Published in final edited form as:

Sex Transm Infect. 2010 December ; 86(7): 514–519. doi:10.1136/sti.2009.042168.

Adolescent women can perform a point-of-care test for trichomoniasis as accurately as clinicians

Jill S Huppert¹, Elizabeth Hesse¹, Grace Kim¹, Michael Kim¹, Patricia Agreda², Nicole Quinn², and Charlotte Gaydos²

¹Division of Adolescent Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, USA

²School of Medicine, Division of Infectious Diseases, STD Laboratory, John Hopkins University, Baltimore, Maryland, USA

Abstract

Objectives—To compare the accuracy (ie, correlation, sensitivity, specificity) of self-performed point-of-care (POC) tests with clinician-performed tests for trichomoniasis in adolescent women.

Methods—Sexually experienced women aged 14–22 years (n=209) collected a vaginal swab and performed a POC test for trichomoniasis. Using a speculum, the clinician obtained vaginal swabs that were tested for trichomoniasis using the POC test, wet mount, culture and transcription-mediated amplification (TMA) using standard and alternative primers. Self and clinician results were compared with true positives, defined as either culture-positive or TMA-positive with both sets of primers.

Results—Participants' mean age was 17.8 years; 87% were African-American; 74% reported vaginal itching or discharge and 51 (24%) had trichomoniasis. Over 99% correctly performed and interpreted her self-test. Self and clinician POC tests were highly correlated (95.7% agreement, κ 0.87). Compared with true positives, the sensitivity of the self-POC test was 78% (CI 65% to 89%), similar to that of the clinician-POC test (84%, CI 71% to 93%) and culture (82%, CI 69% to 92%), and significantly better than wet mount (39%, CI 26% to 54%). The specificity of the self-POC test was 99% (CI 96% to 100%), similar to that of the clinician-POC test (100%, CI 98% to 100%). The sensitivity of the self-POC test was not affected by vaginal symptoms or other variables.

Conclusions—Young women performing a self-POC test detected as many trichomoniasis infections as clinician-POC tests or culture, twice as many as wet mount and slightly fewer than an amplified test. Incorporating self-obtained or self-performed POC tests into routine practice could effectively increase the identification and treatment of trichomoniasis in this vulnerable population.

Correspondence to, Dr Jill S Huppert, Division of Adolescent Medicine, Cincinnati Children's Hospital Medical Center, 3333 Burnet Avenue, MLC 4000, Cincinnati, OH, 45229-3039, USA; jill.huppert@cchmc.org.

Competing interests JSH has received diagnostic kits, speaker's honoraria and unrestricted research funds from Genzyme Diagnostics, Inc. JSH and CG have received kits and reagents from Gen-Probe, Inc. JSH has received diagnostic kits from Gynex Corporation.

Patient consent Obtained.

Ethics approval This study was conducted with the approval of the Cincinnati Children's Hospital Medical Center's institutional review board.

Provenance and peer review Not commissioned; externally peer reviewed.

Trichomoniasis, caused by the flagellated protozoa *Trichomonas vaginalis*, is one of the most common sexually transmitted infections (STI) found in adolescent women. According to estimations by Weinstock *et al.*,¹ approximately 7.4 million new trichomoniasis infections occurred in the USA in 2000, 25% of which were in 15–24-year-old women. In population-based surveys, the cross-sectional prevalence of trichomoniasis was 2–3% in adolescent women, similar to the prevalence of chlamydia and far higher than gonorrhoea in the same samples.^{2–5}

Although trichomoniasis is highly prevalent, the current standard for evaluation (pelvic examination and wet mount) limits our ability to detect infections. Wet mount is estimated to be only approximately 50–60% sensitive compared with culture.^{6,7} Adolescent women find pelvic examinations uncomfortable and embarrassing. Providers often cite a lack of facilities to perform a pelvic examination as a barrier to offering STI testing.^{8–10}

Improved diagnostic tests, self-obtained vaginal swabs and point-of-care (POC) testing are three strategies designed to remove barriers to testing and treatment for trichomoniasis and other STI. In addition to wet mount and culture, two promising new tests for trichomoniasis are a POC antigen test (a lateral flow test strip that detects *T vaginalis* membrane proteins) and transcription-mediated amplification (TMA), a nucleic acid amplification test (NAAT) that uses analyte-specific reagents (ASR) for *T vaginalis* RNA. Using latent class analysis, we have shown that the sensitivities of the POC test, culture and TMA–ASR (90%, 83%, and 98%, respectively) are each significantly higher than wet mount (56%), and only TMA has imperfect specificity.⁷ Therefore, using any test other than wet mount would increase the detection of trichomoniasis.

