AMERICAN SOCIETY FOR MICROBIOLOGY | Journal of Clinical Microbiology®

PARASITOLOGY

Trichomonas vaginalis Detection in Urogenital Specimens from Symptomatic and Asymptomatic Men and Women by Use of the cobas TV/MG Test

Barbara Van Der Pol,[a] Arundhati Rao,[b] Melinda B. Nye,[c] Steven Chavoustie,[d] Aaron Ermel,[e] Clair Kaplan,[f] David Eisenberg,[g] Philip A. Chan,[h] Leandro Mena,[i] Sixto Pacheco,[j] Ken B. Waites,[a] Li Xiao,[a] Smitha Krishnamurthy,[k] Ruchika Mohan,[k] Rasa Bertuzis,[k] Chris L. McGowin,[k] Rodney Arcenas,[k] Elizabeth M. Marlowe,[l] Stephanie N. Taylor[m]

[a]School of Medicine, University of Alabama at Birmingham, Birmingham, Alabama, USA
[b]Baylor Scott & White Health, Temple, Texas, USA
[c]Laboratory Corporation of America Holdings, Burlington, North Carolina, USA
[d]Segal Trials, Inc., Miami Lakes, Florida, USA
[e]Indiana University School of Medicine, Indianapolis, Indiana, USA
[f]Planned Parenthood of Southern New England, New Haven, Connecticut, USA
[g]School of Medicine, Washington University in St. Louis, St. Louis, Missouri, USA
[h]Brown University, Providence, Rhode Island, USA
[i]The University of Mississippi Medical Center, Jackson, Mississippi, USA
[j]BioCollections Worldwide, Inc., Miami, Florida, USA
[k]Roche Molecular Systems Inc., Pleasanton, California, USA
[l]Quest Diagnostics Infectious Disease, San Juan Capistrano, California, USA
[m]Louisiana State University Health Sciences Center, New Orleans, Louisiana, USA

ABSTRACT *Trichomonas vaginalis* is a prevalent sexually transmitted infection (STI). Diagnosis has historically relied on either microscopic analysis or culture, the latter being the previous gold standard. However, these tests are not readily available for male diagnosis, generally only perform well for symptomatic women, and are not as sensitive as nucleic acid amplification tests (NAATs). Men are largely asymptomatic but carry the organism and transmit to their sexual partners. This multicenter, prospective study evaluated the performance of the cobas *T. vaginalis*/*Mycoplasma genitalium* (TV/MG) assay for detection of *T. vaginalis* DNA compared with patient infection status (PIS) defined by a combination of commercially available NAATs and culture using urogenital specimens. A total of 2,064 subjects (984 men and 1,080 women, 940 [45.5%] symptomatic, 1,124 [54.5%] asymptomatic) were evaluable. In women, sensitivity ranged from 99.4% (95% confidence interval [CI] 96.8 to 99.9%) using vaginal samples to 94.7% (95% CI 90.2 to 97.2%) in PreservCyt samples. Specificity ranged from 98.9 to 96.8% (95% CI 95.4 to 97.8%). In men, the cobas TV/MG assay was 100% sensitive for the detection of *T. vaginalis* in both male urine samples and meatal swabs, with specificity of 98.4% in urine samples and 92.5% in meatal swabs. The cobas TV/MG is a suitable diagnostic test for the detection of *T. vaginalis*, which could support public health efforts toward infection control and complement existing STI programs.

KEYWORDS NAAT, *Trichomonas vaginalis*, molecular methods, urogenital

Trichomonas vaginalis is considered one of the most common curable sexually transmitted infections (STIs) (1, 2), with the World Health Organization (WHO) estimating 156 million cases in 2016, a higher prevalence than *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, or syphilis (3). *T. vaginalis* is currently not a reportable disease and the true estimation of disease prevalence is not currently known. Some of the

Citation Van Der Pol B, Rao A, Nye MB, Chavoustie S, Ermel A, Kaplan C, Eisenberg D, Chan PA, Mena L, Pacheco S, Waites KB, Xiao L, Krishnamurthy S, Mohan R, Bertuzis R, McGowin CL, Arcenas R, Marlowe EM, Taylor SN. 2021. *Trichomonas vaginalis* detection in urogenital specimens from symptomatic and asymptomatic men and women by use of the cobas TV/MG test. J Clin Microbiol 59:e00264-21. https://doi.org/10.1128/JCM.00264-21.

