



At-home testing and COVID-19 December 6, 2021

1. What does “at-home” testing mean?

"At-home" testing in the strictest sense refers to a test where the consumer performs the test and obtains the result "at-home." There is some confusion on this term "at-home testing" because there are some tests that are for "at-home" collection, but the sample itself is sent to a central laboratory facility for actual testing. Some tests are now authorized for at-home collection and testing, and these tests include antigen tests and nucleic acid amplification tests. Testing performed by the consumer and outside the laboratory is labeled by the Food and Drug Administration (FDA) as “over the counter” or “OTC” as no health care provider is responsible for requesting the test or interpreting the results.

2. As these tests hit the market what do consumer’s look for?

Accuracy (sensitivity and specificity) is very important, but it is often challenging to identify a test’s true performance using only marketing materials. Often scientific literature using post-market studies provides the most informative information on the performance of at-home tests. Performance of at-homes varies substantially between manufacturers. If the FDA recalls an OTC test for poor performance, the information will be posted online: <https://www.fda.gov/medical-devices/medical-device-safety/safety-communications>.

3. Is specimen collection important and why?

Yes, specimen collection is very important and therefore it's important for consumers to carefully follow the directions provided by the manufacturer. Errors in the collection or testing process can lead to false results; for example, if an inadequate amount of sample is collected on a swab, then there is a higher likelihood for a false negative.

4. How do all these different kinds of tests work?

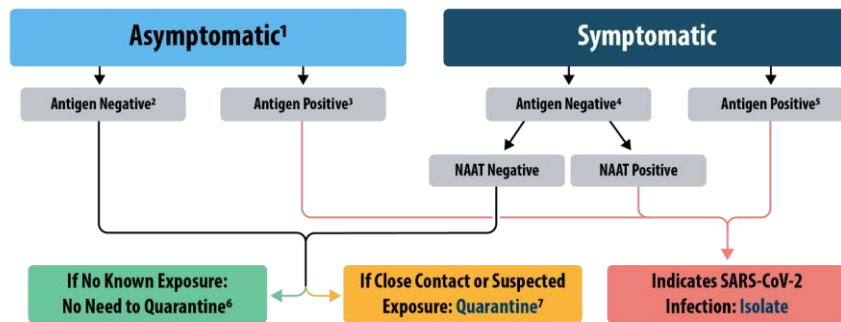
There are multiple at-home tests using different technologies. Most rapid tests are designed to detect SARS-CoV-2 antigens or proteins that are part of the virus. Molecular tests utilize nucleic acid amplification to detect viral RNA. Because these molecular tests can detect much smaller amounts of virus than the antigen tests, they tend to be more sensitive. In general, the consumer swabs their own nose, places the swab into the testing device or into a small container with a special solution that is then tested. The testing device can be as simple as an OTC pregnancy test device, or as complex as a small nucleic acid amplification unit. Most tests can be easily read by the consumer, but some tests require a smartphone and interaction with the manufacturers cloud-based software. Some newer molecular OTC tests will also provide a certified result that can be used in settings where a negative molecular test is required.

5. Can they be trusted?

OTC antigen tests are generally less sensitive than nucleic acid amplification tests like RT-PCR that are performed in clinical laboratories. However, there are a few OTC molecular tests that have received emergency use authorization that are not only rapid, with results in 30 minutes or less, but significantly more sensitive than the current antigen tests. The biggest advantage of all OTC tests is that they increase accessibility, frequency, and rapidity of testing which can facilitate the public safely navigating the pandemic. All of these tests are more likely to detect virus when the viral load is highest, just prior to development of symptoms and for several days after symptoms develop. For this reason, serial testing several times a week with these tests can quickly and accurately identify pre-symptomatic infectious persons. The Centers for Disease Control and Prevention (CDC) has recommendations on how to best utilize and interpret antigen



tests in a variety of clinical settings.: <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>



6. What’s the difference between an “at-home” test and a point-of-care (POC) test that you get in a doctor’s office, hospital, pharmacy, or is there?

OTC tests and rapid POC tests often use similar testing technologies and sometimes the identical test method. One difference is that for at-home tests to be authorized by the FDA they must be simple and easy to use by anyone, whereas POC tests are authorized based on use by a qualified health care professional. The most sensitive tests to detect SARS-CoV-2 are typically more complex and are performed in laboratories by trained scientists.

7. How do you gauge these tests?

Test performance is typically gauged by comparing it to a reference standard (“gold standard”) method such as a highly sensitive RT-PCR. Therefore, manufacturers will have data on test performance that is reviewed by the FDA prior to emergency use authorization. It is also important to consider the use case for these tests. Sometimes, at-home tests are promoted for use as screening tests, but they are designed and marketed as diagnostic tests. These different use cases can alter the positive and negative predictive values associated with interpreting the results. The CDC’s guidance (depicted above) is a useful tool to aid in the interpretation of testing performed at home.

8. What is the CAP watching for when it comes to these tests?

The CAP has no official role in evaluating at-home or OTC SARS-CoV-2 testing which aside from FDA test emergency use authorization is largely unregulated. These OTC tests are now frequently being performed in non- traditional settings such as schools, workplaces, and airports, further complicating the regulatory environment. As frequent rapid screening of asymptomatic persons for SARS CoV-2 becomes more widespread, the utilization of rapid OTC tests will increase as will the number and availability of these tests.

As laboratorians we are always interested in test performance on our patients, especially how testing at homes affects them because they frequently compare at-home tests with our laboratory analysis. For this reason, we keep abreast of developments and performance of at-home tests and how they compare to our laboratory-based tests. Clinicians frequently ask us questions as they are questioned by their patients. This will be especially true with at-home tests for SARS CoV-2.

9. Do OTC COVID tests require any additional oversight?

On November 22, 2021, the Centers for Medicare & Medicaid Services (CMS) published [a new frequently asked questions \(FAQ\) document](#) which outlines how the Clinical Laboratory Improvement Amendments of 1988 (CLIA) apply to OTC home testing (also called self-testing) when used in different settings, particularly when the test is performed by someone other than the individual who needs testing. Refer to this new FAQ



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document to learn more about when CLIA requirements apply to the use of OTC home tests.