Performance of the BD MAX™ CT/GC/TV for Detection of Chlamydia, Gonorrhoea and Trichomonas

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Disclosures

• Atlas Genetics
• **BD Diagnostics** [*provided funding for this study*]
• Beckman Coulter
• Cepheid
• Rheonix
• Roche Molecular
Most recent WHO estimates of incident STI

- Chlamydia 105.7 million 4.1% ↑
- Gonorrhea 106.1 million 21.0% ↑
- Trichomonas 276.4 million 11.2% ↑

Platforms suitable to smaller volume labs are needed to keep testing “local”
- Some level of automation is desirable
BD MAX™ System

- Small platform
- < 24 samples/controls per run
- < 15 min/run hands-on time
- ~ 4 hours per run

**Broad menu**

- BD MAX™ MRSA XT
- BD MAX™ StaphSR
- BD MAX™ CDiff
- BD MAX™ GBS
- BD MAX™ Enteric Bacterial Panel
- BD MAX™ Enteric Parasite Panel*
- BD MAX™ CT/GC*
- BD MAX™ CT/GC/TV*
- BD MAX™ GC rtPCR*
- Partner menu:
  - Diagenode™ Enteric Viral Panel*
  - Diagenode™ Respiratory FLU A/B*

*Not available for use in the US.
Study Design – Patient Samples

- 8 US Recruitment sites, 4 US BD MAX™ System testing sites
- Women
  - Urine
  - 1 self-obtained vaginal swab (SOV)
  - 2 clinician-obtained vaginal swabs (COV)
  - 3 endocervical swabs (EC)
- Men
  - Urethral swab
  - Urine
Study Design – Women

CT/GC Reference Standard (both)
- NAAT 1 EC
- NAAT 1 Urine
- NAAT 2 EC
- NAAT 2 Urine

TV Reference Standard (either)
- Wet prep
- InPouch Culture

Randomize
- Urine
  - BD MAX CT/GC/TV

Randomize
- SOV
  - BD MAX CT/GC/TV

Randomize
- Urine
  - BD MAX CT/GC/TV
  - NAAT 1 CT/GC
  - NAAT 2 CT/GC

Randomize
- COV
  - InPouch culture
- COV
  - Wet Prep

Randomize
- EC
  - NAAT 1 CT/GC
- EC
  - BD MAX CT/GC/TV
- EC
  - NAAT 2 CT/GC
Study Design – Men

CT/GC Reference Standard (2/3)
- NAAT 1 Urethral Swab
- NAAT 1 Urine (+)
- NAAT 2 Urine (+)
- NAAT 3 Urine (+)
## Results* – Chlamydia

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>(+)/n**</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal swab</td>
<td>127/1746 (7.2%)</td>
<td><strong>99.2% (95.7-99.9%)</strong></td>
<td>98.6% (98.0-99.1%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>124/1740 (7.1%)</td>
<td><strong>96.8% (92.0-98.7%)</strong></td>
<td>99.3% (98.7-99.6%)</td>
</tr>
<tr>
<td>Female Urine</td>
<td>128/1758 (7.3%)</td>
<td><strong>92.2% (86.2-95.7%)</strong></td>
<td>99.5% (99.0-99.8%)</td>
</tr>
<tr>
<td>Male Urine</td>
<td>177/803 (22.0%)</td>
<td><strong>96.6% (92.8-98.4%)</strong></td>
<td>99.5% (98.6-99.8%)</td>
</tr>
</tbody>
</table>

*Results presented represent all study sites

**Total PIS +/Total enrolled
## Results* – Gonorrhea

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>(+)/n**</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal swab</td>
<td>39/1746 (2.2%)</td>
<td><strong>94.9% (83.1-98.6%)</strong></td>
<td>99.8% (99.5-99.9%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>39/1733 (2.3%)</td>
<td><strong>94.9% (83.1-98.6%)</strong></td>
<td>99.9% (99.7-100%)</td>
</tr>
<tr>
<td>Female Urine</td>
<td>41/1758 (2.3%)</td>
<td><strong>95.1% (83.9-98.7%)</strong></td>
<td>99.7% (99.3-99.9%)</td>
</tr>
<tr>
<td>Male Urine</td>
<td>107/812 (13.2%)</td>
<td><strong>99.1% (94.9-99.8%)</strong></td>
<td>100% (99.5-100%)</td>
</tr>
</tbody>
</table>

*Results presented represent all study sites
**Total PIS +/Total enrolled
# Results* – Trichomonas

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>(+)/n**</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal swab</td>
<td>152/1048 (14.5%)</td>
<td>96.1% (91.7-98.2%)</td>
<td>98.9% (98.0-99.4%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>152/1039 (14.6%)</td>
<td>93.4% (88.3-96.4%)</td>
<td>99.3% (98.5-99.7%)</td>
</tr>
<tr>
<td>Female Urine</td>
<td>154/1047 (14.7%)</td>
<td>92.9% (87.7-96.0%)</td>
<td>99.3% (98.5-99.7%)</td>
</tr>
</tbody>
</table>

*Results presented represent all study sites
**Total PIS +/Total enrolled
## Results* – Mixed Infections

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>CT (+)/n Sensitivity</th>
<th>GC (+)/n Sensitivity</th>
<th>TV (+)/n Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal swab</td>
<td>25/26 96.2%</td>
<td>15/16 93.8%</td>
<td>18/18 100%</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>25/26 96.2%</td>
<td>16/16 100%</td>
<td>17/18 94.4%</td>
</tr>
<tr>
<td>Female Urine</td>
<td>25/27 92.6%</td>
<td>17/18 94.4%</td>
<td>17/19 89.5%</td>
</tr>
<tr>
<td>Male Urine</td>
<td>30/33 90.9%</td>
<td>33/34 97.1%</td>
<td>---</td>
</tr>
</tbody>
</table>

*Results presented represent all study sites
Summary

• Rates of treatable STI remain high
  – CT: 7% in women, 22% in men
  – GC: 2% in women, 13% in men
  – **TV: 14% in women**
  – The BD MAX™ CT/GC/TV assay is the first true multiplexed commercial assay for all 3 organisms

• Sensitivity & specificity was high for all organism across all specimen types

• The BD MAX CT/GC/TV assay performed well in the presence of mixed infections
• Combined TV with CT/GC is useful in many settings and may provide time/cost savings

• Testing locally may also save time and reduce costs and is therefore desirable in some settings
  – A platform designed for smaller volume labs can facilitate this
My collaborators

- James Williams Indiana University
- DeAnna Fuller Eskenazi Health Services
- Tom Davis Eskenazi Health Services
- Grace Daniel University of Alabama at Birmingham
- Ned Hook University of Alabama at Birmingham
- Stephanie Taylor Louisiana State University

THANKS FOR YOUR ATTENTION