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HEALTH

Companies Bet You're Ready to Test at Home for More Than Covid-19

Developers pursue rapid flu and strep-throat diagnostic products, as pandemic raises consumers' comfort level with monitoring own health



A factory operated by Cue Health, which is in clinical trials for an at-home flu test.

PHOTO: CUE HEALTH

By [Austen Hufford](#) [Follow](#)

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The Covid-19 pandemic has hastened consumers' willingness to test for more medical conditions at home, test makers said, expanding the market for self-diagnostic products.

Manufacturers are developing new types of at-home tests, including for flu and strep throat, aimed at consumers who are increasingly monitoring and managing their own health through fitness apps and smartwatches.

Boulder, Colo.-based fertility company MFB Fertility Inc. received clearance from the U.S. Food and Drug Administration in February 2020 for its Proov test, designed to help women measure their hormone levels and to know when in a

given month they are most likely to become pregnant. A typical kit includes 20 testing strips, allowing a woman to test daily, which the company said would be tough to achieve through visits to a doctor's office.

Amy Beckley, the company's chief executive, said the rise of at-home Covid-19 tests over the past year has made it much easier for people to understand her product.

"All of a sudden, home diagnostics and home testing became a thing," she said.

Growth in rapid, at-home testing follows decades of development and lobbying from test makers and public-health and medical groups, said Nitika Pant Pai, a medical professor at McGill University who studies rapid tests.

Home tests can help more people know whether they are sick and can be faster, less costly and more convenient than laboratory-based tests, Dr. Pai said. Before Covid-19 began spreading world-wide, she said, some medical professionals and public-health officials had been reluctant to embrace at-home testing over concerns that the general public wouldn't know how to perform a test, or overreact to results without doctors' guidance.

Some home-based tests, including for pregnancy and blood-sugar monitoring, have been around for decades. In 2012 the FDA approved the first at-home test for HIV, the virus that causes AIDS.

Manufacturers, testing experts and government regulators said there is enough interest in, and familiarity with, at-home testing that new tests are likely to reach consumers in the coming years.

"Covid has paved the way for home testing," Dr. Pai said.

Some tests, such as those for testing stool for blood, rely on consumers to perform an action themselves and then send the test by mail to a laboratory. Others offer in-home results in minutes using lines that appear on test strips, phone applications or physical readers.

The most complicated tests still need to be done in laboratory settings, with

samples typically collected by medical professionals. The FDA allows simpler tests, including for influenza and hemoglobin, to be performed directly in doctors' offices, typically using automated machines. States have started to allow pharmacists to perform some types of testing directly in stores.

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Some rapid-testing options recommend that patients confirm results with laboratory-based testing. Los Angeles-based Medical Electronic Systems LLC makes laboratory-grade equipment and at-home products for testing male

fertility. The company said FDA reviewers wanted the company to simplify how its home testing kit reported results to users so that they weren't confused, according to general manager Eric Carver. The test's phone application tells users to see a fertility specialist if their results are abnormal.

Some of the biggest competitors in laboratory testing are also expanding at-home testing options in response to rising consumer demand. Laboratory Corp. of America Holdings, better known as Labcorp, and [Quest Diagnostics Inc.](#) have rolled out platforms that let consumers order tests for fertility, blood iron levels and cancer. Some of their offerings have patients draw blood or collect other samples themselves and ship them to a laboratory, while others have customers schedule visits to local collection centers. Rapid tests are typically less accurate than laboratory-based ones, testing experts said, much like laboratory-based PCR tests for Covid-19 [are more accurate](#) than at-home rapid antigen tests.

Quest's consumer-testing service already had \$70 million in revenue in 2021 and expects that to grow to \$250 million by 2025, the company says.

Cathy Doherty, an executive at Quest in charge of the consumer-testing business, said Quest's research shows that consumers are interested in a wider range of at-home tests, but many still prefer visiting a doctor's office or testing center to make sure the tests are performed correctly.

"We think that there is room for both," she said.



An at-home Covid-19 test from Cue Health uses an electronic reader.

PHOTO: CUE HEALTH

In February, Labcorp relaunched an online service allowing consumers to order some tests directly from the company. The company is evaluating whether rapid tests that deliver results at home are high-quality enough to be included in the service, said Chief Marketing Officer Amy Summy. She said that people should continue going to medical professionals for serious issues.

The pandemic has sped up development of some at-home testing capabilities. Detect Inc. was founded at the start of the pandemic to develop an at-home Covid-19 test that was closer in accuracy to laboratory-based tests. The test won emergency approval in October 2021. Now the company is working on using its platform for future tests, including a strep-throat test and a joint Covid-19-flu test, said Owen Kaye-Kauderer, Detect's chief business officer.

San Diego-based Cue Health Inc. has been working on an at-home testing system for the flu and other diseases since 2010. Its first product to get FDA emergency approval was an at-home Covid-19 test that uses an electronic reader plus molecular cartridges for each laboratory-like test.

Cue is in active clinical trials for its at-home flu test and is developing others, including for chlamydia. The company, which ran a Super Bowl advertisement earlier this year, has invested \$250 million in expanding its U.S. factories that produce its tests and building a U.S.-centric supply chain, with the help of government and private funding. The company reported preliminary 2021 revenue of roughly \$616 million, up from \$23 million in 2020, with almost all of it

linked to Covid-19 testing.

“One of the most important, enduring changes in the pandemic will be a shift in how people view diagnostics at home,” Chief Executive Ayub Khattak said. “It is better for people to have access to information more quickly.”

Corrections & Amplifications

A photo caption in an earlier version of this article incorrectly described a Cue Health facility as a lab. The site was a Cue-operated factory. (Corrected on March 3)

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