Editor Bobbi S. Pritt, Mayo Clinic

Address correspondence to Barbara Van Der Pol, bvanderp@uab.edu.

Received 5 February 2021
Returned for modification 11 April 2021
Accepted 6 July 2021
Accepted manuscript posted online 28 July 2021
Published 20 September 2021

factors contributing to this are a lack of routine testing and nonspecific symptomatology, and infected men being predominantly asymptomatic (4, 5).

A large proportion of *T. vaginalis* infections are asymptomatic; however, symptoms can include urethral discharge, primarily in males, and abnormal vaginal discharge, dysuria, itching, irritation, and abdominal pain in females (1). The consequences of untreated *T. vaginalis* infection may include pelvic inflammatory disease (PID) and adverse outcomes of pregnancy (6). *T. vaginalis* infection has also been shown to increase the risk of HIV by 50% via several mechanisms, including damage to the vaginal epithelial membrane by the protozoa (6).

The Centers for Disease Control and Prevention (CDC) recommends that women presenting with symptoms are tested for *T. vaginalis*, but do not recommend generalized screening of asymptomatic women (7). However, screening is recommended for women living in areas with higher than average prevalence or those who report behaviors that may have resulted in exposure to STIs, or who are HIV positive (8). Coinfection of *T. vaginalis* with *C. trachomatis* and/or *N. gonorrhoeae* in women has been previously reported (9) and symptoms can overlap between infections. Therefore, *T. vaginalis* infections may be missed and left untreated if *C. trachomatis* and/or *N. gonorrhoeae* positivity is presumed to be the cause. In populations with high levels of STI exposure, the inclusion of *T. vaginalis* testing alongside *C. trachomatis*/*N. gonorrhoeae* testing is likely to dramatically increase case finding (10). A study by Sena et al. looked at the prevalence of *T. vaginalis* infections in the male partners of women with trichomoniasis and observed that 71.7% of the men were also infected, of which 77.3% were asymptomatic (11). Men are seldom tested for *T. vaginalis* at the time of testing for *C. trachomatis*/*N. gonorrhoeae* due to a lack of recommendations and testing methodologies, which is further complicated by the largely asymptomatic nature of *T. vaginalis* infections. Reliable testing platforms and more data are needed to understand the true prevalence of symptomatic and asymptomatic infections, particularly in male populations.

Laboratory diagnosis of *T. vaginalis* previously relied on either microscopic analysis of a saline wet mount prepared from the female patient's discharge, examination of spun sediment in male urine (rarely available in outpatient settings), or culture, the latter formerly being the gold standard (7, 12). These tests are highly specific, although they generally only perform well for symptomatic women and, even then, they are not as sensitive as nucleic acid amplification tests (NAATs) (7, 12). NAATs for *T. vaginalis* are available, such as the Aptima CV/TV assay (Hologic, San Diego, USA), the cobas TV/MG assay (Roche Diagnostics, Pleasanton, USA), Xpert TV (Cepheid, Sunnydale, USA), and Amplivue Trichomonas Assay (Quidel Corporation, Athens, USA). There are limited studies available on the performance of these assays; however, they generally demonstrate more than 96% sensitivity for the detection of *T. vaginalis* (13–15).

The objective of this study was to evaluate the performance of a new NAAT, the cobas TV/MG assay performed on the cobas 6800/8800 systems, for the detection of *T. vaginalis* in symptomatic and asymptomatic male and female urogenital samples, compared to a prespecified patient infection status (PIS). The PIS was defined using a combination of a Food and Drug Administration (FDA)-cleared NAAT and *T. vaginalis* culture.

MATERIALS AND METHODS

Patient population and ethics. This multicenter, prospective clinical study recruited participants at nine sites in the USA: Birmingham, AL; Indianapolis, IN; Jackson, MS; Miami, FL; New Haven, CT; New Orleans, LA; Oakland, CA; Providence, RI; and St. Louis, MO. Male and female patients, whether symptomatic or asymptomatic, were eligible if they were (i) aged ≥14 years, (ii) reported sexual activity within the past 6 months, and (iii) were attending family planning, obstetrics and gynecology, or STI clinics.

