Trichomonas vaginalis by APTIMA® Nucleic Acid Amplification

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CLINICAL APPLICATION

The APTIMA® Trichomonas vaginalis FDA-approved assay is intended for the detection of T. vaginalis in clinician-collected endocervical and vaginal swab specimens, female urine specimens and PreservCyt® (Thin Prep) liquid Pap specimens in symptomatic or asymptomatic women. Not available on Surepath Liquid Based Cytology samples.

CLINICAL BACKGROUND

Trichomonas vaginalis is the parasite responsible for trichomoniasis, the most common curable sexually transmitted infection worldwide. Sex between women or between men and women can effectively transmit the parasite. CDC estimates there are approximately 7.4 million new cases of Trichomonas infections in the U.S. each year. The CDC sets the U.S. prevalence at 3.1%.

T. vaginalis infections can cause vaginitis, urethritis, and cervicitis. Untreated Trichomonas infections are also linked to pelvic inflammatory disease and tubal infertility. In pregnancy, complications include premature membrane rupture, low birth weight, and preterm birth. T. vaginalis infections may also increase a women risk of acquiring and transmitting HIV.

Up to 50% of women with T. vaginalis infections have minimal or no symptoms. For those who do, symptoms typically appear within 5 to 28 days of exposure. Symptoms may include vaginal discharge with strong odor, painful urination, discomfort during intercourse, and genital irritation and itching.

CLINICAL MANAGEMENT

Trichomoniasis often goes undiagnosed. Not only are infected persons often asymptomatic, but when symptoms do occur they can be generalized.

CDC recommends women who present with vaginal discharge be tested for Trichomonas and screening may be considered for women who have new or multiple sex partners, a history of STDs, injection drug use, or sex for payment.

Trichomoniasis can usually be cured with prescription antibiotics, typically either metronidazole or tinidazole, given by mouth. Both partners should be treated at the same time. Following successful treatment, people can become infected with Trichomonas again.

SELECTED REFERENCES

3. Aptima® Trichomonas vaginalis assay [package insert]. San Diego, CA; Gen-Probe, 2011
Accurate diagnosis of *Trichomoniasis* has been limited by lack of sensitive diagnostic tests. While highly specific, traditional methods used for the diagnosis of *T. vaginalis*, including wet mount, culture, and Pap smear have poor sensitivity compared to the APTIMA® *Trichomonas vaginalis* assay.

<table>
<thead>
<tr>
<th>DIAGNOSTIC METHOD</th>
<th>SENSITIVITY</th>
<th>SPECIFICITY</th>
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</thead>
<tbody>
<tr>
<td>Pap Smear</td>
<td>24%</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>Wet Mount</td>
<td>45 – 60%</td>
<td>&gt; 90%</td>
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<tr>
<td>Culture</td>
<td>75 – 90%</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>APTIMA® NAAT Assay</td>
<td>96 – 100% (Urine 88.4 - 98.1%)</td>
<td>98.9 – 99.6%</td>
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</tbody>
</table>

**TEST INFORMATION**

**CT, GC and Trichomonas by APTIMA® Nucleic Acid Amplification**

<table>
<thead>
<tr>
<th>METHOD</th>
<th>TMA by Gen-Probe APTIMA®</th>
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<tbody>
<tr>
<td>ORDER CODE</td>
<td>APTCGT</td>
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<tr>
<td>CPT CODE</td>
<td>87661, 87491, 87591</td>
</tr>
</tbody>
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**SPECIMEN REQUIREMENTS**

Female endocervical collected with APTIMA® unisex swab specimen collection kit, vaginal swab collected with APTIMA® vaginal swab collection kit, or urine, first void, not clean catch collected in the APTIMA® urine specimen transport tube. ThinPrep® liquid pap also acceptable ONLY if special APTIMA® aliquot is made prior to other testing.

**COMMENTS**

Testing is approved on female patients only. Not available on SurePath™ liquid pap vials. Trichomonas cannot be ordered as a Add-On test.