

FDA Approve First Home Test for Chlamydia and Gonorrhea

Users of the over-the-counter test collect a urine or vaginal swab sample at home which is sent to a laboratory for analysis.

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FDA Grants Marketing Authorization of First Test for Chlamydia and Gonorrhea With At-Home Sample Collection

Today, the U.S. Food and Drug Administration granted marketing authorization to LetsGetChecked for the Simple 2 Test. This is the first diagnostic test for [chlamydia](#) and [gonorrhea](#) with at-home sample collection to be granted marketing authorization. Prior to today's authorization, the only cleared tests for either condition were used with samples collected at the point of care, such as a doctor's office. The Simple 2 Test is available over-the-counter (OTC) and is intended for use in adult patients ages 18 years and older. It is the first FDA-authorized test with at-home sample collection for any sexually transmitted disease other than HIV.

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

According to the Centers for Disease Control and Prevention's [Sexually Transmitted Infections Surveillance Report](#), chlamydia and gonorrhea are the first and second most common bacterial sexually transmitted infections (STIs) in the United States, and the rate of these STIs is steadily increasing, with an estimated 1.6 million cases of chlamydia and more than 700,000 cases of gonorrhea, in 2021 alone. Typically, both infections can be easily treated, but if left untreated, both infections can cause serious health complications for patients, including infertility. Expanding the availability of STI testing can help patients get quicker results and access to the most appropriate treatment, ultimately helping to curb the rising rates of STIs.

The Simple 2 Test which uses vaginal swabs or urine specimens, as appropriate, can detect the presence of the bacteria *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, which cause chlamydia and gonorrhea, respectively. The test is a direct-to-consumer test that can be

purchased without a prescription. The user activates the collection kit online and fills out a health questionnaire for a health care provider to evaluate. The individual collects the specimen at home using the provided collection kit, which is then sent back to the designated laboratory for testing. Results are delivered online, with follow-up from a health care provider in cases of positive or invalid test results.

The Simple 2 Test includes the Simple 2 Home Collection Kits that were validated for use with the cleared Hologic [Aptima 2 Combo Assay](#). The FDA also evaluated data from LetsGetChecked demonstrating lay users can safely use the kit and have a general understanding of the results and any necessary follow up actions and validated their home collection kits with the intended test.

The risks associated with the test are mainly the possibility of false positive and false negative test results. False negative test results can result in delays to effective treatment, progression to disseminated disease, and spread of infection to other persons throughout your community. If exposed to a person with either gonorrhea or chlamydia, CDC guidelines indicate that you should be treated by a healthcare provider with antibiotics, regardless of the test result. False positive results could lead to an inappropriate diagnosis of, and unnecessary treatment for chlamydia and gonorrhea, respectively. This could lead to psychological distress, delay in receiving a correct diagnosis as well as the expense and risk for side effects from unnecessary treatment.

The FDA reviewed the Simple 2 Test under the FDA's [De Novo](#) premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing special controls that define the requirements related to labeling and performance testing. When met, the special controls, in combination with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through FDA's 510(k) premarket process, whereby devices can obtain marketing authorization by demonstrating substantial equivalence to a predicate device, which may save a developer time and expense compared to other review pathways.

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