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FDA Clears Diagnostic Aimed At Reducing STDs In Women

by Brian Bossetta

The US Food and Drug Administration has granted 510(k) clearance to Visby Medical for its product designed to diagnose three of the most common sexually transmitted infections in women.

Visby Medical has received 510(k) clearance for its sexual health test, a second-generation polymerase chain reaction (PCR) diagnostic that uses a self-collected vaginal swab to detect three common sexually transmitted infections (STIs) – chlamydia, gonorrhea, and trichomoniasis.

The San Jose, CA-based medtech company also received a CLIA waiver for the test, which the FDA grants to diagnostics with little to no risk, such as cholesterol or pregnancy tests.

The clearance and waiver apply to licensed healthcare professionals for use by patients during an office visit or at the point of care. Visby says the test provides results in under 30 minutes with 97% accuracy, enabling clinicians to treat STIs with confidence in a single patient visit.

The CDC reported in April that STIs reached an all-time high for the sixth consecutive year, with gonorrhea and chlamydia increasing nearly 30% between 2015 and 2019. Additionally, the CDC estimates that 20% of the US had an STI in 2018, costing $16b to the US healthcare system for that year alone.

Though similar to sexually transmitted disease (STDs), STIs are different, according to Tulane University, in that they haven't fully progressed to an STD, which is more serious and why early detection is so important. Chlamydia, gonorrhea, and trichomoniasis can are easily treated and cured, the CDC says, "if diagnosed early."