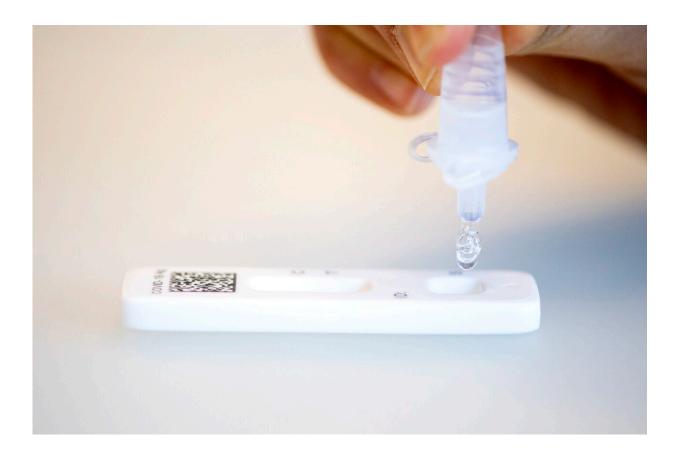


Do at-home COVID-19 tests expire?

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Credit: Matthew Modoono/Northeastern University

Perhaps you stocked up when at-home COVID-19 test kits were hard to come by, before the U.S. federal government started a program to mail some to each household. Or maybe you found a bunch of test kits for a good price at your local pharmacy. Or bought a few when insurance companies started reimbursing the cost.



In any case, if you have a pile of COVID-19 test kits at home, be sure to check the expiration date on the box before using them. The tests do expire, and become more likely to report a false negative result after the expiration date, says Jared Auclair, director of the Biopharmaceutical Analysis Training Lab at Northeastern.

"COVID-19 tests that are past their expiration dates should literally be thrown out," Auclair says. "They'll be less potent and more likely to be inaccurate."

Unlike <u>food labels</u>—which provide a variety of information about when the food will be freshest and taste best but not necessarily when it actually spoils—medical labels indicate crucial information about when the medicine (or <u>test kit</u>) can and can't be used.

"When you buy milk, oftentimes the expiration date is when you need to buy it," Auclair says. "COVID tests—and medicines in general—that have expired are all junk. They need to go in the trash."

According to the federal Food and Drug Administration, at-home COVID-19 tests have expiration dates printed on the boxes that <u>indicate</u> "the end of the test's <u>shelf life</u> and... the date through which the test is expected to perform as accurately as when manufactured."

Over-the-counter COVID-19 testing kits contain antibody tests that respond to cells produced by your body's immune system to fight off SARS-CoV-2, the virus that causes COVID-19. After the test's shelf life, the chemical and molecular components that indicate the presence of those antibodies may degrade or break down, making the tests less sensitive, Auclair says.

Drugmakers and researchers use a process called stability testing to determine the time period during which medicines (or tests) perform



consistently. In other words, the period of time during which their performance is stable.

You may notice that your at-home COVID-19 test kits have a range of expiration windows. Some are good for six months, some for nine, some for 11. According to the FDA, this is due to some variation in stability testing.

Researchers gain the most <u>accurate data</u> from real-time testing, according to the FDA. In this process, "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."

Other times, researchers will use accelerated testing to get results faster. In this process, the manufacturer will store the test or the drug in more extreme conditions (at a higher temperature, for example) for a shorter amount of time.

The accelerated process doesn't give researchers and regulators as much information about long-term stability as real-time testing does, but it does give them enough data ("sufficient assurance") to determine that athome COVID-19 test kits are effective for at least six months, according to the FDA.

That's enough to get the tests out the door while researchers collect more real-time data. As the longer-term data rolls in, the FDA may extend the test's shelf life accordingly. The administration keeps a <u>running database</u> online of authorized over-the-counter COVID-19 tests, and when they expire.

As the stability testing protocols indicate, it's important to store your COVID-19 test kits properly at home, Auclair says. Keep the tests dry



and at <u>room temperature</u>, and don't let them dry out or expose them to extreme heat or freezing.

Still, Auclair says your best bet is just to follow the date stamped on the box.

"You might get a test that still works after the expiration date, but that's not a risk I'm willing to take," he says.

Provided by Northeastern University

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