Detection of Trichomonas Vaginalis in Various Transport Systems and Clinical Specimens Using Analyte Specific Reagents in a Transcription Mediated Amplification Test

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RESULTS

STUDY GROUP I

Table 1. Comparison of TV-ASR and Wet Mount M40 Amass Swab Specimens Collected from a Family Doctor’s Office

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>TV-ASR</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>Wet Mount</td>
<td>35</td>
<td>0</td>
</tr>
</tbody>
</table>

There was 100% concordance between wet-mount and TV-ASR.

STUDY GROUP II

Table 2. Comparison of Results According to Specimen Type From 174 Patients Attending a Street-Youth Clinic

<table>
<thead>
<tr>
<th>Method</th>
<th>Wet-mount</th>
<th>VS</th>
<th>LPT</th>
<th>CS</th>
<th>FCU</th>
<th>LPT, CS</th>
<th>FCU</th>
</tr>
</thead>
<tbody>
<tr>
<td>TV-ASR</td>
<td>22.9 (8/35)</td>
<td>100 (139/139)</td>
<td>100 (8/8)</td>
<td>83.7 (139/166)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALT-AMP</td>
<td>97.1 (34/35)</td>
<td>96.4 (134/139)</td>
<td>97.2 (34/36)</td>
<td>99.3 (134/135)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

STUDY GROUP III

Table 4. Comparison of Results According to Specimen Type From 15 TV Positive Patients

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Wet Mount</th>
<th>VS</th>
<th>LPT</th>
<th>CS</th>
<th>FCU</th>
<th>LPT, CS</th>
<th>FCU</th>
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<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

ENDPOINT DETERMINATION TV-ASR

1. To determine the ability of analyte specific reagents (ASR) in a transcription mediated amplification (TMA) test (Gen-Probe Inc.) to detect TV from two liquid Pap transport (LPT) media (PreservCyt and SurePath), Gen-Probe sample transport media (STM) from the Gen-Probe APTIMA Combo 2 assay and M40 Amies transport media.

2. To determine whether the routine wet-mount preparation microscopy vaginal swabs collected in the M40 Amies collection tube could be used in the APTIMA swab transport system and tested in the TV-ASR assay.

3. To determine the sensitivity and specificity of the TV-ASR assay on self-collected vaginal and FCU samples.

4. To determine the sensitivity and specificity of the TV-ASR assay on physician-collected LPT, cervical, vaginal and patient collected FCU samples.

METHODS

Endpoint Determination: a positive culture (In-Pouch TV+, BioMed Diagnostics) was grown from M40 media and also a positive TV (7 in both VS and FCU), and an additional 32 women were positive initially (24 by VS only, 7 by VS and FCU and 1 by FCU only). Testing with alternate primers confirmed 20/31 VS positives available for testing. In an additional study group of 73 women tested, 13 women were TMA positive by CS, 4 by LPT, and 3 by STM, 1 with 2, or 3 specimen types positive.

Conclusions: The Gen-Probe TV TMA-ASR is easy to use, detecting low levels of TV nucleic acids in various sample diluents. The best demonstrated versatility in detecting positive women from multiple specimen types including VS, CS, FCU and LPT.

INTRODUCTION

• On a worldwide scale, Trichomonas vaginalis (TV) is the most common sexually transmitted disease. WHO in 1999, estimated there are 174 million new cases diagnosed each year.

• Complications include premature labor, low birth weight infants, PID, ectopic pregnancy, TFI, adverse pregnancy outcome and potentially increased risk of acquisition/transmission of other STIs, particularly Chlamydia trachomatis and Neisseria gonorrhoeae.

• Although the Bethesda system recommends reporting the presence of TV, vaginal infections in the conventional Pap test, the sensitivity and specificity range from 44.7% and 83.9% respectively.

• The adaptation of the liquid Pap media for the collection/transportation of cytology samples has shown to improve the diagnosis of squamous lesions, reduce artifacts with better fixation and separation.

• Liquid Pap test (LPT) residual media has shown to be a suitable medium for molecular testing namely HPV, C. trachomatis and N. gonorrhoeae.

OBJECTIVES

1. To determine the ability of analyte specific reagents (ASR) in a transcription mediated amplification (TMA) test (Gen-Probe Inc.) to detect TV from two liquid Pap transport (LPT) media (PreservCyt and SurePath), Gen-Probe APTIMA swab transport media (STM).

2. To determine whether the routine wet-mount preparation microscopy vaginal swabs collected in the M40 Amies collection tube could be used in the APTIMA swab transport system and tested in the TV-ASR assay.

3. To determine the sensitivity and specificity of the TV-ASR assay on self-collected vaginal and FCU samples.

4. To determine the sensitivity and specificity of the TV-ASR assay on physician-collected LPT, cervical, vaginal and patient collected FCU samples.

Specimen Testing: TV-ASR Testing: TMA assay was performed using the APTIMA® General Purpose Reagent (GPR) and T. vaginalis analyte-specific reagents (TV-ASR) in the Gen-Probe Inc. as described previously (Getman et al. 2005, Schenkenwering Molecular Meeting Posters). The GPR base is a ssDNA TV (ALT-AMP) which is a Research Use Only (RUC) assay used for discordant testing which targets a different region of the ribosomal RNA (rRNA). A cut-off value of 50,000 RLU was used to define a positive TV-ASR result. A patient was considered infected if the wet-mount was positive or if two or more tests found a single specimen positive.

CONCLUSIONS

• Swab specimens collected in the M40 Amies transport collection tubes for wet mount/culture can be used for TV-ASR.

• Vaginal and cervical swabs and FCU TV-ASR detected significantly more TV infections than conventional wet-mount microscopy.

• Vaginal and cervical swabs detected significantly more TV infections than FCU testing.

• The lower sensitivity of FCU and LPT (SurePath) in the TV-ASR assay may be due to sample degradation (Shafi et al).

Further studies using an expanded gold standard determined by maximum number of test and specimen types should help determine the usefulness of TMA testing for T. vaginalis.