a self-test should notify their healthcare provider (or LHD if they don't have a healthcare provider) if they are concerned about their health or have questions on what they should do to protect those around them¹. Most importantly, they should immediately [isolate](#) away from others, notify their close contacts and if applicable, notify their worksite, school, or daycare so that precautions can be taken. Information on what to do after testing positive is available on the [NJDOH COVID-19 website](#) and the COVID-19 Information Hub at www.covid19.nj.gov.

Healthcare providers

In addition to providing clinical care/instructions, health care providers who are notified by patients of positive self-test results should provide patients with instructions to isolate and to notify their close contacts. Clinicians should notify their [LHD](#) if there are concerns about exposures in high-risk settings or if the case may be associated with a possible cluster or outbreak so that public health action can be taken. High-risk settings are those with persons at high risk of severe illness and those with high risk of sustained transmission. These settings include healthcare settings, long-term care facilities, shelters, corrections, congregate care settings, K-12 schools, childcare, and institutions of higher education.

Organizations administering screening testing

Organizations using self-tests for routine screening testing programs or other purposes should report positive self-test results to their [LHD](#) if they suspect a cluster or potential outbreak is occurring so that public health action can be taken. Some screening testing programs (e.g., K-12 [Test to Stay](#)) may have additional reporting requirements. Positive self-test results can be reported to public health authorities either through CDRSS (select "COVID-19 Home-Based Test" as the test name) or to their [LHD](#).

Verifying self-test results

The package insert for self-tests includes instructions about how to read the test results, including the appropriate time to read the results (usually 15-30 minutes). Reading the test before or after the specified time could result in false positive or false negative test results. Providing verification of self-test results to someone else (e.g., healthcare provider, school, worksite) is challenging. Some options organizations may consider include:

1. Arranging for individuals to perform the test onsite or via video call where results can be observed, OR
2. Asking individuals to provide an attestation (e.g., form provided by the agency) stating date/time test was taken and the result of the test.

** Agencies that are implementing mandated screening testing programs must refer to appropriate New Jersey [Executive Orders](#) and NJDOH [Executive Directives](#) to ensure compliance with reporting requirements.

Public Health Action

Local health departments should implement public health actions if positive test results are reported, including providing isolation recommendations, advising persons to identify and notify their close

¹ Employers or others administering screening testing programs may require reporting of self-test results.

contacts so they can get tested and quarantine if indicated, and following-up with high-risk settings to identify clusters or outbreaks and provide prevention and control recommendations.

At the LHD's discretion, self-test results can be entered into CDRSS selecting "COVID-19 HOME BASED TEST" under Test Name and classifying the case as POSSIBLE. Self-tests will not be counted in official COVID-19 statistics, but if entered in CDRSS they will transfer over to CommCare for investigation and contact tracing.

Additional Considerations

While self-tests can be used in a variety of settings, additional considerations apply to the following scenarios:

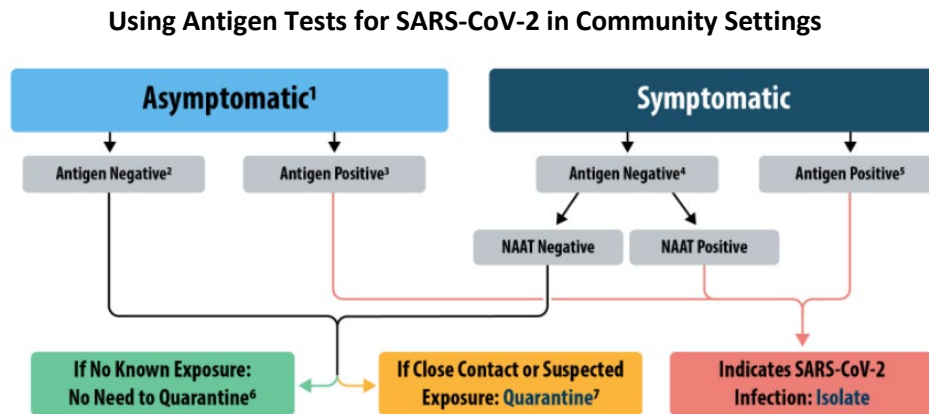
1. Rule-out COVID-19 infection: Testing positive with a self-test when symptomatic can provide quick results that allow for timely isolation and contact notification. Self-tests, like all antigen tests, are less sensitive than PCR tests and self-tests are additionally subject to potential sample collection and testing errors. If persons are symptomatic (and particularly if they also have been in close contact with someone who has COVID-19), a single negative self-test result should not be considered sufficient to rule-out infection and return to normal activities. After a negative self-test result, the symptomatic individual should either take a second self-test at least 24 hours after the first one (per manufacturer's instructions) or seek a test administered by a healthcare provider, either an antigen or a PCR test.
2. 90-day exception to test and quarantine: If a positive self-test result was reported **at the time the test was taken** to public health authorities (and entered into CDRSS), a healthcare provider, or to the individual's employer, school or other coordinating agency, and the test result can be verified by that agency, the individual would not need to be tested or quarantine for 90 days after that positive test result. If previous positive self-tests cannot be verified through either CDRSS, a healthcare provider, or employer/school records, the 90-day exception to test and quarantine would not apply.