Self-obtained vaginal swabs have already been shown to perform well for the diagnosis of chlamydia and gonorrhoea using NAAT^{11–13} Similarly, self-obtained vaginal swabs are equivalent to clinician-obtained swabs in detecting trichomoniasis by culture.¹⁴ Self-obtained vaginal swabs have been used to detect *T vaginalis* using TMA¹⁵ or PCR, another NAAT,^{16,17} but self-obtained swabs for NAAT have not been compared with clinician-obtained samples.

The POC test for trichomoniasis is simple and reliable, but has not yet been tested on self-obtained swabs or as a self-performed test. The aims of this study were: (1) to examine whether young women can reliably perform a POC test for trichomoniasis on self-obtained vaginal swabs; (2) to compare the accuracy (ie, correlation, sensitivity, specificity) of self-performed POC tests with clinician-performed tests for trichomoniasis; and (3) to examine whether clinical factors (eg, vaginal symptoms or the presence of other STI) affect the performance of self-POC tests in adolescent women.

METHODS

Population

We recruited adolescent women aged 14–22 years who were sexually active and presented for a healthcare visit at an urban paediatric hospital's Teen Health Center (THC) or emergency department (ED) between July 2006 and August 2008. Women were ineligible for participation if they had taken antibiotics or had used any vaginal creams or medications in the past 2 weeks or could not collect a specimen at the study visit. This study was approved by the local institutional review board, with a waiver of the requirement for parental permission.

Study procedures

After informed consent, the participants completed a brief survey that included basic demographics, sexual history and gynaecological history questions. Survey questions were coded for race (African-American or other), type of health insurance (Medicaid, private, none/unknown), douching frequency (ever or never), and the number of lifetime male sexual partners (one or two or more (multiple)). Elicited vaginal symptoms were recorded as present if a woman answered 'yes' to either question: 'Do you have a discharge from your vagina today?' or 'Do you have itching or pain in the vaginal area today?' Hormonal contraception was recorded as 'yes' if the woman reported the current use of oral, transdermal or injectable contraceptives that contained oestrogens or progestins. After the survey, participants could perform self-testing either before or after clinician testing, depending on provider preference to minimise disruptions to clinical care.

Specimen collection

Using a speculum, an experienced clinician obtained several swabs from the participant's vagina and gave these to the trained research assistant (RA). The RA gave each woman standardised verbal instructions on how to obtain the vaginal swabs and perform the POC *T vaginalis* test. In addition, we provided a laminated single-page instruction sheet (adapted from the product insert, http://www.genzymediagnosics.com/pdf/OSOM_Trich_181_PI.pdf) that included both words and pictures on the testing procedures. This sheet was left in the room with the participant in case she needed additional guidance. Each woman inserted a rayon swab a few centimetres into the vagina and rotated it for approximately 10 s. Swab POC testing is described below.

Laboratory methods

Each participant performed the POC test (OSOM TV Trichomonas Rapid Test, Genzyme Diagnostics, Cambridge, Massachusetts, USA) as per the manufacturer's protocol. The lateral flow test strip device is similar in concept to a home pregnancy test and requires five steps and 10 min to complete. In short, the RA set up the sample phial containing buffer solution; the participant swirled her self-collected swab in the buffer, then squeezed the phial to remove the extra liquid from the swab while removing it from the solution. She discarded the swab, and added the test strip into the buffer solution. After 10 min, she read the test results. The test is determined to be negative if only the internal control line (red) is displayed and as positive when both the red control line and the test line (blue) are shown. After the woman performed the POC test and recorded her results on a standard form, the RA reviewed her test results and recorded whether the participant's interpretation (negative or positive) was correct. For analyses, we used the participant's interpretation of her self-POC test result.

