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

Background
• 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

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

Study Design – Men

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 hPCR
– Partner menu
  – Diagenode™ Enteric Viral Panel
  – Diagenode™ Respiratory Flu A/R
### Study Design – Men

- Urine
  - BD MAX TM CT/GC/TV
  - Viper CTQ/GCQ
  - AC2 Urine
  - BDPT Urine

- Urethral Swab
  - Viper CTQ/GCQ

**CT/GC Reference Standard (2/3)**
- +
- +
- +

### 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>99.2% (95.7-99.9%)</td>
<td>98.6% (98.0-99.2%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>124/1740 (7.1%)</td>
<td>96.8% (92.0-98.7%)</td>
<td>99.3% (98.7-99.9%)</td>
</tr>
<tr>
<td>Female Urine</td>
<td>128/1758 (7.3%)</td>
<td>92.2% (86.2-95.7%)</td>
<td>99.5% (99.0-99.8%)</td>
</tr>
<tr>
<td>Male Urine</td>
<td>177/803 (22.0%)</td>
<td>96.6% (92.8-98.4%)</td>
<td>99.5% (98.1-99.8%)</td>
</tr>
</tbody>
</table>

### 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>94.9% (83.1-98.6%)</td>
<td>99.8% (98.0-99.9%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>39/1733 (2.3%)</td>
<td>94.9% (83.1-98.6%)</td>
<td>99.8% (98.0-99.9%)</td>
</tr>
<tr>
<td>Female Urine</td>
<td>41/1758 (2.3%)</td>
<td>95.1% (83.9-98.7%)</td>
<td>99.7% (98.0-99.9%)</td>
</tr>
<tr>
<td>Male Urine</td>
<td>107/812 (13.2%)</td>
<td>91.1% (84.9-99.8%)</td>
<td>100% (99.3-100%)</td>
</tr>
</tbody>
</table>

### 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% (98.0-99.8%)</td>
</tr>
<tr>
<td>Endocervical swab</td>
<td>152/1039 (14.6%)</td>
<td>93.4% (88.3-96.4%)</td>
<td>99.9% (99.7-100%)</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 – 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>10/18 (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 (89.3%)</td>
</tr>
<tr>
<td>Male Urine</td>
<td>30/33 (90.9%)</td>
<td>33/34 (97.1%)</td>
<td>---</td>
</tr>
</tbody>
</table>

### 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 TM 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
Application

• 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, with a broad menu, 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