Patients were ineligible if they had (i) previously enrolled in the study; (ii) used antimicrobial agents active against *T. vaginalis* (metronidazole or tinidazole) within the 21 days prior to sample collection; (iii) used Replens (Church & Dwight, Co., Inc., Princeton, NJ), RepHresh Odor Eliminating Vaginal Gel (Church & Dwight, Co., Inc., Princeton, NJ), RepHresh Clean and Balance (Church & Dwight, Co., Inc., Princeton, NJ) or products containing metronidazole within 21 days prior to

specimen collection; (iv) had undergone a total hysterectomy; or (v) had a contraindication to the Papanicolaou test or cervical sampling.

Participants were classified as symptomatic for *T. vaginalis* infection if they reported any of the following: dysuria; coital issues (pain, difficulty, or bleeding); pelvic pain; abnormal vaginal discharge; unusual vaginal odor; pelvic, uterine or ovarian pain; penile discharge; testicular pain; scrotal pain; or swelling, itching, burning, redness, or soreness of the genitals. This study was conducted in compliance with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines and the US FDA regulations. The study protocol was submitted to an Institutional Review Board (IRB) to ensure the local and FDA requirements were met prior to the start of the study. All participants were required to provide informed signed consent. This manuscript was prepared in accordance with the STARD guidelines for reporting of clinical studies (16).

Specimen collection. Women provided specimens in the following order: a first catch urine (FCU); vaginal swabs; an endocervical swab in cobas PCR medium; and a cervical specimen in PreservCyt solution obtained with a spatula, cytobrush, or broom. Participants were randomized to either the self-obtained or the clinician-obtained arm for collection of vaginal swabs used in the cobas assay. Participants within the self-collected arm obtained their self-collected vaginal swab first, and the remaining swabs were clinician-collected. In the clinician-collected arm, all vaginal swabs were clinician collected. The *T. vaginalis* swabs were collected as follows; Hologic APTIMA TV assay, the cobas TV assay, and finally the InPouch TV assay (Biomed Diagnostics, White City, OR) specimen, which was collected last in the series due to the use of a speculum. Following collection, the clinician transferred the swabs to the relevant transport medium, as per the respective comparator test's standard procedure. Participants randomized to the clinician-collected arm had their vaginal swab specimen for cobas testing collected by the clinician. Both the endocervical swab and the liquid-based cytology (LBC) sample were collected for assessment with the cobas assay only.

Men first provided self- or clinician-collected meatal swabs (collected in randomized order) for use with the cobas test, followed by an FCU sample. The FCU sample was aliquoted into the manufacturer's collection device for the test assays as per the instructions for use (the penile meatal swab is not an FDA-cleared sample type for the detection of TV in the cobas TV/MG assay for use on the cobas 6800/8800 systems).

Sample testing. Testing with the cobas TV/MG was performed at three sites using at least three lots of investigational reagents. All cobas specimens from a single subject were tested at one individual test site. Specimens from runs with control/operator failures were retested if sufficient sample remained, and individual invalid results were also repeated if sample volume allowed. If invalid results remained invalid upon retesting and there was insufficient volume for further testing, the result remained invalid.

Female and male urogenital specimens were assessed by NAAT using the APTIMA TV assay and the Cepheid Xpert TV assay (Cepheid, Sunnyvale, CA, USA), respectively, and the InPouch TV Culture System. For female samples, the PIS was deemed positive if their vaginal samples tested positive by either the APTIMA TV assay or the InPouch TV Culture System tests, in accordance with FDA guidelines (17) at the time of the study inception. A negative culture result, plus an invalid NAAT result, was deemed as indeterminate. For male samples, the PIS was deemed positive if male urine samples tested positive via either the Cepheid Xpert TV assay or the InPouch TV Culture System. Again, where there was a negative result and an invalid result, the PIS was deemed indeterminate.

