

## **COVID-19 testing at home is both possible and reliable. Here's what you need to know.**

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Remember when a COVID-19 diagnostic test meant waiting in your car for a nurse wearing head-to-toe PPE to shove a long swab down your throat and send the sample to a lab that would take a week or more to



return results?

That was so 2020.

Now you can get molecular <u>test</u> kits delivered to your door—no prescription needed — then mail a shallow nose swab or a saliva sample to a lab that returns results in a day or two. Or, if you're willing to sacrifice some accuracy for convenience, you can order antigen tests online that give rapid results right at home. You may have to pay for the test, depending on why you need it and what your insurance covers.

The Food and Drug Administration has even authorized emergency use of what sounds like an ideal pandemic diagnostic tool: a highly accurate molecular test that requires no prescription, can be used anywhere, and provides immediate results. Alas, the CUE COVID-19 Test is not yet being sold directly to consumers, just to institutions that contract to buy it in bulk.

All this is happening at a time when COVID-19 tests are considered a key element in bringing the pandemic back under some semblance of control. The White House said President Joe Biden would call for boosting testing in his speech Thursday about battling the pandemic.

Here is an update on the ever-evolving, vast (321 and counting) array of COVID-19 <u>diagnostic tests</u> authorized by regulators:

## **Molecular lab-based tests**

Molecular, or PCR, tests are the gold standard for diagnosing COVID-19 because they can detect trace amounts of viral genetic material.

Molecular test kits can now be ordered online or by phone, but you still have to send your sample back to a lab capable of doing "high



complexity" molecular analysis. Results are usually sent by email within a few days. The list of authorized tests is on the COVID-19 test tracker as well as the FDA website.

Everlywell, for example, charges \$109 for its PCR test kit, no prescription needed. You can submit your receipt for reimbursement "at the discretion of your health insurance provider."

In contrast, the Pixel test, offered by the diagnostics giant LabCorp, will bill insurance directly if you have symptoms, a known COVID-19 exposure, are asked to get tested by health authorities, or live in a congregate setting (or say you do on the website questionnaire). You pay \$119 up front if you want testing for purposes such as work, school, or travel-related screening.

Many companies, including the mail-order behemoth Amazon, have jumped into the COVID-19 testing business. Amazon's direct-toconsumer molecular test kit, developed by one of its subsidiaries, requires no prescription. A sample can be collected at home or anywhere, then sent to a designated lab for analysis.

## **Molecular home tests**

In November 2020, the FDA announced authorization of "the first COVID-19 test for self-testing at home." The Lucira all-in-one test uses a <u>molecular technology</u> called real-time loop mediated amplification reaction. Just put your nasal swab sample into a <u>single-use</u>, battery-operated device and get results in 30 minutes or less.

Although the test received a bit of media coverage and now has over-thecounter status, you can't yet get it. The website invites you to sign up to get an email when it is available. In a news release, Lucira said last month that steps are underway to reach full manufacturing capacity.



The FDA also announced authorization of the CUE test, "the first molecular, non-prescription, at-home test." The respected Mayo Clinic evaluated the test and concluded it has "very good" agreement with PCR tests done at high-complexity labs. But if you call toll-free to order it, you will be told it should be available direct to consumers in the next several months.

## **Antigen tests**

Antigen tests use a front-of-the-nose swab to detect the protein, or antigen, that the coronavirus makes soon after entering cells. This technology has the advantage of being most accurate when the infected person is most contagious. It is also cheap, gives rapid results, and at least seven of the 34 authorized versions can be ordered without a prescription for home use.

But this technology has the disadvantage of being wrong in many cases—and the chance of inaccuracy increases as the prevalence of COVID-19 in the population decreases.

Testing experts who advocate using antigen testing for screening asymptomatic people say this disadvantage can be offset by frequent retesting.

But two widely used rapid <u>antigen tests</u>, Roche's SD Biosensor and Abbott's Panbio, were judged "unsatisfactory" for screening people with no symptoms by a German research group that posted on medRxiv.

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