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IN BRIEF

A Home Test for Chlamydia, Gonorrhea, and Trichomoniasis

The FDA has authorized use of the *Visby Medical Women's Sexual Health Test* (Visby), an at-home test available without a prescription, for detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* infections in women with and without symptoms. It is the first test to become available in the US for these sexually transmitted infections (STIs) that can be performed entirely at home. Other at-home tests are available in the US for diagnosis of chlamydia, gonorrhea, and trichomoniasis, but they require mailing a urine or blood sample to a laboratory. Chlamydia, gonorrhea, and trichomoniasis are the 3 most common STIs in the US.

THE NEW TEST – Nucleic acid amplification tests are the standard for detection of STIs in the genital tract, but they require complex laboratory equipment. The *Visby Medical Women's Sexual Health Test* is a single-use polymerase chain reaction (PCR) diagnostic test. It includes a vaginal swab for collection and a powered testing device. The testing device displays the results in about 30 minutes. A second test may be required if the device indicates that the results are invalid. At-home tests that require the sample be

sent to a laboratory usually take about 3-5 days for results to be delivered, which could delay treatment.¹ Individuals who have a positive result for any of the 3 STIs or have symptoms despite a negative test result should contact their healthcare provider. The cost of the *Visby Medical Women's Sexual Health Test* is not yet available.

CLINICAL STUDIES – In 1555 women 14-80 years old, 98.5% of women with or without symptoms who used the test had an accurate result on the first or second test. The device had a sensitivity and specificity, respectively, of 97.6% and 98.3% for *C. trachomatis*, 97.4% and 99.4% for *N. gonorrhoeae*, and 99.2% and 96.9% for *T. vaginalis*.²

CONCLUSION – The *Visby Medical Women's Sexual Health Test*, the first completely at-home test for detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* infections, offers a convenient, effective, and rapid alternative to diagnostic tests that must be sent to a laboratory. ■

1. EN Kersh and LA Mena. At-home diagnostics solutions for chlamydia and gonorrhea. *JAMA* 2024; 331:1701.
2. SR Morris et al. Performance of a single-use, rapid, point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: a cross-sectional study. *Lancet Infect Dis* 2021; 21:668.

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