Data analysis. Test results for each assay were interpreted according to the instructions for use. All data analyses were performed using SAS/STAT software (version 9.4) (SAS Institute Inc., Cary, NC, USA) and in accordance with FDA guidance (18). The clinical performance of the cobas test for the detection of *T. vaginalis* was evaluated by comparing test results for each sample type to the PIS. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated by sex, specimen type, and symptom status and compared to an infected status algorithm for each sex. In the algorithm, the designation of a subject as infected or noninfected was based on the combination of results obtained from comparator assays. Additionally, results were analyzed separately for self-collected and clinician-collected vaginal and penile meatal swab specimens and by testing sites. The two-sided 95% confidence intervals (CIs) for the estimates of sensitivity, specificity, PPV, and NPV were estimated using the Score method (19).

RESULTS

Patient characteristics. A total of 2,064 subjects were evaluable for *T. vaginalis*, including 984 men and 1,080 women (Table 1). Twenty-six samples were excluded from *T. vaginalis* analyses for invalid results, protocol deviation, or insufficient sample volume: 3 female urine, 1 clinician-collected vaginal swab sample, 1 self-collected vaginal swab sample, 6 PreservCyt samples, 6 endocervical swab samples, 1 male urine sample, 2 male clinician-collected samples, 2 male self-collected samples, 1 vaginal swab without collection method information (self or clinician) and 3 meatal swabs without collection method information (self or clinician). Of the women in the final analysis, 542 were included in the clinician-collected and 535 were included in the self-collected arm of the study, with 1,074 women providing valid samples for PreservCyt and endocervical swab analysis and 1,077 women providing valid urine samples. Of

TABLE 1 Baseline demographics and characteristics

Characteristic[a]	Value(s)
Total (*n*)	2,064
Age, yrs (mean ± SD)	35.5 ± 12.5
Male (*n* [%])	984 (47.7)
Female (*n* [%])	1,080 (52.3)
American Indian/Alaskan Native (*n* [%])	3 (0.1)
Asian (*n* [%])	13 (0.6)
Black/African American (*n* [%])	1,433 (69.4)
Native Hawaiian/Pacific Islander (*n* [%])	5 (0.2)
White (*n* [%])	536 (26.0)
Multiple/other (*n* [%])	54 (2.6)
Not reported (*n* [%])	20 (1.0)
Symptomatic (*n* [%])	940 (45.5)
Asymptomatic (*n* [%])	1,124 (54.5)
Pregnant (female only (*n* [%]))	3 (0.3)
Family planning clinic (*n* [%])	521 (25.2)
Obstetrics/gynecology clinic (*n* [%])	260 (12.6)
STI clinic (*n* [%])	741 (35.9)
Family planning/STI clinic (*n* [%])	542 (26.3)

[a]*n*, number of samples; SD, standard deviation; STI, sexually transmitted infection.

the men, 488 were included in the clinician-collected meatal arm and 489 were included in the self-collected meatal arm of the study. A total of 983 men provided valid urine samples for analysis. Positivity for *T. vaginalis* in this study, based on the PIS, was 15.8% (171/1,080) among all women, and 2.3% (23/983) among all men evaluated (Table 2). The prevalence of *T. vaginalis* in asymptomatic and symptomatic women was 12.1% (55/455) and 18.6% (11/625), respectively. The prevalence of *T. vaginalis* in asymptomatic and symptomatic men was 1.5% (10/668) and 4.1% (13/315), respectively. Additional information regarding male and female *T. vaginalis* positivity by state location can be found in Table S1 in the supplemental information.

Assay performance for the detection of *T. vaginalis*. For female specimens (asymptomatic and symptomatic) the sensitivity ranged from 99.4% (95% CI 96.8 to 99.9%) for vaginal samples to 94.7% (95% CI 94.1 to 99.1%) for LBC samples in PreservCyt (Table 2). Specificity across the female specimen types was >96.8%. The cobas TV/MG assay was 100% sensitive for the detection of *T. vaginalis* in both male urine samples and meatal swabs. Specificity of the cobas assay was higher in male urine samples (98.4%) compared with meatal swabs (92.5%).

