At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions

Español (/medical-devices/coronavirus-covid-19-and-medical-devices/pruebas-de-diagnostico-de-covid-19-en-el-hogar-preguntas-frecuentes)

Diagnostic tests can show if you have an active COVID-19 infection and need to take steps to quarantine or isolate yourself from others.

This page is part of the FAQs on Testing for SARS-CoV-2 (/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2) and provides answers to frequently asked questions related to at-home COVID-19 diagnostic tests.

- When should I test for COVID-19?
- What do my at-home COVID-19 test results mean?
- I got a negative test result on an at-home COVID-19 antigen test. Do I need to take another test?
- Are at-home COVID-19 tests safe to use? Do they contain toxic chemicals?
- Can I use an authorized at-home COVID-19 diagnostic test if it was left outside in freezing temperatures or in the heat?
- How is the expiration date determined for an at-home COVID-19 diagnostic test?
- Can I use an FDA-authorized at-home COVID-19 diagnostic test that is expired?
- Can the expiration date of an at-home COVID-19 diagnostic test be extended?
- How do I know if the expiration date of my at-home COVID-19 test has been extended? Where do I find the updated expiration date?

Q: When should I test for COVID-19?

A: COVID-19 testing is important to find out if you have COVID-19 so that you can get treatment, if needed, as well as to be aware if you are infected and should stay away from people to help reduce the spread of the virus. You should test for COVID-19 in the following situations:

- If you have symptoms (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html), test immediately.
- If you were exposed (https://www.cdc.gov/coronavirus/2019-ncov/your-health/risks-exposure.html) to someone who has COVID-19 and do not have symptoms, wait at least 5 full days after your exposure before testing. If you test too early, you may have an inaccurate result.
- If you are in certain high-risk settings (https://www.cdc.gov/coronavirus/2019-ncov/community/index.html), you may need to test as part of a screening testing program.
- Consider testing before coming into contact with someone who has a high risk for severe COVID-19, especially if you are in an area with a medium or high COVID-19 Community Level (https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html).

Find out more about when and how often to test for COVID-19 at Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results (/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results).

Q: What do my at-home COVID-19 test results mean?

A: If you receive a positive result on any COVID-19 test, assume you have COVID-19. Be sure to follow the CDC's guidelines (https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html#test-positive) for people with COVID-19, including to stay home, isolate from others, and seek follow-up care with a health care provider to determine what steps to take next.

If you receive a negative result on your at-home COVID-19 antigen test, it means the test did not detect the virus that causes COVID-19, but it **does not** rule out an infection because some tests may not detect the virus early in an infection. Always do a repeat test (https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety) after a negative result on an antigen test. Find out more about at-home testing, when and how often to test, and understanding your test results at Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results (/medical-devices/coronavirus-covid-19-and-medical-devices/understanding-home-otc-covid-19-antigen-diagnostic-test-results).

Q: I got a negative test result on an at-home COVID-19 antigen test. Do I need to take another test? (11/17/2022)

A: Yes. The FDA recommends repeat testing following a negative COVID-19 antigen test result whether or not you have COVID-19 symptoms. COVID-19 antigen tests are less accurate than molecular tests and may not detect the SARS-CoV-2 virus early in an infection or in people who do not have COVID-19 symptoms.

You should perform repeat testing following a negative result on a COVID-19 antigen test to reduce the risk an infection may have been missed (false negative result) and to help prevent unknowingly spreading the SARS-CoV-2 virus to others.

- If you have COVID-19 symptoms, test again 48 hours after the first negative test, for a total of at least two tests.

- If you do not have COVID-19 symptoms, 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 positive result on any COVID-19 test, you most likely have COVID-19 and should follow the CDC guidance for people with COVID-19.

In August 2022, the FDA issued a Safety Communication (https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication) on the need to perform repeat testing to reduce your risk of a false negative result. In November 2022 (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), the FDA required all manufacturers of EUA-authorized COVID-19 antigen tests to update

their labeling to reflect the need for repeat testing at least twice over three days for individuals with symptoms of COVID-19 and at least three times over five days for individuals without symptoms of COVID-19, as appropriate based on their authorized uses.

Q. Are at-home COVID-19 tests safe to use? Do they contain toxic chemicals? (3/18/22)

A: FDA authorized at-home COVID-19 tests are safe to use when people follow the manufacturer's step by step instructions. However, incorrect use of at-home COVID-19 tests can cause harm if the parts of the test kit, such as liquid solutions in small vials that may contain chemicals like sodium azide, are swallowed or if the liquid solutions touch a person's skin or eyes. The FDA has provided recommendations to promote the safe use of at-home COVID-19 tests in a Safety Communication (/medical-devices/safety-communications/use-and-store-home-covid-19-tests-properly-avoid-potential-harm-fda-safety-communication) issued March 18, 2022, including to keep all parts of at-home COVID-19 tests out of reach of children and pets before and after use, and to follow the test's step by step instructions exactly, including the Warning, Precautions, And Safety Information.

