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NOTES

Evaluation of the OSOM *Trichomonas* Rapid Test versus Wet Preparation Examination for Detection of *Trichomonas vaginalis* Vaginitis in Specimens from Women with a Low Prevalence of Infection▽

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The OSOM *Trichomonas* rapid test (OSOM Trich) was compared to the wet preparation examination (WP) for the detection of *Trichomonas vaginalis* vaginitis in women with a low prevalence of infection. A total of 19/1,009 (2%) women had *T. vaginalis* infection. OSOM Trich had very good performance, with sensitivity, specificity, efficiency, positive predictive value, and negative predictive value of 94.7, 100, 99.9, 100, and 99.9%, respectively. The implementation of OSOM Trich would decrease labor costs.

Trichomoniasis is the most common nonviral sexually transmitted disease (STD) worldwide, although data are limited for women with a low prevalence of infection (7, 9, 11). Vaginitis due to *Trichomonas vaginalis* clinically manifests with symptoms of vaginal itching, odor, and discharge. Recent studies also show that *T. vaginalis* is an important cause of the premature rupture of membranes, premature delivery, pelvic inflammatory disease, urethritis, and chronic prostatitis (4, 9, 11, 14). Trichomoniasis infection also enhances the transmission of human immunodeficiency virus infection (8, 9, 11–14).

Our regional microbiology laboratory tests a high volume of vaginal swabs each day (i.e., >150) for vaginitis pathogens, and ~30% are positive for bacterial vaginosis or candidiasis, although there is a low prevalence of *T. vaginalis* vaginitis (i.e., <0.5%) based on the detection of motile trichomonads by wet preparation examination (WP) (data not shown). Due to the poor sensitivity of WP (35 to 70%), *T. vaginalis* cases likely were being missed because of lost flagellate viability during specimen transport (10, 14, 15). New diagnostic methods for trichomoniasis recently have become commercially available that do not require the presence of viable flagellate, including rapid antigen immunocapillary and nucleic acid amplification tests (2, 3, 5, 6). It was therefore of interest to compare the performance of the OSOM *Trichomonas* rapid test (OSOM Trich) (Genzyme Diagnostics, Cambridge, MA) to that of WP for the routine detection of *T. vaginalis* vaginitis in our laboratory setting.

For a 3-month period in 2007, the laboratory selected simultaneously collected genital specimens from symptomatic women whose physician had submitted a vaginal swab for the detection of vaginitis pathogens (bacterial vaginosis, *T. vaginalis*, and *Candida*) and an endocervical swab to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. This laboratory selection procedure was designed to rule out other STDs as a cause of symptoms. A vaginal swab submitted in Copan liquid Amies transport medium (Copan Diagnostics Inc., Corona, CA) (1) was used to test for the presence of *T. vaginalis* using both OSOM Trich (Genzyme Diagnostic, Cambridge, MA; the Canadian distributor is Biopacifica Diagnostics Inc., North Vancouver, British Columbia) and WP. Vaginal swabs that were delayed in transport (i.e., >36 h) were rejected. Gram smears were read to detect other vaginitis pathogens, but the presence of either bacterial vaginosis or *Candida* infection was not recorded. Endocervical swabs were collected using the manufacturer's kits and were tested using the Aptima Combo2 *C. trachomatis*/*N. gonorrhoeae* assay (Gen-Probe, San Diego, CA).

OSOM Trich is an immunochromatographic capillary-flow enzyme immunoassay dipstick test that was performed according to the manufacturer's instructions. Vaginal swabs were tested in batches of 10, and analysis required 10 to 15 min. A positive result has both a red internal control and a blue positive test line, while the negative result has only a red internal control line. Invalid tests had an absent internal control line. Discrepant results between OSOM Trich and WP were resolved using the Aptima *Trichomonas* transcription-mediated amplification assay performed according to the manufacturer's instructions (Gen-Probe, San Diego, CA). Specimens were tested in a Gen-Probe DTS 400 instrumentation system using *T. vaginalis*-specific reagents and Aptima general-purpose reagents (target capture, transcription-mediated amplification, and hybridization protection using primers and probes that specifically target *T. vaginalis* rRNA). A *T. vaginalis* patient culture in Diamonds medium was used to inoculate a Gen-Probe Aptima swab specimen transport tube and an uninoculated Gen-Probe Aptima swab specimen transport tube, which were used as positive and negative controls, respectively. En-