Compared with patient infection status (PIS), both clinician-collected and self-collected male and female samples had similar performance with the cobas TV assay (Table 3). Self-collected vaginal swab samples had slightly higher sensitivity and specificity versus clinician-collected samples; however, the differences were not significant ($P = 1.00$ and $P = 0.21$ for sensitivity and specificity, respectively). Self-collected meatal swab samples showed similar sensitivity (both 100%) and specificity (92.5% versus 92.6%) performance to clinician-collected samples ($P = 1.00$ for both sensitivity and specificity, respectively). In female samples, the PPV of the cobas assay for *T. vaginalis* across different clinics and sample types was 50.0 to 100% and the NPV was 97.3 to 100% (Table S2). In male samples, the PPV of the cobas assay for *T. vaginalis* was 13.3 to 100% and the NPV was 100% (Table S2).

Figure 1 illustrates cobas *T. vaginalis* positivity across all samples, regardless of infection status. For female samples, most positive samples were positive across all sample types (Fig. 1A). In Fig. 1B, the data show 71/104 meatal swab-only positives. For male urine, only 23/41 positives were confirmed by PIS. However, the cobas meatal swab and urine results were both positive for 10 patients not identified as such by the

TABLE 2 Clinical performance compared with PIS by gender, sample type, and symptom status[a]

Sample type	Total (*N*)	% Prevalence (*n*/*N*)	% Sensitivity (*n*/*N*)	95% CI	% Specificity (*n*/*N*)	95% CI
Female participants						
Urine						
Symptomatic	622	18.6 (116/622)	97.4 (113/116)	92.7–99.1	98.8 (500/506)	97.4–99.5
Asymptomatic	455	12.1 (55/455)	98.2 (54/55)	90.4–99.7	98.5 (394/400)	96.8–99.3
Overall	1,077	15.9 (171/1077)	97.7 (167/171)	94.1–99.1	98.7 (894/906)	97.7–99.2
Vaginal swab (both clinician- and self-collected)						
Symptomatic	623	18.6 (116/623)	100 (116/116)	96.8–100	97.0 (492/507)	95.2–98.2
Asymptomatic	454	12.1 (55/454)	98.2 (54/55)	90.4–99.7	96.5 (385/399)	94.2–97.9
Overall	1,077	15.9 (171/1077)	99.4 (170/171)	96.8–99.9	96.8 (877/906)	95.4–97.8
PreservCyt samples						
Symptomatic	622	18.5 (115/622)	93.9 (108/115)	88.0–97.0	99.2 (503/507)	98.0–99.7
Asymptomatic	452	12.2 (55/452)	96.4 (53/55)	87.7–99.0	98.5 (391/397)	96.7–99.3
Overall	1,074	15.8 (170/1074)	94.7 (161/170)	90.2–97.2	98.9 (894/904)	98.0–99.4
Endocervical swab						
Symptomatic	620	18.5 (115/620)	97.4 (112/115)	92.6–99.1	98.8 (499/505)	97.4–99.5
Asymptomatic	454	12.1 (55/454)	98.2 (54/55)	90.4–99.7	97.2 (388/399)	95.1–98.5
Overall	1,074	15.8 (170/1074)	97.6 (116/170)	94.1–99.1	98.1 (887/904)	97.0–98.8
All female subjects[b]						
Symptomatic	625	18.6 (116/625)				
Asymptomatic	455	12.1 (55/455)				
Overall	1,080	15.8 (171/1080)				
Male participants						
Urine						
Symptomatic	315	4.1 (13/315)	100 (13/13)	77.2–100	98.3 (297/302)	96.2–99.3
Asymptomatic	668	1.5 (10/668)	100 (10/10)	72.2–100	98.5 (648/658)	97.2–99.2
Overall	983	2.3 (23/983)	100 (23/23)	85.7–100	98.4 (945/960)	97.4–99.1
Meatal swab (both clinician- and self-collected)						
Symptomatic	315	4.1 (13/315)	100 (13/13)	77.2–100	91.1 (275/302)	87.3–93.8
Asymptomatic	662	1.7 (11/662)	100 (11/11)	74.1–100	93.2 (607/651)	91.0–94.9
Overall	977	2.5 (24/977)	100 (24/24)	86.2–100	92.5 (882/953)	90.7–94.1
All male subjects[b]						
Symptomatic	315	4.1 (13/315)				
Asymptomatic	668	1.5 (10/668)				
Overall	983	2.3 (23/983)				

[a]CI, confidence interval; *N*, total number of samples; *n*, number of *T. vaginalis*-positive samples (for prevalence), number of positive samples with accurate result (for sensitivity), or number of negative samples with accurate result (for specificity); PIS, patient infected status.
[b]These numbers represent the overall prevalence of TV infection in male and female subjects.