The clinician-obtained vaginal swabs were tested for trichomoniasis in real time using wet mount, POC test and culture. Additional swabs were used to assess vaginal pH and the presence of amines. One swab was stored, frozen for NAAT testing by TMA for *T vaginalis*, *Chlamydia trachomatis* and *Neisseria gonorrhoeae* after the study was completed.

The wet mount (a microscopic examination of a saline preparation of vaginal secretions) was performed in a standard fashion: One vaginal swab was placed into a sterile tube containing 0.5 ml saline and transported to the laboratory. For women recruited from the THC, the clinician performed the wet mount in an on-site laboratory. On wet mount, the presence of motile trichomonads was considered positive for *T vaginalis*; the presence of buds or pseudohyphae was positive for yeast. Based on Amsel's criteria, clue cells were characterised as none, some (>20% of epithelial cells), or many (>50% of epithelial cells),¹⁸

and white blood cells were characterised as none, few (1–5 per high-powered field (hpf)), moderate (6–10/ hpf), or many (>10/hpf).¹⁹ For participants recruited from the ED, the wet mount was performed in the clinical laboratory by trained laboratory technicians and only the presence of motile trichomonads was recorded. ED participants had an additional swab submitted for Gram stain, which was performed in the clinical laboratory by trained laboratory technicians. The Gram stain was examined for white blood cells, clue cells and yeast forms using the same criteria described for the wet mount above.

One clinician-obtained vaginal swab was used to inoculate the culture medium (InPouchTV, BioMed, White City, Oregon, USA). Culture was submitted to the microbiology laboratory where it was examined daily for motile trichomonads by trained laboratory personnel for up to 5 days or until a positive result was obtained.

Using swabs obtained by the clinician, the RA performed the POC test as described above as well as the pH and amine test. For the pH, a vaginal swab was rolled across pH paper (pHydriion, Mikro Essentials Laboratories, Brooklyn, New York, USA) and the colour change was compared immediately with the accompanying colour chart. The pH was recorded in increments of 0.5 (range 3.0–5.5). An abnormal pH was any result greater than 4.5.²⁰ For the amine test, a drop of potassium hydroxide was added to the vaginal swab. The detection of a strong fishy odour was considered a positive result.

NAAT testing

One swab was frozen, dry, at –80°C until the close of the study. After thawing, swabs were eluted in phosphate-buffered saline. One aliquot was transferred to a vaginal specimen transport medium (APTIMA Vaginal Swab Specimen Collection Kit, Gen-Probe, Inc, San Diego, California, USA) for NAAT testing using TMA. Specimens were analysed following similar manufacturers' directions for the US Food and Drug Administration-cleared assay for chlamydia and gonorrhoea (APTIMA Combo-2, Gen-Probe, Inc). For *T vaginalis* detection, each specimen was tested first using ASR with primers directed to the 16S rRNA gene. Testing was also performed using an alternative primer set, specific for a different region of the trichomonas genome, which was available as research use only reagents from GenProbe. For both assays, the relative light units cut-off for a positive test was set at 60 000 relative light units, consistent with earlier studies.⁷¹⁵ For this study, we defined a true positive case of trichomoniasis as either culture positive or TMA positive with both standard ASR and alternative research use only primers. Because we had multiple clinical providers performing the pelvic examination, we could not reliably ascertain the subjective 'homogeneous vaginal discharge' that is included in Amsel's original clinical criteria for bacterial vaginosis (BV). Therefore, we defined clinical BV based on modified Amsel's criteria, as the presence of three objective findings: more than 20% of clue cells, a positive amine test and abnormal vaginal pH (>4.5). Together, these three criteria have greater than 95% specificity for BV compared with Nugent's Gram stain criteria.¹⁸²⁰²¹

Analysis

Data were entered into a spreadsheet and analysed with statistical software. We generated descriptive frequencies to characterise our sample and performed χ^2 tests of association between POC test results and participant characteristics. We compared the correlation between self and clinician-POC tests using a κ statistic. We generated point estimates and 95% CI for sensitivity and specificity for each diagnostic test method. We stratified data by variables such as reported vaginal symptoms (present, absent), vaginal pH (normal, abnormal), and amine positive to assess for differences in test performance (sensitivity or specificity) by these characteristics.

