

OSOM

BV Blue & *Trichomonas*

Rapid Tests

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Bacterial vaginosis (BV)

- ❑ BV is the most common cause of vaginal symptoms.
- ❑ Women with BV are at a higher risk of acquiring HIV and other STIs
- ❑ The clinical diagnosis (Amsel criteria) is less sensitive than the Nugent score of a vaginal Gram stain for detecting abnormal flora.
- ❑ Gram stain is not a point-of-care test and results are not immediately available.

HPTN 035 Amsel vs. Gram stain

Test	Nugent 0-3	Nugent 4-6	Nugent 7-10	Overall	Sensitivity	Specificity
	1098	422	937	2457		
pH > 4.5	32%	64%	83%	57%	83%	59%
Clue cells	2%	8%	35%	16%	35%	96%
Whiff	2%	11%	37%	17%	37%	95%
Vaginal discharge	17%	1%	28%	21%	28%	83%
Amsel's Criteria (3 of 4)	1%	9%	33%	15%	33%	96%

Data from enrollment visits at 6 sites

OSOM BV Blue

- ❑ Tests for high levels of sialidase produced by organisms associated with BV.
 - *G. vaginalis*, *Prevotella* sp., and *Mobiluncus* sp.
- ❑ Approximately 12 minutes to perform
- ❑ Swabs can be held at room temperature for 48 hours prior to testing.
- ❑ FDA approved and CLIA waived test.

Comparison of OSOM BV Blue to Gram stain and Amsel

- ❑ Study done by Bradshaw, et al. J Clin Micro 2005
- ❑ 288 symptomatic women

	Sensitivity	Specificity
Amsel criteria (3 of 4)	88%	91%
Gram stain	88%	95%

MTN NL Evaluation of OSOM BV Blue and *Trichomonas* rapid test

- 500 women (116 completed)
- symptomatic and asymptomatic
- 7 swabs were collected in no set order for:
 - pH
 - amine odor and clue cells
 - Gram stain
 - *Trichomonas* culture
 - *Trichomonas* PCR
 - OSOM *Trichomonas* test
 - OSOM BV Blue test

Preliminary Results of OSOM BV Blue evaluation from 116 women

Comparison test	Sensitivity	Specificity
Amsel criteria	59%	93%
Gram stain score 7-10	47%	100%

Why was the sensitivity of this study lower than other researchers?

- No difference in discrepant results in:
 - Symptomatic vs. asymptomatic
 - Lot number of kits
 - Personnel collecting the swabs
 - Personnel performing the test
 - Age of participants
 - Use of vaginal products or douching
- Swabs collected for BV Blue were collected last in 1/3 of the participants

Lessons Learned

- ❑ Small variations from a procedure can affect the performance of a test.
- ❑ Don't wait until the end of a study or validation to assess the performance of a test.
- ❑ Due to the low sensitivity, swab collection will not be randomized for the remainder of the evaluation.
- ❑ Swabs for the BV Blue test will be collected first.