PIS. On average, both male urine and meatal swab samples that were positive by cobas and negative by PIS had higher cycle threshold (C_T) values compared with those samples positive by both cobas and PIS (Fig. 2). The C_T values for male urine and meatal swab samples that were positive by the cobas assay can be found in Table S3.

DISCUSSION

In this study, the cobas assay was highly sensitive and specific for the detection of *T. vaginalis* in both male and female urogenital samples, with sensitivities greater than or similar to those seen with other NAATs for *T. vaginalis* (7, 9, 12, 20, 21). The sensitivity and specificity of cobas, when compared to the PIS, showed that male urine samples and female vaginal swab samples are preferred for detection of *T. vaginalis* infection. It is interesting to observe that regardless of the PIS, cobas TV-positive results for men show a higher detection rate in penile meatal swabs (104) versus urine (41), and only 33 men had *T. vaginalis* detected in both their urine and meatal swab samples (Fig. 1B). A previous study observed that among the paired specimens of meatal swabs and urine, *T. vaginalis* was detected in a higher percentage of meatal swabs compared with urine samples (80.4% versus 39.3%) (22). Similar to our clinical trial study, Dize et al. collected the meatal swabs prior to the

TABLE 3 Clinical performance of self-collected versus clinician collected vaginal/meatal swab samples[c]

Sample type	Total (*N*)	% Sensitivity (*n*/*N*)	95% CI	% Specificity (*n*/*N*)	95% CI
Female vaginal swab samples[a]					
Clinician-collected					
Symptomatic	335	100 (71/71)	94.9–100	96.6 (255/264)	93.6–98.2
Asymptomatic	207	96.4 (27/28)	82.3–99.4	95.0 (170/179)	90.7–97.3
Overall	542	99.0 (98/99)	94.5–99.8	95.9 (425/443)	93.7–97.4
Self-collected					
Symptomatic	288	100 (45/45)	92.1–100	97.5 (237/243)	94.7–98.9
Asymptomatic	247	100 (27/27)	87.5–100	97.7 (215/220)	94.8–99.0
Overall	535	100 (72/72)	94.9–100	97.6 (452/463)	95.8–98.7
Male meatal swab samples[b]					
Clinician-collected					
Symptomatic	169	100 (7/7)	64.6–100	91.4 (148/162)	86.0–94.8
Asymptomatic	319	100 (7/7)	64.6–100	93.3 (291/312)	89.9–95.6
Overall	488	100 (14/14)	78.5–100	92.6 (439/474)	89.9–94.6
Self-collected					
Symptomatic	146	100 (6/6)	61.0–100	90.7 (127/140)	84.8–94.5
Asymptomatic	343	100 (4/4)	51.0–100	93.2 (316/339)	90.0–95.4
Overall	489	100 (10/10)	72.2–100	92.5 (443/479)	89.8–94.5

[a]Overall difference in sensitivity (95% CI) and specificity (95% CI) for clinician-collected versus self-collected vaginal swabs was −1.0 (−3.0, 1.0), $P = 1.00$; and −1.7% (−4.0%, 0.6%), $P = 0.21$, respectively.
[b]Overall difference in sensitivity (95% CI) and specificity (95% CI) for clinician-collected versus self-collected meatal swabs was 0% (−23.2%, 30.9%), $P = 1.00$; and 0.1% (−3.2%, 3.5%), $P = 1.00$, respectively.
[c]CI, confidence interval; *N*, total number of samples; *n*, number of positive samples with accurate result (for sensitivity) or number of negative samples with accurate result (for specificity).