Based on our hypothesis that self-performed POC tests would be at least 80% sensitive and 95% specific using clinician-obtained culture and TMA results as the combined reference standard, we determined that a sample size of 48 true positive and at least 150 true negative cases would have 80% power to detect this effect, at an α of 0.05. In addition, this sample size would have adequate power (80%) to detect an alternative hypothesis of a strong κ statistic of 0.75 versus null hypothesis of moderate κ statistics of 0.4 between self and clinician-POC tests.

RESULTS

Two hundred and seventy-four women initially agreed to participate. Twenty-seven women withdrew without completing surveys or testing, and 247 completed both self and clinician-POC testing. Of these, eight were missing swabs for culture and 30 were missing swabs for TMA. Therefore, 209 women had complete data on all test methods and comprise the study sample (figure 1). The mean age of women was 17.8 years, 87% were African-American, and over half (58%) had Medicaid as their insurance carrier. Vaginal symptoms (ie, itching or discharge) were elicited from 74% of women, and 51 (24.4%) had trichomoniasis as defined by our reference standard (table 1). Of these 51 true positives, 41 (80%) were positive by both culture and TMA, nine (18%) were only TMA positive, and one (2%) was culture positive but TMA negative.

All 209 women performed the self-POC test correctly and 207 (99%) interpreted the self-test results correctly. Two women misinterpreted a positive test as negative (reported a false-negative result). Self-performed and clinician-performed POC tests were highly correlated, with 95.7% agreement and a κ of 0.87 (table 2). Of the five cases in which the clinician POC test was positive and the self-POC test was negative (including the two false negatives described above), four were culture positive and all five were TMA positive. Of the four cases in which the clinician-POC test was negative and the self-POC test was positive (and confirmed positive by the RA), one was culture and TMA positive and one was TMA positive (confirmed positives). The remaining two had no confirmatory *T vaginalis* test positive and are presumed false positives. The RA comment entered on the day of testing for these two presumed false-positive cases that ‘clinician swabs appeared dry’.

Correlation of POC test with participant characteristics

We examined which clinical, demographic and laboratory characteristics were related to having a positive POC test (either self or clinician test) (table 1). We found no significant relationship between a positive POC test and the order of testing, vaginal symptoms, age, race, a history of multiple partners, douching, health insurance status, clinical BV, or clue cells on wet mount. However, a positive POC test was significantly associated with several variables. Women recruited from the ED were more likely to have a positive POC test than those recruited from the THC (36.2% vs 17.2%, $p=0.003$). Those with a positive amine test had a higher prevalence of positive POC trichomoniasis test results than those with a negative amine test (28.9% vs 14.1%, $p=0.01$). Of those with an abnormal vaginal pH test, 28.1% had a positive POC test, compared with only 16.9% of those with a normal vaginal pH ($p=0.06$).

Sensitivity and specificity of POC test relative to true positives

Compared with true positives, the sensitivity of the self-POC test was 78.4%, similar to that of the clinician-POC test (84.3%) and culture (82.4%), and significantly better than wet mount (39.2%) (table 3). The specificity of the self-POC test was 99%, not significantly different from that of the clinician-POC test (100%), culture, or TMA. In stratified analyses,

the sensitivity of the self-POC test was not affected by vaginal symptoms, recruitment from the ED, a positive amine test, or an abnormal pH (data not shown).

DISCUSSION

Our study demonstrated that a POC test for *T vaginalis* (a rapid antigen test using lateral flow technology), performed on self-obtained or clinician-obtained vaginal swabs was more sensitive than wet mount and equal to culture. In addition, we showed that young women can accurately perform a simple POC STI test and interpret their own results. In our previous work we used latent class analysis to confirm the 100% specificity of the POC test.⁷ Therefore, the two apparent 'false positive' self-POC tests are most likely to represent a sampling error: the woman may have obtained a better sample than the clinician. However, there is also the possibility that the test is not truly 100% specific.

