Visby gets FDA clearance, CLIA waiver for POC STI test

Aug. 30, 2021—Visby Medical announced it has received FDA 510(k) clearance and was granted a CLIA waiver to market its single-use PCR diagnostic test for the multiplexed detection of sexually transmitted infections caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* using a self-collected vaginal swab.

"This FDA clearance and CLIA Waiver further validate our technology and allows us to start changing how infectious diseases are identified and treated to improve patient lives and public health monitoring," Visby Medical founder and CEO, Adam de la Zerda, PhD, said in a press statement. "Accurate results can ensure the clinician is able to make informed decisions that can shorten infection duration, prevent transmission, and may lower the risk of complications, all while improving the patient and clinician experience."

The Visby Medical Sexual Health Click Test offers a hands-on time of less than 15 seconds, results in 28 minutes, and an accuracy of about greater than 97 percent for all three pathogens. The device measures 3.3" (L) x 1.5" (W) x 4" (H), and no additional instruments are required to perform testing.