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TABLE 1. Performance of OSOM Trich for the detection of *T. vaginalis*

Result by OSOM Trich[a]	Result by CPS[b]		Total
	Positive	Negative	
Positive	18	0	18
Negative	1	990	991
Total	19	990	1,009

[a] Sensitivity, 18/19 (94.7%); specificity, 990/990 (100%); positive predictive value, 19/19 (100%); negative predictive value, 990/991 (99.9%); and efficiency, 1,008/1,009 (99.9%).
[b] For the CPS, true positives were defined as those that were positive by Aptima and either WP slide exam or the OSOM Trich test.

docervical samples with an Aptima result of >50,000 relative light units were considered positive.

Resource utilization costs from the study period were extrapolated to estimate the projected costs of the routine utilization of both methods during a routine testing month in order to project the annual resource impact of implementing OSOM Trich. All costs were calculated in Canadian dollars. Labor costs were calculated based on the current hourly rates paid to medical laboratory assistants (MLAs) and medical laboratory technologists (MLTs). Supply costs included the Canadian goods and services tax. The performance of OSOM Trich was compared to that of a composite reference standard (CPS) (i.e., a positive Aptima test plus either a positive OSOM Trich or WP test) for calculating sensitivity, specificity, efficiency, and positive and negative predictive values. Data were entered into a Microsoft Excel (version 3.0) spreadsheet and analyzed using Analyze-it software using standard statistical methods (Microsoft Corporation, Seattle, WA).

The mean age of the 1,009 enrolled women was 31.7; the standard deviation was ±11 years. Only 19 (2%) women had *T. vaginalis* vaginitis, and 3 of these women also had either *C. trachomatis* or *N. gonorrhoeae* cervicitis. Of the 39 (3.9%) patients who had *C. trachomatis* cervicitis, only 2 of them also had *T. vaginalis* vaginitis. Of the four (0.4%) patients who had *N. gonorrhoeae* cervicitis, only one patient also had *T. vaginalis* infection. No women had dual infection with *C. trachomatis* and *N. gonorrhoeae*.

Table 1 shows the performance data for OSOM Trich. WP missed two *T. vaginalis* cases that were detected by both Aptima and OSOM Trich. One sample had a falsely negative OSOM Trich result (i.e., the internal control was positive) but was positive by both of the other methods. OSOM Trich had very good performance compared to that of the CPS, with sensitivity, specificity, efficiency, positive predictive value, and negative predictive value of 94.7, 100, 99.9, 100, and 99.9%, respectively.

Table 2 shows the component costs of performing *T. vaginalis* vaginitis testing using WP or OSOM Trich during a typical testing month. The implementation of OSOM Trich would increase material costs but decrease monthly labor costs by 46.2% (0.21 full-time equivalent [FTE]).

Our study is the first to evaluate the performance and feasibility of the implementation of OSOM Trich instead of WP in a high-volume laboratory providing service to a population of women with a low prevalence of *T. vaginalis* and other STD infections. Our study confirms that OSOM Trich had improved sensitivity (94.7%) compared to that of WP (89.4%) in this context. OSOM Trich also had the excellent specificity required for screening patients with a low prevalence of infection. Huppert et al. (5, 6) recently evaluated OSOM Trich in two separate studies in female populations with a high prevalence of *T. vaginalis* infection. The initial evaluation used OSOM Trich to rapidly detect *T. vaginalis* in vaginal specimens collected from sexually active women ≥18 years of age (n = 449) presenting with symptoms of vaginitis, exposure to *T. vaginalis*, or multiple sexual partners (5). Their study population had a high prevalence of *T. vaginalis* at 23.4%. OSOM Trich detected more *T. vaginalis* cases, with a sensitivity of 83.3%; that for WP was 71.4%. In a more recent study, sexually active adolescent women aged 14 to 21 years (n = 330) were recruited from a teen health center and the emergency department (6). Vaginal swabs were tested for *T. vaginalis* using WP, culture (In Pouch *T. vaginalis*; BioMed Diagnostics), OSOM Trich, and Aptima. Their study group also had a high prevalence of trichomoniasis at 18.5%. The sensitivity of each method was compared to that of a CPS (i.e., any test with positive results). WP had the lowest sensitivity (56%), while Aptima had the highest sensitivity (98.4%). Although OSOM Trich (83%) had lower sensitivity than that of culture (90%), test results were available the same day, whereas it takes a several days' delay for culture.