Our findings have two main implications for addressing the epidemic of STI that disproportionately affects young women. First, we have demonstrated that self-obtained vaginal specimens were feasible and reliable for the diagnosis of trichomoniasis using a POC test. Others have demonstrated that self-collected vaginal swabs perform well in detecting chlamydia and gonorrhoea using NAAT^{11–13,22} and trichomoniasis using culture and/or PCR.^{14,16} The use of self-obtained vaginal specimens for the diagnosis of STI using NAAT has been promoted by many researchers,²³ as well as the CDC.²⁴ We thus now have another diagnostic method that can reliably be used on self-obtained vaginal specimens.

Self-swabs remove the requirement for a speculum examination, a factor that deters both women from accepting and clinicians from offering STI testing. Adolescent women express a clear preference for non-invasive methods over a pelvic examination.²⁵ Among adolescent women offered self-obtained vaginal swabs for STI testing in a school setting, the majority rated self-swabs as easy to perform and preferable to a pelvic examination, and half of those with a diagnosed STI said they would not have sought STI testing if self-collection was not offered.²⁶ Therefore, for asymptomatic women for whom a speculum and full pelvic examination are not indicated, a self-obtained vaginal swab may be the specimen of choice to detect trichomoniasis, as has been recommended for chlamydia. In this study, we collected survey data assessing the acceptability of self-testing compared with clinician testing at baseline and after testing. However, this complex dataset is still being analysed.

Second, we have shown that women can accurately perform their own STI tests, especially a simple device based on familiar lateral flow technology. We could not find literature to assess whether women could perform a home human chorionic gonadotrophin test for pregnancy (also lateral flow technology) before it became available over the counter, but it is possible that this was considered market research and did not get published in the scientific literature. The only other over-the-counter self-test device available to women is a self-pH test (pHEM_ALERT, <http://Gynex.com>, Redmond, Washington, USA). Before its release, two studies evaluated the pH test. The first used a questionnaire to assess whether adult women could understand the package insert, and 97.1% gave correct answers to at least 75% of the questions. In another study, pH results obtained by adult women were highly correlated with healthcare professional's results ($\kappa=0.9$).^{27,28} Vaginal pH may be useful in distinguishing candidiasis from BV; however, while we and others have shown that abnormal pH is associated with trichomoniasis, pH is neither sensitive nor specific enough to use as a diagnostic tool for trichomoniasis or other STI.

If young women had access to a simple POC test for trichomoniasis, they could identify twice as many cases as a clinician could using the insensitive wet mount examination, and nearly as many as NAAT testing. In fact, many clinicians no longer perform the wet mount,

as it requires a microscope and because of Clinical Laboratory Improvement Amendment regulations. POC testing also provides the patient with her results within minutes, allowing immediate counselling and treatment and reducing the risk of transmission and the proportion of women who are lost to follow-up. In addition, we have shown that women who are aware of their POC test results are more likely to report safer sexual behaviours in the weeks after diagnosis.²⁹ These issues are especially important for adolescent women who may be concerned about confidentiality and have limited access to health care. Another potential use of this POC *T vaginalis* test would be in resource-limited settings such as less developed areas of the world, where both diagnostic tests for trichomoniasis and access to pelvic examinations are limited.

A self-performed STI test would be a novel strategy to address barriers to STI testing in adolescent women. Gaydos *et al*³⁰ recently demonstrated that adults can reliably perform their own HIV POC test in an ED setting. We believe we are the first to show that adolescent women can accurately perform and interpret an STI test. Unfortunately, intellectual property licensing may prevent over-the-counter marketing of this simple and effective tool. As other simple STI tests become available, we expect that our findings can be used to inform future decisions about the use of these tests by adolescent women.

If women could accurately perform a POC test for trichomoniasis in a clinical setting, they would avoid a pelvic examination, improve the accuracy over wet mount and receive immediate feedback that would allow treatment. Furthermore, self-POC testing could be expanded for use in non-clinical settings and even home use. In these scenarios, the convenience and confidentiality of self-testing may encourage more women to seek testing, thus impacting the overall epidemic of trichomoniasis in the USA.

