FDA approves first at-home test for chlamydia, gonorrhea

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The first home test for chlamydia and gonorrhea will soon hit the market, following its approval Wednesday by the U.S. Food and Drug Administration.

People will be able to buy the Simple 2 Test over-the-counter at a pharmacy, take a specimen in the comfort of their home and send their sample to a designated laboratory for testing, the FDA said.

The test is produced by LetsGetChecked, a global health care solutions company focused on managing health from home. The company offers the test on its website for $99, and promises results back in two to five days.

It's the first FDA-approved test with at-home sample collection for any sexually transmitted disease other than HIV, the agency said. Until now, people would have to go to a doctor's office to be tested.

"This authorization marks an important public health milestone, giving patients more information about their health from the privacy of their own home," Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, said in an agency news release announcing the approval.

Chlamydia and gonorrhea are the first and second most common bacterial sexually transmitted diseases in the United States, according to the U.S. Centers for Disease Control and Prevention.

The rates of both are steadily increasing, with an estimated 1.6 million cases of chlamydia and more than 700,000 cases of gonorrhea in 2021, the FDA said.

Both infections can be easily treated with antibiotics, but if left untreated can lead to serious health complications, including infertility.

A person using the Simple 2 Test will provide a sample via vaginal swabs or urine specimens. As part of the approval process, the FDA evaluated data showing that average folks can safely use the kit and have a general

understanding of both the results and what they need to do afterward.

Users will fill out an online health questionnaire prior to sending off their sample, and their test results will be delivered online. A health care provider will follow up in cases of positive or invalid test results, the FDA said.

The FDA reviewed the Simple 2 Test under a regulatory pathway for new types of devices that are of low-to-moderate risk. The approval creates a new regulatory classification for this type of home test

As a result, subsequent devices of the same type can go through FDA review by showing they are much the same as the Simple 2 Test, potentially saving developers some hassle and expense, the FDA noted.

"We are eager to continue supporting greater consumer access to diagnostic tests, which helps further our goal of bringing more health care into the home," Shuren said.

More information: The U.S. Centers for Disease Control and Prevention has more about sexually transmitted infections.