FDA Authorizes First Home Test for Three STIs

The test, which is only authorized for women, detects chlamydia, gonorrhea and trichomoniasis.

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FDA Grants Marketing Authorization of First Home Test for Chlamydia, Gonorrhea and Trichomoniasis

Today's Action also Opens the 510(k) Pathway for Other Home Tests for Sexually Transmitted Infections

Today, the U.S. Food and Drug Administration [FDA] granted marketing authorization to Visby Medical for the Visby Medical Women's Sexual Health Test. This is the first diagnostic test for chlamydia, gonorrhea and trichomoniasis that can be purchased without a prescription and performed entirely at home. The test is intended for females with or without symptoms and delivers results in approximately 30 minutes.

"Home tests can give people information about their health from the privacy of their home. This can be particularly important for sexual health tests for which patients may experience fear or anxiety, possibly resulting in delayed diagnosis or treatment," said Courtney Lias, PhD, director of the Office of In Vitro Diagnostic Devices in the FDA's Center for Devices and Radiological Health. "Expanding access to tests for sexually transmitted infections is an important step toward earlier and increased diagnosis, which can result in increased treatment and reduced spread of infection."

According to the Centers for Disease Control and Prevention's Sexually Transmitted Infections (STI) Surveillance Report, more than 2.2 million cases of chlamydia and gonorrhea were diagnosed and reported in the U.S. in 2023. Additionally, it is estimated that trichomoniasis is the most prevalent nonviral STI worldwide, affecting approximately 2.6 million people in the U.S., according to the CDC's treatment guidelines. Typically, all three infections can be treated with antibiotics, but if left untreated, can cause serious health complications for patients, including infertility.

The Visby Medical Women's Sexual Health Test is a single use, at home test, that includes a collection kit (self-collected vaginal swab) and a powered testing device, which communicates securely to the Visby Medical App, which displays results when the test is complete.

In individuals with and without symptoms, the Visby Medical Women's Sexual Health Test correctly

identified 98.8% of negative and 97.2% of positive Chlamydia trachomatis samples, 99.1% of negative and 100% of positive Neisseria gonorrhoeae samples and 98.5% of negative and 97.8% of positive Trichomonas vaginalis samples.

Individuals with positive results for any of the three infections should seek medical care. Individuals with symptoms, recent exposure to an STI or other concerns despite a negative result should contact their health care provider for additional testing.

As with many other tests, the risks associated with this test are mainly the possibility of false positive and false negative test results. False negative test results can result in delays to effective treatment and spread of infection to other persons. False positive results could lead to unnecessary treatment and/or a delay in receiving a correct diagnosis and appropriate treatment.

The FDA reviewed this 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 notification 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.

This announcement follows last year's authorization of the first at-home syphilis test, as well as the authorization of the first diagnostic test for chlamydia and gonorrhea with at-home sample collection in 2023, which was the first FDA-authorized test with at-home sample collection for any sexually transmitted infection other than HIV.

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