Key messages

- ▶ Self-obtained vaginal swabs are reliable specimens for POC trichomoniasis testing.
- ▶ Adolescent women can accurately collect and perform a POC test for trichomoniasis.
- ▶ Self-performed POC trichomoniasis tests were highly correlated with clinician-performed tests.
- ▶ Self-obtained and self-performed testing could eliminate barriers and increase STI testing in vulnerable populations.

Acknowledgments

The authors would like to thank the staff and clinicians at the Teen Health Center who allowed us to recruit their patients. The support and guidance provided by Frank Biro and Lorah Dorn were critical to their success. The authors gratefully acknowledge statistical support from Justin Bates and Bin Huang and technical support from Mary Jett-Goheen. Finally, they are also indebted to the women who participated for their valuable time.

Funding The study was supported by grant number 5K23AI063182-04 (JSH, PI) from the NIH/NIAID and by grant number 1U54EB007958-01 (CG, PI) from the NIH/NIBIB.

REFERENCES

1. Weinstock H, Berman S, Cates W Jr. Sexually transmitted diseases among american youth: incidence and prevalence estimates, 2000. *Perspect Sex Reprod Health*. 2004; 36:6–10. [PubMed: 14982671]

2. Sutton M, Sternberg M, Koumans EH, et al. The prevalence of *Trichomonas vaginalis* infection among reproductive-age women in the United States, 2001–2004. *Clin Infect Dis*. 2007; 45:1319–1326. [PubMed: 17968828]
3. Miller WC, Swygard H, Hobbs MM, et al. The prevalence of trichomoniasis in young adults in the United States. *Sex Transm Dis*. 2005; 32:593–598. [PubMed: 16205299]
4. Miller WC, Ford CA, Morris M, et al. Prevalence of chlamydial and gonococcal infections among young adults in the United States. *JAMA*. 2004; 291:2229–2236. [PubMed: 15138245]
5. Datta SD, Sternberg M, Johnson RE, et al. Gonorrhea and chlamydia in the United States among persons 14 to 39 years of age, 1999 to 2002. *Ann Intern Med*. 2007; 147:89–96. [PubMed: 17638719]
6. Wiese W, Patel SR, Patel SC, et al. A meta-analysis of the Papanicolaou smear and wet mount for the diagnosis of vaginal trichomoniasis. *Am J Med*. 2000; 108:301–308. [PubMed: 11014723]
7. Huppert JS, Mortensen JE, Reed JL, et al. Rapid antigen testing compares favorably with transcription-mediated amplification assay for the detection of *Trichomonas vaginalis* in young women. *Clin Infect Dis*. 2007; 45:194–198. [PubMed: 17578778]
8. Torkko KC, Gershman K, Crane LA, et al. Testing for Chlamydia and sexual history taking in adolescent females: results from a statewide survey of Colorado primary care providers. *Pediatrics*. 2000; 106:E32. [PubMed: 10969116]
9. Cook RL, Wiesenfeld HC, Ashton MR, et al. Barriers to screening sexually active adolescent women for Chlamydia: a survey of primary care physicians. *J Adolesc Health*. 2001; 28:204–210. [PubMed: 11226843]
10. St Lawrence JS, Kuo WH, Hogben M, et al. STD care: variations in clinical care associated with provider sex, patient sex, patients' self-reported symptoms or high-risk behaviors, partner STD history. *Soc Sci Med*. 2004; 59:1011–1018. [PubMed: 15186901]
11. Schachter J, McCormack WM, Chernesky MA, et al. Vaginal swabs are appropriate specimens for diagnosis of genital tract infection with *Chlamydia trachomatis*. *J Clin Microbiol*. 2003; 41:3784–3789. [PubMed: 12904390]
12. Schachter J, Chernesky MA, Willis DE, et al. Vaginal swabs are the specimens of choice when screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*: results from a multicenter evaluation of the APTIMA assays for both infections. *Sex Transm Dis*. 2005; 32:725–728. [PubMed: 16314767]
13. Shafer MA, Moncada J, Boyer CB, et al. Comparing first-void urine specimens, self-collected vaginal swabs, and endocervical specimens to detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by a nucleic acid amplification test. *J Clin Microbiol*. 2003; 41:4395–4399. [PubMed: 12958275]
14. Schwebke JR, Morgan SC, Pinson GB. Validity of self-obtained vaginal specimens for diagnosis of trichomoniasis. *J Clin Microbiol*. 1997; 35:1618–1619. [PubMed: 9163499]
15. Hardick A, Hardick J, Wood BJ, et al. Comparison between the Gen-Probe transcription-mediated amplification *Trichomonas vaginalis* research assay and real-time PCR for *Trichomonas vaginalis* detection using a Roche LightCycler instrument with female self-obtained vaginal swab samples and male urine samples. *J Clin Microbiol*. 2006; 44:4197–4199. [PubMed: 16943353]
16. Madico G, Quinn TC, Rompalo A, et al. Diagnosis of *Trichomonas vaginalis* infection by PCR using vaginal swab samples. *J Clin Microbiol*. 1998; 36:3205–3210. [PubMed: 9774566]
17. Rompalo AM, Gaydos CA, Shah N, et al. Evaluation of use of a single intravaginal swab to detect multiple sexually transmitted infections in active-duty military women. *Clin Infect Dis*. 2001; 33:1455–1461. [PubMed: 11568849]
18. Amsel R, Totten PA, Spiegel CA, et al. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. *Am J Med*. 1983; 74:14–22. [PubMed: 6600371]
19. Geisler WM, Yu S, Venglarik M, et al. Vaginal leucocyte counts in women with bacterial vaginosis: relation to vaginal and cervical infections. *Sex Transm Infect*. 2004; 80:401–405. [PubMed: 15459411]
20. Eschenbach DA, Hillier S, Critchlow C, et al. Diagnosis and clinical manifestations of bacterial vaginosis. *Am J Obstet Gynecol*. 1988; 158:819–828. [PubMed: 3259075]