Our study is also the first to evaluate the resource outcomes of implementing OSOM Trich in a high-volume laboratory setting (>100 samples/day). The decreased hands-on time of performing OSOM Trich significantly decreased the amount of MLA/MLT time devoted to WP microscopy. The projected FTE savings can be utilized to perform other laboratory procedures. Although the overall resource costs increased, as projected, after the implementation of OSOM Trich (1 November 2007) as our routine testing method, this has been medically justified by the improved detection of *T. vaginalis* vaginitis

TABLE 2. Comparison of Calgary Laboratory Services study costs for using OSOM Trich and the WP slide exam for *T. vaginalis* detection

Test	Cost ($) of total materials[a]	Cost ($) of total MLA/MLT time	Total FTE/mo	No. of tests/mo	Total monthly cost[b] ($)	Total annual cost[c] ($)
Wet Prep Exam	426.00	4,767.21	0.55	1700	5,193.21	62,318.52
OSOM Trich	9,360.54	2,564.73	0.34	1700	11,925.27	143,103.24
Immediate effects of change to OSOM Trich	+8,934.54	−2,202.48	−0.21	No change	+6,732.06	+80,784.72

[a] Total material costs included the cost of all supplies and reagents.
[b] Total costs include the Canadian goods and services tax, but not shipping and handling; costs were calculated based on a volume of 1,700 specimens per month and a positivity rate of 2%.
[c] The projected annual resources used were extrapolated from the monthly labor/materials costs.

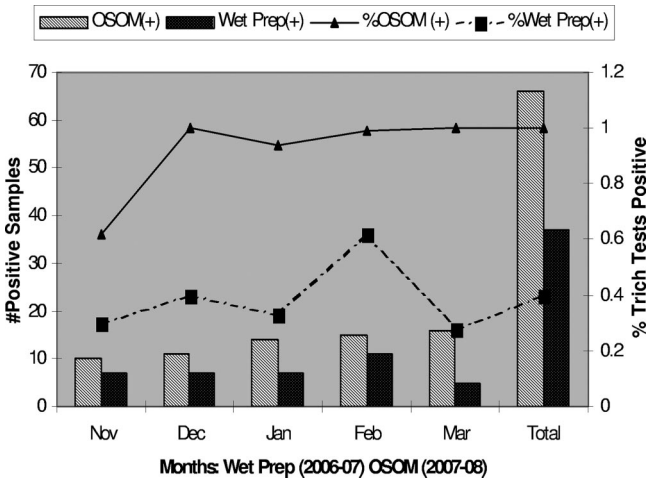

FIG. 1. Performance of OSOM Trich and WP for the routine detection of *T. vaginalis*.

cases. Figure 1 shows that the rate of detection of *T. vaginalis* vaginitis cases in the 5 months after the implementation of OSOM Trich has increased to ~1%, up from <0.5% using WP. Proportional savings based on annual testing for vaginitis pathogens would occur in other laboratory setting, since the test volumes remain constant throughout the year with little seasonal variability. Further studies should confirm these findings in other low-prevalence populations and laboratory settings, particularly the performance of OSOM Trich compared to that of molecular *T. vaginalis* detection in this setting.

Genzyme Diagnostics (Cambridge, MA), through their Canadian distributor (Biopacifica Diagnostics Inc., North Vancouver, British Columbia, Canada), provided the OSOM Trich test kits for this study. Aptima *Trichomonas* assay kits were provided by Gen-Probe (San Diego, CA). The MLAs and MLTs that provided assistance to this study are gratefully acknowledged for their efforts.

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