At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative Results: FDA Safety Communication

November 17, 2022, Update: The FDA took an additional action related to the need for repeat testing following a negative COVID-19 test result on COVID-19 antigen tests -- revising the emergency use authorizations (EUAs) of all authorized COVID-19 antigen tests on November 1, 2022. For details, see FDA Actions below.

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The U.S. Food and Drug Administration (FDA) is advising people to perform repeat testing, also called serial testing, following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result) and to help prevent people from unknowingly spreading the SARS-CoV-2 virus to others.

Perform repeat, or serial testing following a negative result on any at-home COVID-19 antigen test, whether or not you have symptoms.

The FDA recommends repeat testing following a negative result whether or not you have COVID-19 symptoms.

At-home COVID-19 antigen tests detect proteins, called antigens, from the SARS-CoV-2, the virus that causes COVID-19. At-home COVID-19 antigen tests are less likely to detect the SARS-CoV-2 virus than molecular tests, such as polymerase chain reaction (PCR) tests. This is especially true early in an infection or in people who do not have COVID-19 symptoms. Currently, all at-home COVID-19 antigen tests are FDA-authorized for repeat use. This means people should use multiple tests over a certain time period, such as 2-3 days, especially when the people using the tests don't have COVID-19 symptoms. Today, the FDA is highlighting the continued need for repeat testing when people get a negative result with an at-home COVID-19 antigen test, including recommending additional testing over a longer period of time.

Over the course of the COVID-19 pandemic, public health scientists have continued to learn about the SARS-CoV-2 virus and the impact of variants on diagnostic tests that detect SARS-CoV-2. Today's recommendations are based on the latest study results from people with likely omicron infection showing that repeat testing after a negative at-home COVID-19 antigen test result increases the chance of an accurate result. COVID-19 diagnostic testing remains a cornerstone of our nation's fight against COVID-19. At-home COVID-19 antigen tests, while not perfect, provide a fast and convenient COVID-19 testing option.

Recommendations:

Before you use a COVID-19 antigen test:

- Be aware that at-home COVID-19 antigen tests are less accurate than molecular tests. COVID-19 antigen tests may not detect the SARS-CoV-2 virus early in an infection, meaning testing soon after you were exposed to someone with COVID-19 could lead to a false-negative result, especially if you don't have symptoms. This is the reason why repeat testing is important.
- If you plan to use at-home COVID-19 antigen tests, have several tests on hand so you can test more than once. You do not need to use the same brand of test each time for repeat testing. Visit At-Home OTC COVID-19 Diagnostic Tests (/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests) for a list of all FDA-authorized home tests and for more information about who can use a test and for what ages.
- Be aware the FDA expects similar performance with Point of Care (POC) COVID-19 antigen tests performed at a clinic or doctor's office. A negative POC COVID-19 antigen test result should also be followed up with repeat testing and an at-home test could be used.

When you use an at-home COVID-19 antigen test:

Follow the test's step by step instructions exactly to perform the test and to read the test's results.

After you use an at-home COVID-19 antigen test:

- **If you receive a positive result initially or after a repeat test**, this means the test detected the SARS-CoV-2 virus and you most likely have COVID-19.
    - Follow the Centers for Disease Control and Prevention (CDC) guidance (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.cdc.gov/respiratory-viruses/prevention/precautions-when-sick.html) for people with COVID-19, including to stay home, isolate from others, and seek follow-up care with a health care provider to determine the next steps.
- **If you receive a negative result,** the test did not detect the SARS-CoV-2 virus at the time of that test.
    - **If you have COVID-19 symptoms** (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)**, test again 48 hours after the first negative test, for a total of at least two tests.**
        - If you get a negative result on the second test and you are concerned that you could have COVID-19, you may choose to test again 48 hours after the second test, consider getting a laboratory molecular-based test, or call your health care provider.
    - **If you do not have COVID-19 symptoms and believe you have been exposed to COVID-19, test again 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.**
        - If you get a negative result on the second test, test again 48 hours after the second test.
        - If you get a negative result on the third test and you are concerned that you could have COVID-19, you may choose to test again using an antigen test, consider getting a laboratory molecular-based test, or call your health care provider.
    - **If you get a positive result on any repeat test with an at-home COVID-19 antigen test**, you most likely have COVID-19 and should follow the CDC guidance for people with COVID-19.

