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Letters to the Editor

Assessment of a Rapid Antigen Detection System for *Trichomonas vaginalis* Infection

Trichomonas vaginalis is a common sexually transmitted pathogen found in 5 to 10% of women in the general population, with an incidence of more than 200 million cases worldwide (1). Current methods of diagnosis include direct visualization through microscopy, which is rapid but only 58 to 82% sensitive (9); culture, which has a sensitivity of up to 95% but requires a week to produce accurate results (4, 5); and PCR, which has a sensitivity of 95 to 100% and can be used for vaginal or urine specimens (4, 6). The Xenotope (Xenotope Diagnostics, Inc., San Antonio, Tex.) diagnostic kit is a monoclonal antibody-based detection system for *T. vaginalis* antigen that requires 10 min to use and can detect the presence of 10 to 100 organisms in 0.5 ml of vaginal fluid. To assess its sensitivity and specificity, we compared the Xenotope test to the In-Pouch culture method (BioMed Diagnostics, Inc., San Jose, Calif.).

We used vaginal swab specimens collected during a large sexually transmitted disease project in Peru that had been approved by the National Institutes of Mental Health, the University of California, San Francisco, and the U.S. Navy. Participants were women randomly selected from neighborhoods of lower socioeconomic status. Two self-administered sterile Dacron vaginal swabs were obtained from project participants. One swab was immediately inoculated into the In-Pouch for *T. vaginalis* culture, which was performed in accordance with the manufacturer's directions. The second swab was placed in a sterile tube in which 1 ml of molecular-grade water was added. Each tube was vortexed for 30 s. The swab was discarded, and each specimen was frozen at −70°C for 3 to 7 months. Using the Xenotope diagnostic kit, we tested specimens from 20 women with positive In-Pouch culture results and 40 specimens from randomly selected culture-negative women. The 60 frozen samples were thawed to room temperature, and 1 ml of Xenotope sample buffer was added to each specimen. The tubes were vortexed for 10 s, and then the Xenotope test strips were inserted. At 20 min, the strips were removed and the results were read. Samples for which In-Pouch results and Xenotope results were discordant were analyzed by PCR. A touchdown PCR, known as "touchdown enzyme time release" (TETR), utilizing primer set BTUB9 and BTUB2 was performed for each of these samples. In addition, a real-time assay, utilizing a modified version (primer set BTUB9/B) of the BTUB 9/2 primer set was used in conjunction with two fluorescent probes (BTUBFL and BTUBLC) specific for the beta-tubulin gene (3, 7, 8; J. Hardick, N. Mobasherry, D. Duncan, and C. Gaydos, Abstr. 102nd Gen. Meet. Am. Soc. Microbiol., p. 132, abstr. C-181, 2002). If the results agreed, no further testing was performed. In the case of discrepant results between these two PCRs, a third PCR, utilizing primer set TVK3 and TVK4, was performed (2). The result that was reported in the case of discrepant analysis was the one obtained with whichever two of three assays agreed.

The Xenotope test identified 18 of the 20 positives detected by the In-Pouch culture, as well as an additional three positive specimens. These three Xenotope-positive, In-Pouch-negative specimens were all negative by TETR, BTUB fluorescent resonance energy transfer (FRET), and TVK3/TVK4. The two Xenotope-negative, In-Pouch-positive specimens were both negative by TETR PCR but both positive by TVK3/TVK4. One was positive and the other was negative by BTUB FRET.

Compared to culture, Xenotope has a 90% (95% confidence interval, 69.9 to 97.2%) sensitivity and a 92.5% (95% confidence interval, 80.1 to 97.4%) specificity. The manufacturer's stated performance for Xenotope is 100% sensitivity and 98.1% specificity when compared to culture. However, PCR is documented to be more sensitive than culture (3).

The specimens used in this study had been frozen for 3 to 7 months. Specimens used in the manufacturer's testing of the Xenotope test had been frozen for up to 10 years at −80°C and had perfect correlation with the wet mount (John Alderete, personal communication). Our unpublished personal experience suggests that freeze-thawing *Trichomonas* DNA decreases the sensitivity of PCR.

The Xenotope test is a rapid, accurate diagnostic tool for vaginal swab specimens, with a sensitivity approaching that of culture. However, molecular diagnostic techniques suggest that Xenotope might be slightly less specific than culture. This was a small study with promising results but wide confidence intervals, and further evaluation of this diagnostic assay is necessary.

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