Sensitivity and Specificity of Antigen Tests (*including self-tests*)

The sensitivity of antigen tests (including self-tests) varies, but antigen tests are generally less sensitive than most laboratory-based Nucleic Acid Amplification Tests (NAATs) such as PCR. The antigen level in specimens collected either before symptom onset or late in the course of infection, may be below these tests' limit of detection. This may result in a negative antigen test result, while a more sensitive test, such as most NAATs, may return a positive result. Antigen tests have comparable sensitivity to laboratory-based NAATs when viral load in the specimen is high and the person is likely to be most contagious. The specificity of antigen tests is generally as high as most NAATs, which means that false positive test results are unlikely when an antigen test is used according to the manufacturer's instructions. Despite the high specificity of antigen tests, false positive results can occur, especially when used in communities where the prevalence of infection is low. Interpreting the results of an antigen test for SARS-CoV-2 depends primarily on the clinical and epidemiological context of the person who has been tested (e.g., symptoms, close contact to others with COVID-19, [vaccination status](#), previous infection status, and disease prevalence in their geographic location).

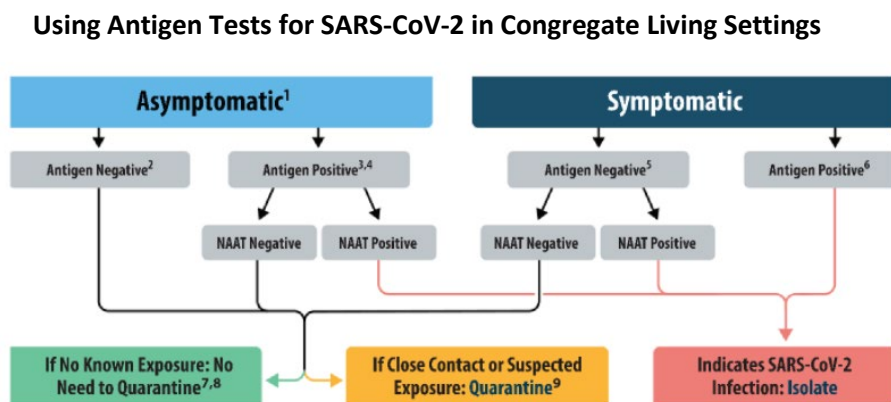
Confirmatory Testing

The gold standard for clinical diagnostic detection of SARS-CoV-2 remains laboratory-based (moderate- and high-complexity) NAATs, including PCR. If an antigen test result is inconsistent with the clinical context, a confirmatory PCR test performed within 2 days can be considered. Because antigen tests are less sensitive than PCR tests, if a symptomatic person has a negative antigen test (particularly if that person has also had close contact with someone having COVID-19), a confirmatory PCR test should be considered. If PCR testing is not available, a second antigen test collected at least 24 hours after the initial negative test, can also increase the reliability of negative antigen test results in symptomatic persons.



Congregate Living Settings

In congregate living settings where significant actions are taken in response to positive COVID-19 test results, in addition to considering confirmatory testing if a symptomatic person tests negative, confirmatory testing can also be considered if an asymptomatic person tests positive.



Healthcare Settings

Viral testing (antigen or NAAT) is recommended following a higher-risk exposure and might also be used to inform when healthcare providers (HCP) with SARS-CoV-2 infection may return to work. Using

laboratory-based or point-of-care tests is generally preferred in these situations to help ensure the test was administered correctly by a trained provider and to allow for verified results to be shared with occupational health services. Some facilities may consider having HCPs use self-tests in some situations, with the following considerations: self-tests may inappropriately transfer the cost of testing to HCPs, they require trust that the HCP self-administered and interpreted the test result correctly; and they require that HCPs report their own results to occupational health services.

If self-tests are used, consideration should be given to performing a second test at least 24 hours following an initial negative test; if the second test is negative; this increases the confidence the HCP are not infectious. Facilities could also consider having HCPs present for a proctored test to assist with ensuring appropriate collection and interpretation.

International Travel

Travel requirements vary by country. Travelers should check COVID-19 travel requirements for their [country of destination](#). Travelers should also check [CDC travel guidance](#) for current information on requirements for arrival into the U.S. to see if self-tests are acceptable.

Resources

[Self-Testing](#)

[Test for Current Infection](#)

[Interim Guidance for Antigen Testing for SARS-CoV-2](#)

[International Travel](#)