Background

COVID-19 diagnostic tests (/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.fda.gov/consumers/consumer-updates/covid-19-test-basics) detect the SARS-CoV-2 virus. There are at-home COVID-19 diagnostic tests that are FDA-authorized (/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) for self-testing at home, or anywhere. The FDA has authorized both molecular and antigen COVID-19 diagnostic tests for home use.

Overall performance of at-home COVID-19 antigen tests

Most at-home COVID-19 tests are antigen tests and do not detect the SARS-CoV-2 virus as well as molecular tests, most of which are laboratory-based such as polymerase chain reaction (PCR) tests. Molecular COVID-19 tests are generally expected to detect the SARS-CoV-2 virus at least 95% of the time when someone is infected. However, at-home COVID-19 antigen tests are generally expected to detect the SARS-CoV-2 virus at least 80% of the time when someone is infected.

When you perform an at-home COVID-19 antigen test, and you get a positive result, the results are usually accurate. However, if you perform an at-home COVID-19 antigen test, you could get a false negative result. This means that the test may not detect the SARS-CoV-2 virus that is in your nasal swab sample. This could happen if you test soon after you get an infection, especially if you don't have COVID-19 symptoms (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html). If you receive a false negative test result, you may unknowingly spread the SARS-CoV-2 virus to others.

Studies to better understand at-home COVID-19 antigen test performance

When at-home COVID-19 antigen tests were initially FDA-authorized, the FDA knew that for people to get accurate results, test instructions would need to include directions for repeat testing. The FDA believed the best way to better understand COVID-19 infections and evaluate test accuracy was to require test developers to perform follow up studies with their tests. The studies would need to assess how well COVID-19 antigen tests could detect the SARS-CoV-2 virus, especially in people without COVID-19 symptoms. Therefore, the FDA required each at-home COVID-19 antigen test manufacturer to assess how well their test works when used by people with and without COVID-19 symptoms following repeat testing instructions.

In parallel, the FDA collaborated with the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School and together they designed a comprehensive study (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.medrxiv.org/content/10.1101/2022.08.04.22278274v1) (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer) to assess at-home COVID-19 antigen test performance. The study was funded by the NIH's Rapid Acceleration Diagnostics (RADx) Program and included more than 7,000 participants. The results of the study would be available as a resource to all at-home COVID-19 antigen test manufacturers.

The study participants collected their nasal sample and performed an at-home COVID-19 antigen test. Participants who got a negative test result performed repeat testing every 48 hours, over 14 days. All participants also collected their nasal sample using a home collection kit and then sent the sample to a clinical laboratory for testing with an FDA-authorized molecular test. The study compared the performance of at-home COVID-19 antigen tests to performance of a laboratory-based molecular test. Results from this study (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1) (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer) show that repeat testing over a longer timeframe improves test performance and increases the likelihood that an at-home COVID-19 antigen test will detect an infection. These results have further guided the FDA's thinking that repeat testing after a negative result with an at-home COVID-19 antigen test reduces the risk of a false negative result.

FDA Actions

On November 1, 2022, based on the data discussed in this safety communication, the FDA revised the authorized uses and required updates to the labeling for all currently authorized COVID-19 antigen tests regarding repeat testing after a negative COVID-19 test result.

For additional information about the EUA revision, visit: Antigen EUA Revisions for Serial (Repeat) Testing (/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/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#SerialTesting)

For additional information about at-home tests, visit: At-Home OTC COVID-19 Diagnostic Tests (/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests)

The FDA is committed to assuring appropriately accurate and reliable at-home COVID-19 diagnostic tests for all Americans and will keep the public informed if significant new information about COVID-19 antigen test performance becomes available.

Reporting Problems with Your Device

If you think you had a problem with your COVID-19 test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://us.pagefreezer.com/en-US/replay/w/id-04720ef89910/:522d47d9ad324fbe0b6cedd601b2563d/20240811064815mp_/https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.