Evaluation of Vaginal Swab Specimens for Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* by BDProbeTec™ ET

L. A. COSENTINO, D. V. LANDERS AND S. L. HILLIER
Magee-Womens Research Institute and The University of Pittsburgh, Pittsburgh, PA

**OBJECTIVES**

- To evaluate whether vaginal swab specimens were equivalent to cervical swabs for detection of *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) using the strand displacement amplification assay (SDA).
- To compare SDA to the polymerase chain reaction (Amplicor, Roche Diagnostics, Branchburg, NJ) for detection of CT from vaginal swab specimens and SDA to culture for detection of GC.

**INTRODUCTION**

- BDProbeTec™ ET (BD Diagnostic Systems, Sparks, MD) is based on strand displacement amplification (SDA) technology.
- SDA is an isothermal, *in vitro* nucleic acid amplification technique based upon the combined action of a DNA polymerase and a restriction enzyme.
- Vaginal swabs may be more acceptable to women than cervical specimens because no speculum exam is required for specimen collection.
- Vaginal swabs are easier to transport than liquid specimens such as urine, which has also been shown to be an acceptable specimen for SDA.

**ACKNOWLEDGMENTS:**

Funding for this study was provided by the Department of Defense DAMD 17-96-1-6298. Reagents for SDA were provided free of charge by BD.
Vaginal and cervical swabs were obtained from 455 symptomatic-women aged 18-40. 37 women were + for CT (rate = 8.1%) and 39 women were + for GC (rate = 8.6%).

**SUMMARY AND CONCLUSIONS**

- Vaginal specimens are equivalent to cervical specimens for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.
- Since vaginal specimens are equivalent to cervical specimens with respect to performance, vaginal specimens are preferred specimen type because no speculum examination is needed for specimen collection.
- Additional studies are needed to assess the level of agreement between self-collected and clinician-collected vaginal specimens for detection of STDs.
- Both vaginal and cervical swab specimens tested by BDProbeTec™ ET yielded sensitivity superior to culture for GC.
- Nearly 1 in 4 gonococcal infections would be missed using standard culture methodology.
- All culture negative, SDA positive specimens for *Neisseria gonorrhoeae* were also positive by LCR, supporting the excellent specificity of SDA.
- SDA was equivalent to PCR for the detection of CT.

**RESULTS**

Vaginal and cervical swabs were obtained from 455 symptomatic-women aged 18-40.
- 37 women were + for CT (rate = 8.1%)
- 39 women were + for GC (rate = 8.6%)

---

**DEFINITION OF TRUE POSITIVES**

*Chlamydia trachomatis*: Positive by two molecular tests. Discrepant results between SDA and PCR were resolved by ligase chain reaction (LCX, Abbott Laboratories, Chicago, IL). *Neisseria gonorrhoeae*: Positive by culture of by two molecular tests (PCR, SDA, LCR).

---

**METHODS**

Recruitment Sites:
- Allegheny County Health Department Clinic n = 321
- Student Health Clinic, University of Pittsburgh n = 24
- Primary Care Clinic, Aliquippa, PA n = 110

2 vaginal swabs

3 cervical swabs

**RESULTS**

Table 1. Performance of Strand Displacement Amplification and Polymerase Chain Reaction for Detection of *Chlamydia trachomatis* from Vaginal and Cervical Specimens

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Site</th>
<th>True Positive</th>
<th>False Positive</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDA</td>
<td>Cervix</td>
<td>34/37</td>
<td>2/418</td>
<td>91.9%</td>
<td>99.5%</td>
</tr>
<tr>
<td>SDA</td>
<td>Vag</td>
<td>34/37</td>
<td>1/718</td>
<td>91.9%</td>
<td>99.7%</td>
</tr>
<tr>
<td>PCR</td>
<td>Vag</td>
<td>33/37</td>
<td>2/418</td>
<td>89.2%</td>
<td>99.5%</td>
</tr>
</tbody>
</table>

Table 2. Performance of Culture and Strand Displacement Amplification for Detection of *Neisseria gonorrhoeae* from Vaginal and Cervical Specimens

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Site</th>
<th>True Positive</th>
<th>False Positive</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td>Cervix</td>
<td>30/39</td>
<td>0/416</td>
<td>77%</td>
<td>100%</td>
</tr>
<tr>
<td>SDA</td>
<td>Cervix</td>
<td>39/39</td>
<td>0/416</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>SDA</td>
<td>Vag</td>
<td>39/39</td>
<td>1/416</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>