21. Schwebke JR, Hillier SL, Sobel JD, et al. Validity of the vaginal gram stain for the diagnosis of bacterial vaginosis. *Obstet Gynecol.* 1996; 88:573–576. [PubMed: 8841221]
22. Masek BJ, Arora N, Quinn N, et al. Performance of three nucleic acid amplification tests for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by use of self-collected vaginal swabs obtained via an Internet-based screening program. *J Clin Microbiol.* 2009; 47:1663–1667. [PubMed: 19386838]
23. Hobbs MM, Van der Pol B, Totten P, et al. From the NIH: proceedings of a workshop on the importance of self-obtained vaginal specimens for detection of sexually transmitted infections. *Sex Transm Dis.* 2008; 35:8–13. [PubMed: 18157061]
24. Association of Public Health Laboratories. Guidelines for the laboratory testing of STDs. Silver Spring, MD: Association of Public Health Laboratories; 2008.
<http://www.aphl.org/aphlprograms/infectious/std/Pages/stdtestingguidelines.aspx>
25. Serlin M, Shafer MA, Tebb K, et al. What sexually transmitted disease screening method does the adolescent prefer? Adolescents' attitudes toward first-void urine, self-collected vaginal swab, and pelvic examination. *Arch Pediatr Adolesc Med.* 2002; 156:588–591. [PubMed: 12038892]
26. Wiesenfeld HC, Lowry DL, Heine RP, et al. Self-collection of vaginal swabs for the detection of Chlamydia, gonorrhea, and trichomoniasis: opportunity to encourage sexually transmitted disease testing among adolescents. *Sex Transm Dis.* 2001; 28:321–325. [PubMed: 11403188]
27. Roy K, Wang SA, Meltzer MI. Optimizing treatment of antimicrobial-resistant *Neisseria gonorrhoeae*. *Emerg Infect Dis.* 2005; 11:1265–1273. [PubMed: 16102317]
28. Roy S, Caillouette JC, Faden JS, et al. Improving appropriate use of antifungal medications: the role of an over-the-counter vaginal pH self-test device. *Infect Dis Obstet Gynecol.* 2003; 11:209–216. [PubMed: 15108867]
29. Reed JL, Simendinger L, Griffeth S, et al. Point-of-care testing for sexually transmitted infections increases awareness and short-term abstinence in adolescent women. *J Adolesc Health.* 2010; 46:270–277. [PubMed: 20159505]
30. Gaydos, C.; Hsieh, H-Y.; Burrah, A., et al. Can we ever expect to have individuals perform their own HIV rapid tests?. Philadelphia: Infectious Disease Society of America; 2009. (Abstract 180).

