



The Sensitivity and Specificity of OSOM® Rapid *Trichomonas vaginalis* and Bacterial Vaginosis (BVBlue®) Tests

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INTRODUCTION

- Trichomoniasis, caused by *Trichomonas vaginalis* (TV), and bacterial vaginosis (BV) are two disorders frequently associated with adverse outcomes among women, including acquisition of HIV¹.
- Both trichomoniasis and BV are often asymptomatic in women².
- TV and BV are commonly diagnosed in the clinic with a wet mount for TV and the Amsel's criteria for BV. However, these methods are less sensitive than culture for TV and Gram stain for BV performed in the laboratory³.
- The BVBlue® test detects elevated levels of sialidase, a byproduct of *Prevotella sp.* and *G. vaginalis* found in high concentrations among women with BV.
- OSOM® rapid TV test detects TV antigen.
- BVBlue® and rapid TV tests are CLIA waived tests that can deliver results within 15 minutes.

OBJECTIVE

- To compare the OSOM TV to wet mount, culture, and Gen-Probe Aptima Transcription-mediated amplification test for diagnosis of trichomoniasis, and the BVBlue test to Amsel's criteria and Gram stain Nugent score for diagnosis of BV in symptomatic and asymptomatic women.

METHODS

Seven vaginal swabs were sequentially collected for:

Test	Performed by
1. BVBlue	Medical assistant
2. OSOM Rapid TV	Medical assistant
3. Vaginal pH	Clinician
4. Wet mount for clue cells and TV and KOH for amine odor	Clinician
5. TV culture	Lab technologist
6. Gen-Probe Aptima TMA for TV	Lab technologist
7. Gram stain	Lab technologist

- Personnel were blinded to the results of the comparison tests.
- Diagnosis of BV by the Amsel's criteria required at least 3 of the 4 following clinical signs: pH >4.5, amine odor, homogeneous discharge, and the presence of clue cells.
- Nugent score of ≥ 7 was used to define BV by Gram stain.

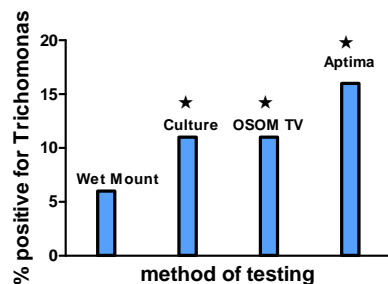
RESULTS

Demographics

- Number of women: 397
- Age: 18 to 58, mean=26
- Race: African-American 230, Caucasian 128, other 39
- Vaginal symptoms: 192, No symptoms 205
- Women with symptoms were more likely to be African-American (p=0.001)

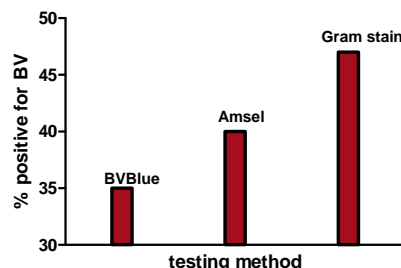
RESULTS

Figure 1. OSOM TV, culture, and Gen-Probe Aptima diagnosed significantly more women with trichomoniasis



* p < 0.01 compared to wet mount

Figure 2. BVBlue diagnosed significantly fewer women with BV than Gram stain



- BVBlue (35%) vs. Gram stain (47%): p<0.001
- BVBlue (35%) vs. Amsel's criteria (40%): p=0.2
- Amsel's criteria (40%) vs. Gram stain (47%): p=0.02

Table 1. Performance characteristics of BV tests stratified by vaginal symptoms shows BVBlue with inferior sensitivity for diagnosis of BV compared to gram stain

	All (N=394) Sens/spec	Symptomatic (N=190) Sens/spec	Asymptomatic (N=204) Sens/spec
BVBlue compared to Gram stain	73%/99%	77%/100%	69%/98%
Amsel's criteria compared to Gram stain	80%/98%	88%/94%	69%/100%

- BVBlue was less sensitive than Amsel's criteria for detection of BV in women with symptoms. P=0.02

Table 2. Characteristics of trichomoniasis tests stratified by vaginal symptoms shows OSOM TV is superior to wet mount

	All (N=394) Sens/spec	Symptomatic (N=190) Sens/spec	Asymptomatic (N=204) Sens/spec
OSOM TV compared to culture	96%/99%	100%/100%	88%/99%
Wet mount compared to culture	52%/99.7%	56%/99%	47%/100%
Aptima TV compared to culture	100%/95%	100%/96%	100%/94%

- OSOM TV sensitivity was significantly higher than wet mount. (p < 0.009)

SUMMARY OF TEST PERFORMANCE

Methods for detection of <i>Trichomonas</i> or BV	Sensitivity	Estimated Turn Around Time
Wet Mount	52%	5-10 minutes
Culture	Gold standard	1-5 days
OSOM Rapid Antigen	96%	15 minutes
Aptima NAAT	100%	24-48 hours
BVBlue	73%	15 minutes
Gram stain	Gold Standard	24-48 hours

SUMMARY & CONCLUSIONS

- The OSOM test for TV was superior to wet mount, and equivalent to culture for the diagnosis of trichomoniasis.
- Gen-Probe Aptima had the best performance characteristics for diagnosis of trichomoniasis.
- The OSOM TV test can be performed in a clinic setting and may be preferable to both wet mount and culture for rapid detection of TV.
- For all women tested the BVBlue test was less sensitive than Gram stain for diagnosis of BV and not statistically different from Amsel's criteria.
- Because of the frequency of asymptomatic trichomoniasis and BV, BVBlue and OSOM TV may be inferior to current laboratory diagnostic gold standards.

REFERENCES

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