collection of urine (22). Another study also observed a higher detection rate among the paired collections of meatal swabs (8.0%) versus urine (1.7%) (23). It is important to note that in this particular study, Chernesky et al. randomized the sequence of collection between these two specimens (23) and therefore this mitigates the concern that the meatal swab collected the majority of *T. vaginalis* if it was collected prior to the urine collection. This would suggest that the higher detection rates in meatal swabs may be inherently due to the parasite's pathophysiology; *T. vaginalis* might adhere to the urethra and be less likely to detach in urine versus other samples (24). The higher C_T values for male samples positive by cobas and negative by PIS compared with the lower C_T values for samples positive by both cobas and PIS may also indicate the increased sensitivity of cobas for detecting samples with lower parasite load compared with the previous methods used to define PIS (Fig. 2). Ultimately, the clinical significance of meatal swabs as a viable alternative sample type compared to urine remains to be determined.

Although there are no official guidelines or recommendations for *T. vaginalis* testing in men, if testing becomes readily available then those guidelines may change, and male partners of females diagnosed with *T. vaginalis* infection can be offered testing with urine or urethral swabs to confirm diagnosis prior to treatment (25). The clinical significance and utility of the penile meatal swab is currently unknown, although this sample has been shown to have potential utility in a number of studies for the detection of *T. vaginalis* and other STI pathogens (*C. trachomatis*, *N. gonorrhea*, and *M. genitalium*) (22, 23, 26). The collection process for penile meatal swabs may also be more comfortable for patients compared with urethral swab collection.

The high performance of the vaginal swab samples collected in cobas PCR medium indicate that this sampling method is the optimal specimen type for use with the cobas CT/NG assay, which should facilitate ease of testing during a patient clinic visit (27). Only one sample tested positive with the APTIMA TV alone, in an asymptomatic female patient, who would have been defined by PIS as infected.

As noted, both the clinician-collected and self-collected male meatal and female vaginal swab samples were highly sensitive and specific. This is very important, as self-testing can increase the likelihood that patients will access testing and, in light of the

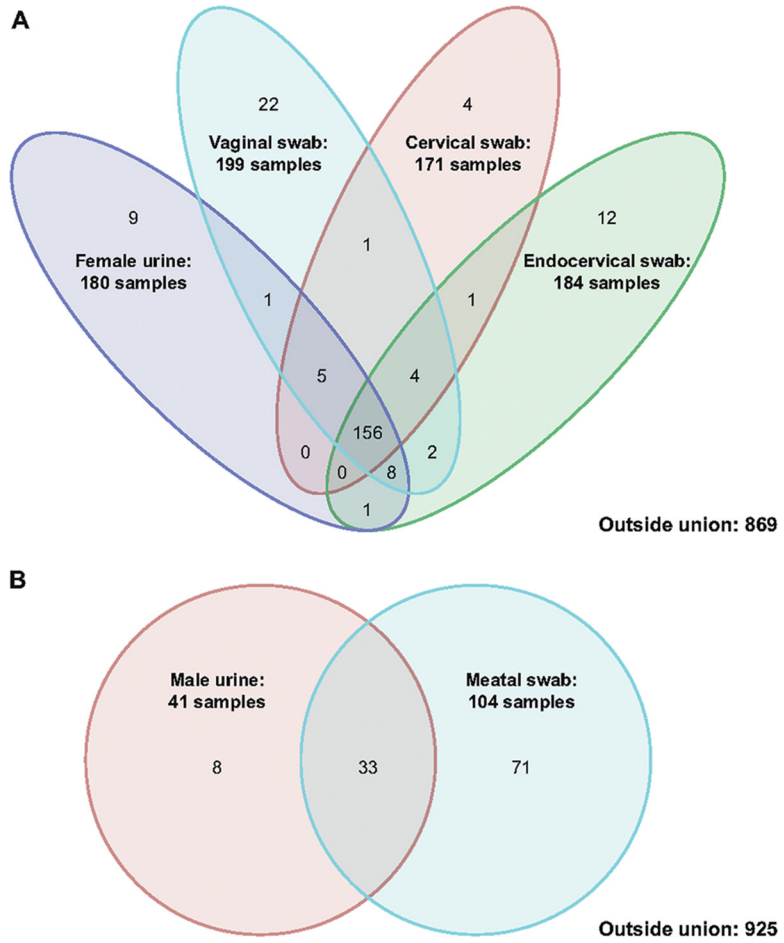

FIG 1 Venn diagrams comparing the cobas *T. vaginalis* positives in female urogenital samples (A) and male urogenital samples (B).

current COVID-19 pandemic and rising incidence of STIs, it may be increasingly important in enabling patients to access medical care and diagnosis (28).

