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FDA authorizes first at-home test for syphilis

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As syphilis cases surge throughout the United States, the U.S. Food and Drug Administration on Friday approved the first diagnostic at-home test to spot the bacterial disease.

"This is the first at-home, over-the-counter test to detect Treponema

pallidum [syphilis] antibodies in human blood," the FDA said in a news release. "Results from this type of test alone are not sufficient to diagnose syphilis infection and should be followed by additional testing to confirm a diagnosis of syphilis."

There's a pressing need for quicker diagnostics to help stop the spread of syphilis.

According to the U.S. Centers for Disease Control and Prevention, cases jumped 80% between 2018 and 2022—from 115,000 to more than 207,000 known cases of syphilis per year.

The illness is typically transmitted via sex.

"If left untreated, syphilis can seriously damage the heart and brain and can cause blindness, deafness and paralysis," the FDA noted. "When transmitted during pregnancy, it can cause miscarriage, lifelong medical issues and infant death."

According to the agency, the new self-administered NOWDiagnostics blood test can deliver a result within 15 minutes.

However, the FDA stressed that people should view test results as a preliminary step to a fully confirmed, lab-based diagnosis, accessed through a visit to a doctor or clinic.

People who've been previously infected with syphilis will test positive on the at-home test, even if they were successfully treated, the FDA noted. That's one reason why follow-up in a clinic is so important.

"Access to home tests may help increase initial screening for syphilis, including in individuals who may be reluctant to see their health care provider about possible sexually transmitted infection exposure," said

Dr. Michelle Tarver, acting director of the FDA's Center for Devices and Radiological Health.

"This can lead to increased lab testing to confirm diagnosis, which can result in increased treatment and reduction in the spread of infection," she added in the FDA news release.

Like many diagnostic tests, the NOWDiagnostics screen can deliver false-positive results (the person tests positive, but is not infected) or false-negative results (the test misses an actual infection).

"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," the FDA noted. "False positive results could lead to additional unnecessary testing and delay in receiving a correct diagnosis."

Again, confirmation of any NOWDiagnostics test result should come from a follow-up lab-based test, the agency said.

The advent of the first OTC at-home test for syphilis follows the authorization in 2023 of a similar at-home test for two other leading sexually transmitted infections, chlamydia and gonorrhea.

"We continue to see advancements in tests, particularly tests for sexually transmitted infections, which can give patients more information about their health from the privacy of their own home," Tarver said.

More information: Find out more about syphilis at the Mayo Clinic.