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

<table>
<thead>
<tr>
<th>Test</th>
<th>Nugent 0-3</th>
<th>Nugent 4-6</th>
<th>Nugent 7-10</th>
<th>Overall</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1098</td>
<td>422</td>
<td>937</td>
<td>2457</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH &gt; 4.5</td>
<td>32%</td>
<td>64%</td>
<td>83%</td>
<td>57%</td>
<td>83%</td>
<td>59%</td>
</tr>
<tr>
<td>Clue cells</td>
<td>2%</td>
<td>8%</td>
<td>35%</td>
<td>16%</td>
<td>35%</td>
<td>96%</td>
</tr>
<tr>
<td>Whiff</td>
<td>2%</td>
<td>11%</td>
<td>37%</td>
<td>17%</td>
<td>37%</td>
<td>95%</td>
</tr>
<tr>
<td>Vaginal discharge</td>
<td>17%</td>
<td>1%</td>
<td>28%</td>
<td>21%</td>
<td>28%</td>
<td>83%</td>
</tr>
<tr>
<td>Amsel’s Criteria (3 of 4)</td>
<td>1%</td>
<td>9%</td>
<td>33%</td>
<td>15%</td>
<td>33%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Data from enrollment visits at 6 sites
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

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amsel criteria (3 of 4)</td>
<td>88%</td>
<td>91%</td>
</tr>
<tr>
<td>Gram stain</td>
<td>88%</td>
<td>95%</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Comparison test</th>
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<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amsel criteria</td>
<td>59%</td>
<td>93%</td>
</tr>
<tr>
<td>Gram stain score 7-10</td>
<td>47%</td>
<td>100%</td>
</tr>
</tbody>
</table>
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 trichomononaisis 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

![Graph showing percent motile over hours in saline](image-url)
Methods of Detecting *T.vaginalis*

<table>
<thead>
<tr>
<th>Method</th>
<th>Reported Sensitivity</th>
<th>Time Required</th>
<th>Supply Costs/test*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet Mount</td>
<td>36-92%</td>
<td>2 minutes</td>
<td>&lt; $1.00</td>
</tr>
<tr>
<td>Culture</td>
<td>83-98%</td>
<td>1-5 days</td>
<td>$2.50</td>
</tr>
<tr>
<td>Rapid Antigen</td>
<td>83-90%</td>
<td>15 minutes</td>
<td>$7- $9.00</td>
</tr>
<tr>
<td>NAAT</td>
<td>92-98%</td>
<td>24-48 hours</td>
<td>$5.10</td>
</tr>
</tbody>
</table>

* *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

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</thead>
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<tr>
<td>Wet mount</td>
<td>100%</td>
<td>95%</td>
</tr>
<tr>
<td>InPouch culture</td>
<td>79%</td>
<td>98%</td>
</tr>
</tbody>
</table>
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.