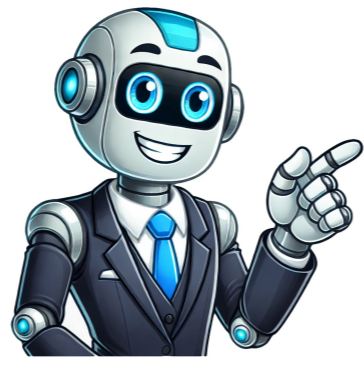


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Covid test extended expiration

U.S. Food and Drug Administration sent this bulletin at 10/29/2024 09:03 AM EDT If your email program has trouble displaying this email, view as a webpage. Did you know that there are several over-the-counter (OTC) COVID-19 tests that have extended expiration dates? If you have at-home OTC COVID-19 tests with extended expiration dates, they can be used beyond the expiration date that is printed on the box. *Tis the season to check, confirm, and test holiday celebrations are fast approaching. With an increase in social gatherings comes the likelihood of an increase in positive COVID-19 cases. Testing helps prevent and contain the spread of COVID-19 This holiday season, the U.S. Food and Drug Administration (FDA) encourages you to check, confirm, and test. Check the FDA’s website: Search the current list of authorized at-home COVID-19 tests that have extended expiration dates. Confirm expiration dates: Make sure your at-home tests have not expired. If your at-home tests do not have an extended expiration date and they have expired, do not use them. Test for COVID-19: Use an at-home test if you feel sick, have symptoms of COVID-19, or have been exposed to someone who has COVID-19 and you do not have symptoms. Our website includes a list of authorized, at-home OTC COVID-19 tests that have extended expiration dates, along with images of each test and additional details. You can search the list by test name or manufacturer. To protect public health and support health equity, this list is also available in Spanish. What does an extended expiration date mean? The shelf-life is how long the test should work as expected and is measured from the date the test was manufactured. The expiration date 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. An extended expiration date means the manufacturer provided data showing that the shelf-life is longer than was known when the test was first authorized. Learn more For more information about how the expiration date is determined and why it may be extended, see the At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions (FAQ). The FAQ is also available in Spanish. To receive email alerts and updates on an array of topics related to medical devices and radiation-emitting products, subscribe to our mailing lists. Powered by Privacy Policy | Cookie Statement | Help Español Many COVID-19 tests have extended expiration dates, so you may be able to use your COVID-19 tests after the expiration date that is printed on the box. To find out if your test has an extended expiration date, check the list of extended expiration dates. On this page:General Information About At-Home OTC COVID-19 Diagnostic Tests At-home over-the-counter (OTC) COVID-19 diagnostic tests can show if you have an active COVID-19 infection.These at-home OTC COVID-19 diagnostic tests are FDA authorized for self-testing at home (or in other locations) without a prescription. Tests are available online or at local stores and you collect your own sample, perform the test, and read the result yourself without the need to send a sample to a laboratory.With most at-home OTC COVID-19 diagnostic tests, you should repeat testing following a negative result, whether you have symptoms or not, to reduce your risk of a false negative test result. The FDA encourages you to voluntarily and anonymously report your positive or negative test results every time you use an at-home COVID-19 test. You can send your test result to MakeMyTestCount.org or use an app or other digital option for self-reporting that may be included with your test. For additional information on reading and understanding your test results, see Understanding At-Home OTC COVID-19 Antigen Diagnostic Test Results. For more information, including answers to frequently asked general questions about at-home COVID-19 diagnostic tests, visit At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions.Authorized At-Home OTC COVID-19 Diagnostic Tests and Expiration DatesThe table below is updated regularly and lists FDA-authorized at-home OTC COVID-19 diagnostic tests, including information on expiration dates, who can use the test, links to home use instructions for each test, and other details that may help you decide what test is right for you. For additional information about each Emergency Use Authorization (EUA), see In Vitro Diagnostics EUAs: Tables of IVD EUAs.In the table below, the "Expiration Date" column lists where to find the expiration date for that test, and the "Other Details" column lists the shelf-life for the test. The shelf-life is how long the test should work as expected and is measured from the date the test was manufactured. The expiration date 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. In some cases, the expiration date for a test may be extended.An extended expiration date means the manufacturer provided data showing that the shelf-life is longer than was known when the test was first authorized. For more information about how the expiration date is determined and why it may be extended, see the At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions.To see if the expiration date for your at-home OTC COVID-19 test has been extended, first find the row in the below table that matches the manufacturer and test name shown on the box label of your test. If the expiration date has been extended, then the Expiration Date column states "Extended Expiration Date" and links to a document that lists the lot numbers, original expiration dates, and the extended expiration dates. If your lot number and/or original expiration date do not appear, or if the Expiration Date column states "Expiration Date: See box label," do not use the test beyond