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Kimber L. Munson
Wheaton Franciscan Laboratory

Maureen Napierala
Wheaton Franciscan Laboratory

Erik Munson
Marquette University, erik.munson@marquette.edu

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LETTER TO THE EDITOR

Suboptimal *Trichomonas vaginalis* Antigen Test Performance in a Low-Prevalence Sexually Transmitted Infection Community

Kimber L. Munson,[a] Maureen Napierala[a] Erik Munson[a,b]

Wheaton Franciscan Laboratory, Milwaukee, Wisconsin, USA[a]; College of Health Sciences, Marquette University, Milwaukee, Wisconsin, USA[b]

Trichomonas vaginalis is the most common nonviral etiology of sexually transmitted infection (STI) worldwide (1). The OSOM Trichomonas rapid test (OSOM; Sekisui Diagnostics, San Diego, CA) is a rapid surrogate to microscopic analysis in symptomatic patients (2), but its performance in low-prevalence STI populations has been assessed on a limited basis in the literature (3). OSOM has widespread usage, as accreditation data from the College of American Pathologists report that over 300 participant laboratories utilize this assay on an annual basis (4). We sought to characterize the analytical and clinical performance of OSOM in a low-prevalence STI population on the basis of a commercial transcription-mediated amplification (TMA) reference.

Results from the performance of OSOM with 1,421 consecutive vaginal saline suspensions were audited from a 4-month interval in a low-prevalence southeastern Wisconsin STI population (5). The concomitant Aptima specimen transport tube from the health care encounter (98.7% endocervical, 1.3% vaginal), previously subjected to *Chlamydia trachomatis* and *Neisseria gonorrhoeae* TMA (Aptima Combo 2 assay; Hologic, San Diego, CA), was forwarded for retrospective *T. vaginalis* TMA (Aptima Trichomonas vaginalis assay; Hologic) evaluation on a TIGRIS direct tube sampling (DTS) system per the manufacturer's specifications (6). A previous assessment of *T. vaginalis* TMA showed 100% molecular concordance between the data from vaginal saline suspension aliquots and endocervical specimens maintained in Aptima specimen transport tubes (7). In addition, Napierala et al. (8) have shown equivalent *T. vaginalis* TMA detection rates from endocervical swabs and vaginal swabs in our population. This study was governed by the Wheaton Franciscan Healthcare Institutional Review Board.

The low-prevalence STI population exhibited TMA detection rates of 6.4% and 0.6% for *C. trachomatis* and *N. gonorrhoeae*, respectively, while the *T. vaginalis* TMA detection rate was 4.0%. On the basis of a *T. vaginalis* TMA reference standard, the sensitivity and specificity of OSOM were 35.1% and 99.9%, respectively (Table 1). The kappa value for this data set was 0.502 (95% confidence interval, 0.346 to 0.658), and agreement was 0.973 (95% confidence interval, 0.963 to 0.981).

TABLE 1 Performance of OSOM Trichomonas rapid test and Aptima Trichomonas vaginalis assay in a low-prevalence STI community

OSOM Trichomonas rapid test result	No. of specimens with indicated result by Aptima Trichomonas vaginalis assay		Total no. of specimens
	Positive	Negative	
Positive	20	1[a]	21
Negative	37	1,363	1,400
Total	57	1,364	1,421

[a] Repeat Aptima Trichomonas vaginalis assay testing yielded a negative result.

TABLE 2 Performance of OSOM Trichomonas rapid test and Aptima Trichomonas vaginalis assay in an increased-prevalence STI community

OSOM Trichomonas rapid test result	No. of specimens with indicated result by Aptima Trichomonas vaginalis assay		Total no. of specimens
	Positive	Negative	
Positive	18	0	18
Negative	3	77	80
Total	21	77	98

In an analogous fashion, 98 consecutive tandem vaginal saline suspensions and endocervical swabs from an increased-prevalence STI setting (*C. trachomatis* TMA detection rate, 11.2%; *N. gonorrhoeae* TMA detection rate, 6.1%; setting characterized previously [7, 9]) were retrospectively analyzed via OSOM and *T. vaginalis* TMA, respectively, per the manufacturer's guidelines (2, 6). Improved concordance between OSOM and *T. vaginalis* TMA was observed within this study set, with a 21.4% *T. vaginalis* TMA detection rate (Table 2). An increased kappa value of 0.904 (95% confidence interval, 0.797 to 1.000) was calculated, with agreement of 0.969 (95% confidence interval, 0.907 to 0.992).

Campbell et al. (3) reported 94.7% sensitivity for OSOM compared to microscopy in a population with a 1.9% *T. vaginalis* detection rate. Molecular diagnostics did not factor into the determination of the overall *T. vaginalis* incidence. For a high-prevalence population, Huppert and colleagues (10, 11) reported 83 to 90% sensitivity for OSOM. One can hypothesize that the significant *T. vaginalis* TMA/*T. vaginalis* antigen discordance frequency in our low-prevalence population is related to organism burden (12) or to *T. vaginalis* TMA detection in asymptomatic patients. However, 56.8% of OSOM-negative/*T. vaginalis* TMA-positive data in the low-prevalence population were derived from symptomatic patients (determined by chart review to have pelvic pain, abdominal pain, vaginal discharge, irritation, or itching). This rate of symptom incidence did not differ from that for patients yield-

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Address correspondence to Erik Munson, Erik.Munson@wfhc.org.

TABLE 3 Symptomatic status of Aptima Trichomonas vaginalis assay-positive patients from low- and increased-prevalence STI communities stratified by OSOM Trichomonas rapid test result

OSOM Trichomonas rapid test result	No. (%) of patients positive by Aptima Trichomonas vaginalis assay exhibiting symptoms	
	Low-prevalence community	Increased-prevalence community
Positive	15 (75.0)	16 (88.9)
Negative	21 (56.8)[a]	3 (100.0)[b]

[a] $P = 0.17$, versus those with positive OSOM result; significance test of proportions.
[b] $P = 0.54$, versus those with positive OSOM result; significance test of proportions.

ing positive OSOM and *T. vaginalis* TMA results ($P = 0.17$; Table 3). Moreover, symptomatic status did not impact concordant and discordant OSOM/*T. vaginalis* TMA frequencies in the increased-prevalence population ($P = 0.54$).

It has been documented that up to 70% of infections with *T. vaginalis* are asymptomatic (13). Detection of subclinical trichomoniasis is important, as studies have demonstrated persistent indolent infection via laboratory detection of the agent following previously negative results in the face of sexual abstinence (14, 15). In further support of this paradigm, 27% of the 37 patients with OSOM-negative/retrospective *T. vaginalis* TMA-positive results in our low-prevalence population returned for clinical evaluation of an STI (data not shown). In conclusion, poor reliability of OSOM in a low-prevalence population combined with the inability to detect the organism in a significant proportion of symptomatic patients may warrant consideration of *T. vaginalis* TMA for accurate laboratory diagnosis of this protozoan.

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