Q: Can I use an authorized at-home COVID-19 diagnostic test if it was left outside in freezing temperatures or in the heat? (4/28/22)

A: Since shipping conditions may vary, test developers perform stability testing to ensure that the test performance will remain stable when tests are stored at various temperatures, including shipping during the summer in very hot regions and in the winter in very cold regions.

However, test performance may be impacted if the test is used while it is still cold, such as being used outdoors in freezing temperatures or being used immediately after being brought inside from freezing temperatures, or in a hotter than expected environment, such as outside in the summer. The stated performance generally assumes the test is being performed in an environment that is between 15-30°C (approximately 59-86°F). The specific conditions that were validated are included in the authorized Instructions for Use for each test.

In order to ensure appropriate test performance with a test that is delivered to you in below freezing temperatures or in very hot temperatures, you should bring the package inside your home and leave it unopened at room temperature for at least two hours before opening it. Once the package is at room temperature, you may open it and perform the test according to the authorized instructions for use. As long as the test line(s) appear as described in the instructions, you can be confident that the test is performing as it should. If the line(s) do not appear in the correct location(s) and within the correct time as shown in the test instructions when you perform the test, then the results may not be accurate, and a new test is needed to get an accurate result.

In addition, long exposure to high temperatures may impact the test performance. If your test has been left in a high temperature environment beyond the normal shipping time to be delivered to you, such as being left outside in the heat for several days, the FDA recommends considering using a different test.

Q: How is the expiration date determined for an at-home COVID-19 diagnostic test? (4/28/22)

A: COVID-19 test manufacturers perform studies to show how long after manufacturing COVID-19 tests perform as accurately as the day the test was manufactured. The **shelf-life** is how long the test should perform as expected and is measured from the date the test was manufactured. The **expiration date** listed on the box label for at-home COVID-19 tests is set at the end of the shelf-life and is the date through which the test is expected to perform as accurately as when manufactured.

The testing to determine this time period is called stability testing because it is confirming the time period over which the performance is expected to remain stable. There are different types of stability testing. The most accurate is real-time stability testing, where the manufacturer stores the tests for the time period of the proposed shelf-life (plus a little extra time to ensure the expiration date can be relied upon) and then evaluates its ability to perform accurately. For example, for a proposed 12-month shelf-life, the manufacturer would evaluate the performance after storing the test for 13 months.

In some cases, accelerated testing provides a faster way to estimate the stability of a test's performance over time by storing the test for a shorter time at a higher temperature, and then evaluating its ability to perform accurately. However, since accelerated testing only estimates the test stability, it does not provide as much assurance as real-time data, especially for longer time periods. Based on experience with tests and stability testing, accelerated testing typically provides sufficient assurance to label tests with a shelf-life of up to six months.

Since it takes time for test manufacturers to perform stability testing, the FDA typically authorizes at-home COVID-19 tests with a shelf-life of about four to six months from the day the test was manufactured, based on initial study results, and it may be extended later as additional data is collected. You can check the Expiration Date column of the List of Authorized At-Home OTC COVID-19 Diagnostic Tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list) to see if the expiration date for your at-home OTC COVID-19 test has been extended and how to find any new expiration date.

Q. Can I use an FDA-authorized at-home COVID-19 diagnostic test that is expired? (4/28/22)

A: No, the FDA does not recommend using at-home COVID-19 diagnostic tests beyond their authorized expiration dates. COVID-19 tests and the parts they are made of may degrade, or break down, over time. Because of this, expired test kits could give inaccurate or invalid test results.

However, the expiration dates for at-home COVID-19 diagnostic tests may be extended as additional stability data is collected. You can check the Expiration Date column of the List of Authorized At-Home OTC COVID-19 Diagnostic Tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list) to see if the expiration date for your at-home OTC COVID-19 test has been extended and how to find any new expiration date.

Q: Can the expiration date of an at-home COVID-19 diagnostic test be extended? (4/28/22)

A: Yes. Once the test manufacturer has more stability testing results, such as 12 or 18 months, the test manufacturer can contact the FDA to request that the FDA authorize a longer shelf-life. When a longer shelf-life is authorized, the expiration dates will be extended and the test manufacturer may send a notice to customers to provide the new authorized expiration dates, so the customers know how long they can use the tests they already have. If you did not purchase your at-home COVID-19 diagnostic test directly from the test manufacturer, you may not receive such a notice. You can check the Expiration Date column of the List of Authorized At-Home OTC COVID-19 Diagnostic Tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list) to see if the expiration date for your at-home OTC COVID-19 test has been extended and how to find any new expiration date.

Q: How do I know if the expiration date of my at-home COVID-19 test has been extended? Where do I find the updated expiration date? (4/28/22)

A: You can check the Expiration Date column of the List of Authorized At-Home OTC COVID-19 Diagnostic Tests (https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests#list) to see if the expiration date for your at-home OTC COVID-19 test has been extended and how to find any new expiration date.

Resources

- At-Home OTC COVID-19 Diagnostic Tests (/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests)

- COVID-19 Test Basics (/consumers/consumer-updates/covid-19-test-basics)

- If you think you had a problem with a COVID-19 test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

- If you have other questions about COVID-19 testing, 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. You may also contact the customer service department for the COVID-19 test you are using.