the original expiration date on your test. Search the table below by manufacturer, test name, or other details shown in the table to find more information on the test, including if the expiration date has been extended. To see complete information on smaller screens, select the blue plus (+) button beside the test name.Manufacturer and Test Name (Links to Instructions for Use)Expiration DateWho can use this test: SymptomsWho can use this test: AgeOther DetailsAbbott Diagnostics Scarborough, Inc.:BinaxNOW COVID-19 Ag Card Home Test People with symptoms that began within the last 7 days. The test is to be performed two times over three days (serial testing).People without symptoms. The test is to be performed three times over five days (serial testing).Age 15 years and olderAge 2 years and older when collected by an adultAntigen testNasal swabResults in 15 minutesShelf Life: 22 monthsAccess Bio, Inc.:CareStart COVID-19 Antigen Home Test Alternate brand name: People with symptoms that began within the last 7 daysPeople without symptoms. The test is to be performed two times over three days (serial testing)Age 14 years and olderAge 2 years and older when collected by an adultAntigen testNasal swabResults in 15 minutesShelf Life: 22 monthsAccess Bio, Inc.:CareStart COVID-19 Antigen Home Test Alternate brand name: People with symptoms that began within the last 7 daysPeople without symptoms. 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The test is to be performed three times over five days (serial testing).Age 14 years and olderAge 2 years and older when collected by an adultAntigen testNasal swabResults in 15-30 minutesShelf Life: 21 monthsPfizer Inc.:Lucira by Pfizer COVID-19 & Flu Home Test Age 14 years and olderAge 2 years and older when collected by an adultMolecular testNasal swabResults in 30 minutesShelf Life: 18 monthsPrinceton BioMeditech Corp.:Status COVID-19 Antigen Rapid Test for Home Use Expiration Date: See box labelPeople with symptoms that began within the last 5 days. The test is to be performed two times over three days (serial testing).People without symptoms. 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The test is to be performed two times over three days (serial testing).Age 14 years and olderAge 2 years and older when collected by an adultAntigen testNasal swabResults in 15 minutesShelf Life: 21 monthsAptitude Medical Systems Inc.: Metrix COVID/Flu Test Expiration Date: See box labelAge 14 years and olderAge 2 years and older when collected by an adult Molecular testNasal swabResults in 20 minutesShelf Life: 12 monthsRelated Information: The FDA has extended the shelf life for some COVID-19 tests.Now that allergy season is here, many are finding themselves with symptoms asking: Is it allergies or a cold? COVID? Something else? Since allergies, colds and COVID can have symptoms that overlap, it can be difficult to figure out what you have. That’s when an at-home COVID test can come in handy. Even if you says it’s expired, many tests have had their shelf lives extended past the expiration date.To determine whether your COVID test is still usable, you can check the at-home COVID-19 tests listed on the FDA’s website to see which brands have had their shelf lives extended. COVID-19 Tests: How to Get Free At-Home Kits in the MailSee at CNETWhat do COVID-19 test expiration dates mean?The expiration date listed on your box of COVID-19 tests is the last day the test is expected to perform effectively. Generally, the FDA authorizes at-home test kits with a shelf life of about four to six months, but that shelf life could be extended if the manufacturer finds more data that shows the tests are still accurate past the expiration date.Can I use a COVID test kit after it expires?Unless the FDA has extended the shelf life of your box of COVID-19 tests, it’s not recommended you use them after they’ve expired. Here’s why:The COVID-19 test parts could degrade or break down over time, leading to inaccurate or invalid test results.See below to find out if your box of COVID-19 tests is still OK to use, as it’s possible the expiration date has been extended.How do I know if the shelf life of my COVID tests has been extended?The manufacturer finds that the shelf life is longer than the expected four to six months, it can request that the FDA authorize an extended expiration date. Once that happens, the manufacturer may notify customers of the new expiration dates. However, if you didn’t buy the tests via the manufacturer, you likely won’t receive any notifications.For the latest information on the expiration dates for your COVID-19 test kits, be sure to check the FDA’s At-Home OTC COVID-19 Diagnostic Tests webpage.On that page, the FDA page lists COVID-19 tests alphabetically, or you can use a search box to find your test directly. In the far right column of a table, the FDA lists the shelf life for each test and whether it’s been extended. If the expiration date has been extended, an additional link is sometimes provided with information on the exact expiration dates for specific test lots.The links below include lot numbers and expiration dates for the brands of at-home COVID-19 tests that have had their expiration dates extended by the FDA.If you don’t see anything on the FDA page, you can also check the manufacturer to see if they’ve posted a letter from the FDA that their tests have been extended.How to find lot number on COVID testYou can find the lot number for your at-home COVID test on its box, usually on a sticker with its expiration date. It may be a combination of both numbers and letters. According to the FDA, "If your lot number and/or original expiration date do not appear, or if the Expiration Date column states "Expiration Date: See box label," do not use the test beyond the original expiration date on your test."