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Clinical performance of the Solana® Point-of-Care Trichomonas Assay from clinician-collected vaginal swabs and urine specimens from symptomatic and asymptomatic women

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Abstract

Background—Solana® (Quidel) is a new rapid (<40 min.) point-of-care (POC) test for qualitative detection of *Trichomonas vaginalis* (TV) DNA. The assay has two steps: 1) specimen preparation, and 2) amplification and detection using isothermal Helicase-Dependent Amplification (HDA). The objective was to demonstrate the performance of Solana for vaginal swabs and female urines based on comparison to wet mount and TV culture. Performance was also compared to the Aptima-TV assay.

Methods—Urine and four clinician-collected vaginal swabs were collected. The first two were used for FDA composite reference (wet mount; InPouch TV Culture). The third swab was used for Solana. Sensitivity/specificity were based on the reference method. A specimen was considered positive if either test was positive. The fourth swab was for Aptima-TV.

Results—Vaginal swabs and urines were obtained from 501 asymptomatic and 543 symptomatic women. Prevalence of TV by was 11.5%. For swabs, Solana® demonstrated high sensitivity and specificity from asymptomatic (100%/98.9%) and symptomatic (98.6%/98.5%) women, as well as for urines from asymptomatic (98.0%/98.4%) and symptomatic (92.9%/97.9%) women, compared to the reference method. Compared to Aptima-TV, the sensitivity/specificity was 89.7%/99.0% for swabs and 100%/98.9% for urines.

Conclusions—The Solana® assay performed well compared to the reference assays.

Keywords

Trichomonas vaginalis; trichomoniasis; Point-of-Care test; Solana

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Declaration of Interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

1. Introduction

Trichomonas vaginalis (TV), a motile protozoan parasite, causes the most prevalent nonviral sexually transmitted infection (STI) in the world. It is estimated to infect 3.7 million people in the United States.¹ The World Health Organization estimates that 276.4 million new cases of trichomonas per year in adults between the ages of 15 and 49 years in 2008.² These infections represent the most common curable STI in young, sexually active men and women.²

Trichomonas infections in women have been associated with poor reproductive outcomes such as low birth weight (LBW) and premature birth.^{3–5} There was a reported attributable risk of trichomonas associated with LBW in Blacks of 11% vs. 1.6% in Hispanics, and 1.5% in Whites in a cohort of over 13,000 women.³ The National Health and Nutrition Examination Survey (NHANES) 2001–2004 estimated that 3.1% of women in the United States have TV.⁶ TV has been associated with other STIs among women in the U.S. population and importantly over 80% of cases were asymptomatic.⁷ *T. vaginalis* infection has been also associated with two to three-fold significant increased risks of HIV acquisition, and pelvic inflammatory disease (PID) among HIV-infected women.^{8–11} Older age and health disparities are also significant epidemiological factors in trichomonas infections which have been reported to affect over 11% of women age 40 years and 13% of black women in the United States.^{12,13} Because of such sequelae and the asymptomatic nature of *T. vaginalis* infections, it is important to test women for these infections.

The conventional methods to detect *T. vaginalis* in vaginal swabs are wet mount/saline microscopy and culture techniques, but both are insensitive (40–60%) compared to newer nucleic acid amplification tests (NAATs).^{4,12,14–17} The OSOM test is a rapid point of care (POC) test that is CLIA waived and more sensitive than either wet preparation and culture sensitivities with reported sensitivities of >80% compared to NAAT assays (>90%), making it ideal for POC testing.^{14,17} NAAT assays have been shown to be the most sensitive but are not CLIA waived or POC yet.^{12,14–17} The objective of this study was to demonstrate the performance of the new rapid Solana® TV-Assay (Quidel Corporation, Athens Ohio) for clinician-collected vaginal swabs and female urines in a multi-center study, based on comparison of Solana results to those by wet mount and TV culture. A secondary objective was to determine performance compared to the Aptima-TV assay.