Figure 1.
Study recruitment diagram and case definition by diagnostic method. POC, point-of-care;
TMA, transcription-mediated amplification.

Table 1

Associations between positive POC tests (either self or clinician-obtained) compared with clinical and demographic factors

Participant characteristics	Total (%)	POC test positive (%)	p Value
Age, years	n=209		0.26
14–17	96 (46.0)	25 (26.0)	
18–21	113 (54.0)	22 (19.5)	
African-American	n=209		0.13
Yes	182 (87.0)	44 (24.2)	
No	27 (13.0)	3 (11.1)	
Hormonal contraception	n=201		0.34
Yes	73 (36.3)	14 (19.2)	
No	128 (63.7)	32 (25.0)	
Multiple partners	n=196		0.18
Yes	183 (93.4)	44 (24.0)	
No	13 (6.6)	1 (7.7)	
Douching	n=205		0.35
Never	138 (67.3)	29 (21.0)	
Ever	67 (32.7)	18 (26.9)	
Health insurance	n=197		0.13
Medicaid	115 (58.4)	33 (28.7)	
Private	33 (16.6)	4 (12.1)	
None/don't know	49 (25.3)	10 (21.2)	
Recruitment site	n=209		0.003
THC	151 (72.3)	26 (17.2)	
ED	58 (27.7)	21 (36.2)	
Vaginal symptoms	n=209		0.42
Yes	155 (74.2)	37 (23.9)	
No	54 (25.8)	10 (18.5)	
Clinical BV	n=201		0.52
Yes	38 (18.9)	7 (18.4)	
No	163 (81.1)	38 (23.3)	
Amine test	n=203		0.01
Positive	104 (51.2)	30 (28.9)	
Negative	99 (48.8)	14 (14.1)	
Abnormal pH	n=203		0.06
Yes	114 (56.2)	32 (28.1)	
No	89 (43.8)	15 (16.9)	
Clue cells >20%	n=207		0.35
Yes	69 (33.2)	13 (18.8)	
No	138 (66.8)	34 (24.6)	

Some factors less than 209 due to missing data, p Value represents chi-squared test of significance.

BV, bacterial vaginosis; ED, emergency department; POC, point-of-care; THC, Teen Health Center.

Table 2

Correlation between self and clinician-POC tests for trichomoniasis

N = 209	Clinician-POC test positive	Clinician-POC test negative	κ	% Agreement
Self-POC test positive	38	4 [*]	0.87	95.7
Self-POC test negative	5 [†]	162		

Cells=number of participants.

^{*} Two of four confirmed positive.[†] Five of five confirmed positive.

POC, point-of-care.

Table 3

Test performance (sensitivity, specificity, 95% CI for each diagnostic method, in a sample of 51 true positives and 158 true negatives for trichomoniasis)

Diagnostic test	No of positive tests	Sensitivity %	95% CI	No of negative tests	Specificity %	95% CI
Wet mount	20	39.2	26 to 54	158	100	98 to 100
Culture	42	82.4	69 to 92	158	100	98 to 100
Self-POC test	40	78.4	65 to 89	156	98.7	96 to 100
Clinician-POC test	44	84.3	71 to 93	158	100	98 to 100
TMA-ASR	51	100	93 to 100	140	88.6	82 to 93
TMA-RUO	50	98	89 to 100	151	95.6	91 to 98
TMA (both primers)	50	98	89 to 100	158	100	98 to 100

ASR, analyte-specific reagents; POC, point-of-care; RUO, research use only; TMA, transcription-mediated amplification.