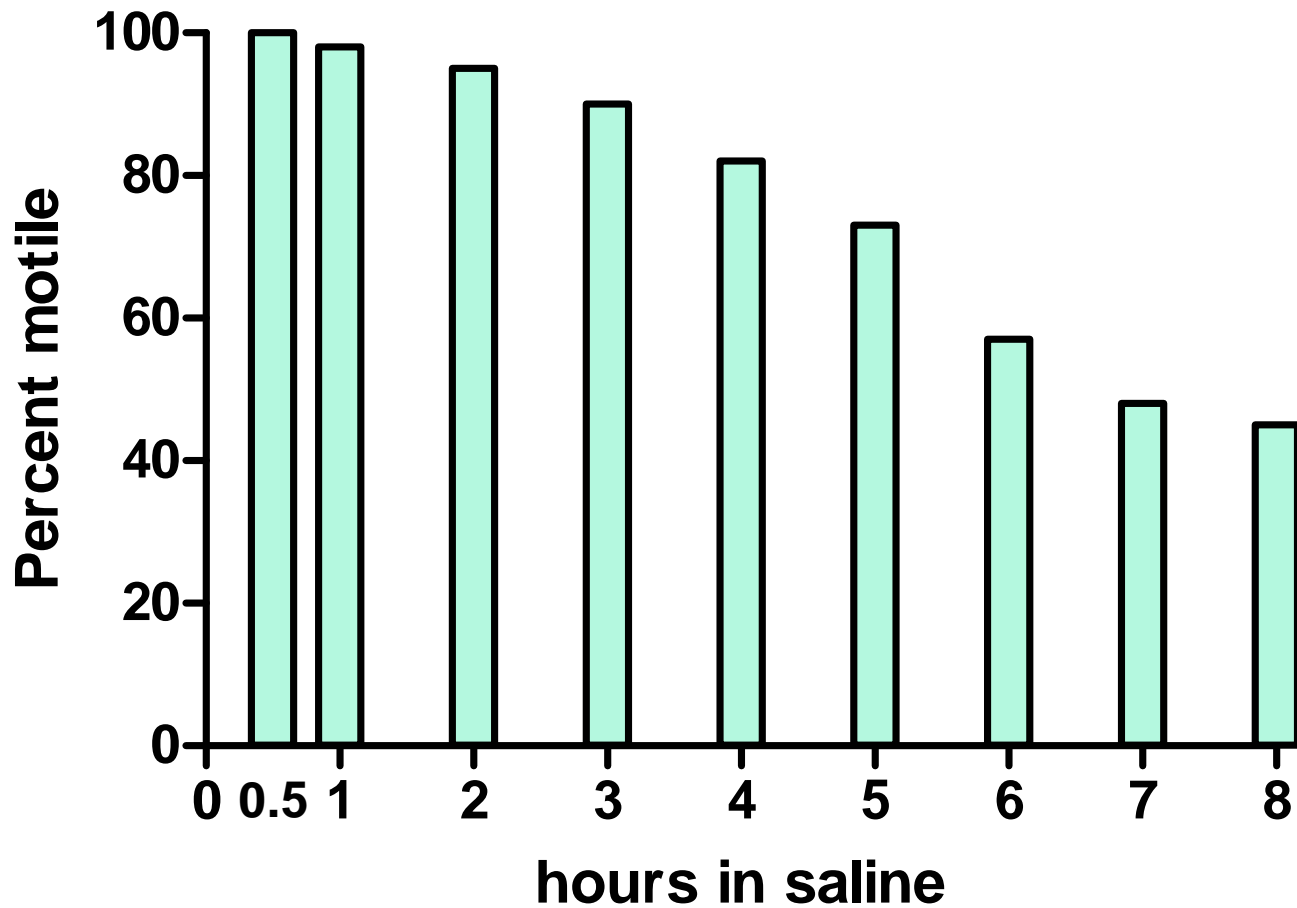
Trichomonas vaginalis

- ❑ The World Health Organization estimated the global incidence is 173 million cases annually.
- ❑ Women with trichomoniasis have a greater risk of acquiring HIV than women without. (OR 2.4, C.I 1.28-4.53) Van Der Pol, JID 2008.
- ❑ The sensitivity of wet mount is less than culture, rapid antigen, or nucleic acid amplification tests.
- ❑ The reported sensitivity of wet preparation ranges from 35% to 92% compared to culture.

How long does *Trichomonas* remain motile in saline ?

- ❑ A study was done at MWRI to evaluate detection of *Trichomonas* by wet mount.
- ❑ 60 specimens positive for *T.vaginalis* were held at room temperature for 24 hours
- ❑ Wet mounts were read at 30 minutes and every hour

Results of *T.vaginalis* survival evaluation



Methods of Detecting *T.vaginalis*

Method	Reported Sensitivity	Time Required	Supply Costs/test*
Wet Mount	36-92%	2 minutes	< \$1.00
Culture	83-98%	1-5 days	\$2.50
Rapid Antigen	83-90%	15 minutes	\$7- \$9.00
NAAT	92-98%	24-48 hours	\$5.10

* Cost do not include instrument or personnel

OSOM *Trichomonas* Rapid Test

- ❑ Detection of *Trichomonas* protein antigen
- ❑ A capillary flow dipstick
- ❑ Takes approximately 12 minutes to perform
- ❑ Swabs can be held at room temperature for 24 hours or refrigerated for 36 hours before testing.
- ❑ FDA approved and CLIA waived test.

MTN NL Evaluation of OSOM Trichomonas Rapid Test

- 116 women
- symptomatic and asymptomatic

Comparison test	Sensitivity	Specificity
Wet mount	100%	95%
InPouch culture	79%	98%

Additional information about the OSOM tests

- ❑ CAP panel is available for the *Trichomonas* rapid test(VS1) but not the BV Blue test.
- ❑ Menstrual blood does not interfere with either test unless the amount of blood is excessive.
 - If excessive blood is present it may cause the background color to be pink on the *Trichomonas* test and prevent detection of the test bands.