2. Methods

Symptomatic women and asymptomatic women who were 14 years or older were enrolled from high and low prevalence clinics from five geographically diverse areas. The study was performed January to March 2016 at four locations in the United States. Specimens were obtained from each subject after written informed consent was obtained. Inclusion criteria included women who presented with symptoms of *T. vaginalis* and asymptomatic women who were scheduled for a pelvic examination or screening for *T. vaginalis*. Patient age or date of birth was obtained.

The study was conducted in accord with the Health Insurance Portability and Accountability Act (HIPAA) and approved by the associated Institutional Review Boards.

For each subject, 4 vaginal swab specimens were clinician-collected and were used for reference (wet mount and culture (InPouch™ TV, BioMed Diagnostics, Inc., White City, Oregon).), Solana®, and Aptima-TV (Gen-Probe/Hologic, San Diego, CA) testing. The first two swabs were used for saline wet mount, read by the clinician, and TV culture. The 3rd polyester swab was used for Solana Assay testing. The 4th was used for Aptima-TV. A first-catch urine was collected from each subject for testing by all 4 methods. All sensitivity/specificity calculations were initially based on a FDA-composite reference method (saline wet mount and InPouch-TV-culture). A specimen was considered positive if either test was positive. For samples that were positive by Solana® and negative by saline wet mount and culture, the Aptima TV was used as a confirmation of a true positive.

The Solana® Trichomonas Assay is an in vitro qualitative nucleic acid amplification test for the detection of *T. vaginalis* to aid in the diagnosis of trichomoniasis using the Helicase-Dependent Amplification (HDA) technology and the Solana® instrument (Figure 1). To detect *T. vaginalis* directly from trichomoniasis-suspected specimens, the assay targets a conserved repeat sequence of the *T. vaginalis* genome. The assay consists of two major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to *T. vaginalis* DNA using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe. The assay is intended for use in clinical laboratories as an aid in the diagnosis of trichomoniasis.

3. Data Analysis

Descriptive statistical data analyses were performed to summarize the data in numbers and percentages. We also used the point estimate and its corresponding confidence intervals to determine the statistical significance. P-values of <0.05 were considered significant. SAS version 9.4 (SAS Institute, Cary, North Carolina, USA) was used for all statistical analyses.

4. Results

Clinician-collected vaginal swabs and urines (N=1044) were obtained from 501 asymptomatic and 543 symptomatic women (Table 1). The prevalence of TV by swabs and/or urines was 11.5%. For clinician-collected swabs, the Solana Trichomonas Assay demonstrated high sensitivity and specificity from asymptomatic (100%/98.7%) and symptomatic (98.6%/98.5%) women, as well as for urines from asymptomatic (98.0%/98.4%) and symptomatic (92.9%/97.9%) women, when compared to the FDA-composite reference method (Table 2). Compared to Aptima-TV, the sensitivity/specificity performance was 89.7%/99.0% for swabs and 100%/98.9% for urines (Table 3).

5. Discussion

The Solana® TV Assay demonstrated high sensitivity and specificity, regardless of symptoms, compared to the routinely used for standard of care tests of saline wet preparation microscopy and culture. Additionally, this assay also showed high agreement

compared to a NAAT assay with an overall agreement of 97.8%. There are now two FDA cleared NAAT assays for trichomonas^{12,18}, and it is generally accepted that NAATs for TV are more sensitive than culture.¹⁵ However, the reference standard set by the FDA for this study was saline wet preparation microscopy and culture, which was the composite positive comparator (CPC). Thus, the study design and the CPC used may have overestimated the point estimates for this trial, since NAATs have been demonstrated to be more sensitive than culture.

The rapid Solana® TV Assay appeared to perform better than saline microscopy/culture by detecting more positive results than the defined CPC. However, it did not detect more positives than the NAAT.