The prevalence of *T. vaginalis* in this study, at 15.8% in female subjects and 2.3% in male subjects, was higher than some previous estimates of *T. vaginalis* prevalence, particularly in asymptomatic female subjects, which was 12.1% in this study (7, 9, 12). The prevalence of *T. vaginalis* in male subjects was low, as was expected based on data in the literature (7, 12, 26), and may have been underestimated due to the collection of meatal swabs prior to urine specimens which were used to define infection status. If one assumes that those meatal swabs that gave positive results when the cobas urine result was also positive, but where PIS was negative, were in fact true positives, then positivity would have been 4.2% (41/983). Furthermore, if the 71 meatal samples that were not confirmed with other urine tests were compared head to head with meatal samples using a comparator NAAT (which is a study limitation due to the lack of another FDA-cleared NAAT for the detection of *T. vaginalis* in men) the positivity would be estimated to be 11.5% (113/983).

In conclusion, the high performance of the cobas TV/MG assay for use on the cobas 6800/8800 systems, in both clinician- and self-collected urogenital samples from symptomatic and asymptomatic men and women, means the cobas assay can reliably detect the presence and absence of *T. vaginalis* in urogenital samples and is a suitable clinical test for the diagnosis of *T. vaginalis*. The cobas 6800/8800 offers an optimal systems approach for use alongside other commercially available STI tests. The

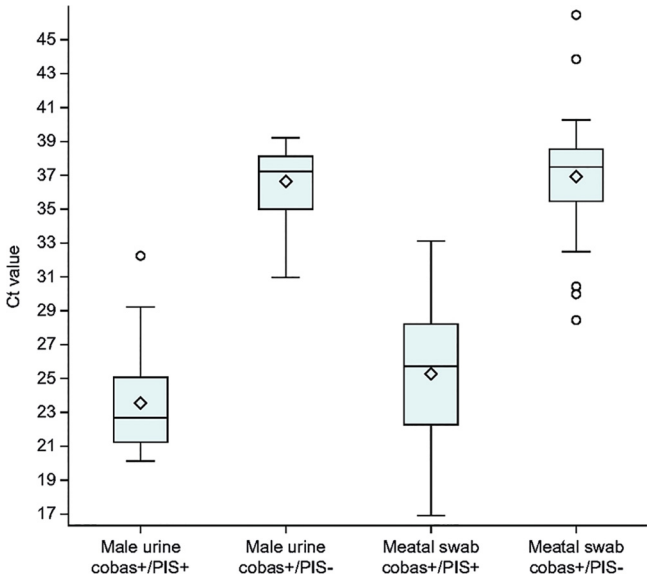

FIG 2 Distribution of C_T values from *T. vaginalis* positive results with the cobas TV/MG assay in evaluable males. The diamonds represent the mean values and the lines inside the boxes represent the median values. The error bars represent standard deviation, with the circles representing individual samples outside of the error bars. C_T, cycle threshold; PIS, patient infection status.

cobas TV/MG assay fulfils an unmet medical need for the testing of patients for diagnosis, supports public health efforts toward the control of *T. vaginalis*, and complements existing STI programs.

SUPPLEMENTAL MATERIAL

Supplemental material is available online only.

SUPPLEMENTAL FILE 1, PDF file, 0.1 MB.

ACKNOWLEDGMENTS

Roche Molecular Systems would like to acknowledge the efforts of Merlin Njoya and Sai Kotha from our Clinical Operations & Biometrics team for the data provided in the manuscript. This study was funded by Roche Molecular Diagnostics.

Medical writing support was provided by Rose Falconer, Elements Communications, Westerham, UK, and was funded by Roche Molecular Diagnostics.

The findings and conclusions in this article are those of the authors and do not necessarily reflect the views of Planned Parenthood Federation of America, Inc. COBAS is a trademark of Roche. All other product names and trademarks are the property of their respective owners.

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