Validation of the new STI panel for Abbott Alinity m

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Disclosure

- Materials support for this study were provided by Abbott
- Speaking at the request of Abbott
- Alinity m STI assay is not yet FDA approved
- The views expressed are those of the authors and do not reflect the views and policies of the Department of Veterans Affairs.
• Molecular testing platform from Abbott Molecular

• Performs all steps of nucleic acid testing including, sample processing, amplification, detection, and data reduction.

• 300 samples per 8 hour shift from first sample aspiration to last test result

• Random access

• Greatly improved turn-around time
Chlamydia trachomatis

- most frequently reported bacterial infectious disease in the U.S.⁵
- Multiple serious sequelae including PID, ectopic pregnancy, and infertility
- Asymptomatic infection is common among both men and women³
- Annual screening of all sexually active women aged <25 years and older women with risk factors is recommended
- Recommended treatment: 
  - Doxycycline
  - Alternative Regimens:
    - Azithromycin
    - OR
    - Levofloxacin
Neisseria gonorrhoeae

- Second most commonly reported bacterial communicable disease
- Can be asymptomatic in women
- Annual screening for *N. gonorrhoeae* infection is recommended for all sexually active women under 25 and those over 25 with risk factors.  
- Can have serious complications including PID or disseminated gonococcal infection.
- MSM are at high risk. Those at risk for HIV acquisition should be screened at all anatomic sites of exposure every 3–6 months.  
- Recommended treatment:
  - **Ceftriaxone** in a single dose
  - Alternative treatment: **Gentamycin + Azithromycin**
Trichomoniasis is estimated to be the most prevalent nonviral STI worldwide.  
- 3.7 million cases in U.S. 
- Can cause urethritis, epididymitis, or prostatitis 
- Most have minimal or no genital symptoms, and untreated infections might last from months to years 
- *T. vaginalis* infection is associated with a 1.5-fold increased risk for HIV acquisition and is associated with an increase in HIV vaginal shedding. 

**Recommended treatment:**
- **Metronidazole**
- **Tinidazole**
Mycoplasma genitalium

- causes symptomatic and asymptomatic urethritis among men and it is estimated to be the cause of approximately 40% of persistent or recurrent urethritis
- Causes cervicitis, PID, preterm delivery, spontaneous abortion, and infertility.¹
- Symptoms mimic those of Chlamydia²
- Developing resistance to drugs normally used to treat Chlamydia. (especially macrolides)²
- No commercially available test for MG until recently.
- Recommended treatment:
  - **Doxycycline** followed by **Azithromycin** OR
  - Alternative (if resistant to azithromycin)
  - **Doxycycline** followed by **Moxifloxacin**
Abbott Alinity m STI panel

4-IN-1 REACTION

- Chlamydia trachomatis (CT)
- Neisseria gonorrhoeae (NG)
- Trichomonas vaginalis (TV)
- Mycoplasma genitalium (MG)
Alinity m STI kit
Controls

1 Positive and 1 Negative control must be run once every 24 hours.
Alinity m multi-collect Specimen Collection kit

Pierceable caps

One collection tube for all sources
Validation Study Summary

• 249 total tested
• Specimen split into appropriate tubes
• CT & NG results compared to Abbott m2000.
• TV & MG compared to sendout test at Quest Diagnostics.

<table>
<thead>
<tr>
<th>Spec source</th>
<th>TOTAL TESTED</th>
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<tr>
<td>Male urine</td>
<td>131</td>
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<tr>
<td>Female urine</td>
<td>35</td>
</tr>
<tr>
<td>Rectal</td>
<td>21</td>
</tr>
<tr>
<td>Throat</td>
<td>12</td>
</tr>
<tr>
<td>Cervix/vaginal</td>
<td>11</td>
</tr>
<tr>
<td>CAP survey</td>
<td>10</td>
</tr>
<tr>
<td>Preservcyt</td>
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</tr>
<tr>
<td>Total</td>
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## Results

<table>
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<tr>
<th>Spec source</th>
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<th>NG+</th>
<th>TV+</th>
<th>MG+</th>
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<tbody>
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<td>Female urine</td>
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<td>1</td>
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<td>CAP</td>
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<td>Thinprep</td>
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<tr>
<td><strong>confirmed +</strong></td>
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- 1 discrepant CT result
- 2 discrepant NG results
- 90 sent out for TV - 100% agreement
- 17 sent out for MG – 100% agreement
## Clinical Performance

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<thead>
<tr>
<th></th>
<th>sensitivity</th>
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<th>NPP</th>
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<tbody>
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<tr>
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<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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<tr>
<td>MG</td>
<td>100</td>
<td>100</td>
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Conclusion


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