There are limitations to the interpretation of our study in that the Solana appeared to detect more positives than the CPC. There may have been lower number of positives in the CPC assays due to delays in incubating cultures and reading saline microscopy tests, transportation delays or variability in interpretation of the results of the comparator assays, both of which are subjective in nature. The possibility of false positives by the NAAT test also cannot be excluded, but they are unlikely since the platform is a closed, robotic platform, which should lower the likelihood of cross contamination by a laboratory.

The Solana® TV Assay provided evidence that an amplified molecular assay can perform as well as saline microscopy/culture and provided comparable results as another FDA cleared NAAT assay for detection of trichomoniasis in symptomatic and asymptomatic women, while yielding results in 45 minutes. Although the requirement of equipment and a time of 45 min are not attributes of a perfect POC test, but this platform can still be useful in many clinical situations, but its usefulness in remote clinics without trained personnel and in resource-poor settings will need to be further evaluated. It is now FDA cleared as moderately complex, but its potential to be CLIA waived in the future may increase its usefulness as a POC test that can be used for treatment of patients in remote areas before they leave the clinic. It appeared to yield a similar or slightly better sensitivity in this study to another rapid, commercially available unamplified antigen trichomonas assay.¹⁴

Because of the data accumulating for the association of trichomonas infections with adverse events, such as HIV transmission and perinatal morbidity, it seems judicious to promote public health recognition for more screening for trichomonas, especially since modeling studies demonstrate the potential to improve health outcomes.^{11,18–22} Interestingly, recent research linking trichomonas infections to prostate cancer in men has been accumulating and may add reasons to be more actively screen men for trichomonas.^{23–24} The availability of serological detection of circulating antibody to trichomonas may be an additional epidemiological tool for diagnosis of chronic infections, when only very limited amount of pathogens are released in urine or in vaginal secretions.²⁵

In summary, the rapid Solana® TV Assay showed a high sensitivity and specificity in both asymptomatic and symptomatic women in 45 minutes of test time, when compared to the composite reference method that included saline microscopy and InPouch TV culture.

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Figure 1.
Solana Platform.

Table 1

Characteristics of women enrolled in the Solana study for *Trichomonas vaginalis*

Characteristics	Category	Combined (%)	Symptomatic (%)	Asymptomatic (%)
		N=1044	N=543	N=501
Age (years)	16 – 24	33.0% (344/1044)	37.4% (203/543)	28.1% (141/501)
	25 – 29	23.6% (246/1044)	25.4% (138/543)	21.6% (108/501)
	30 – 34	11.8% (123/1044)	12.2% (66/543)	11.4% (57/501)
	35	31.7% (331/1044)	25.0% (136/543)	38.9% (195)

Table 2

Sensitivity and Specificity of the Solana Assay for *Trichomonas vaginalis* compared to the Composite Reference Methods of Saline Wet Mount and Culture

Vaginal Swabs	Sensitivity	%CI 95	Specificity	%CI 95
Asymptomatic women	100%	92.7% to 100%	98.7%	97.1% to 99.4%
Symptomatic women	98.6%	92.3% to 99.7%	98.5%	97.0% to 99.3%
Total	99.2%	95.4% to 99.9%	98.6%	97.6% to 99.2%
Urine				
Asymptomatic women	98.0%	89.5% to 99.6%	98.4%	96.8% to 99.2%
Symptomatic women	92.9%	84.3% to 96.9%	97.9%	96.2% to 98.8%
Total	95.0%	89.5% to 97.7%	98.2%	97.1% to 98.8%

Table 3Sensitivity and Specificity of the Solana Assay for *Trichomonas vaginalis* compared to the Aptima-TV

Vaginal Swabs	Sensitivity	%CI 95	Specificity	%CI 95
Combined	89.7%	83.5% to 93.89%	99.0%	98.1% to 99.5%
Urine				
Combined	100%	96.9% to 100%	98.9%	98.0% to 99.4%