Overview

Useful For
Detection of *Trichomonas vaginalis* in female patients

Method Name
Transcription Mediated Amplification

NY State Available
Yes

Specimen

Specimen Type
Varies

Necessary Information
Specimen source is required.

Specimen Required
This test is performed only on female patients.

Submit only 1 of the following specimens:

Specimen Type: Endocervix

Supplies: Swab, Aptima Male/Female Collection (T583) (also known as APTIMA Collection Unisex Swab)

Specimen Volume: Adequate amount

Collection Instructions:

1. **Endocervix specimens must be collected** using the APTIMA Collection Unisex Swab (T583)

2. Use cleaning swab (white shaft) to remove excess mucus from endocervix and discard.

3. Insert second swab (blue shaft) 1 to 1.5 cm into endocervical canal, and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.

4. Place second swab (blue shaft) into APTIMA transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.

5. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

Specimen Stability Information: Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 180 days.

Specimen Type: Vaginal
**Test Definition: TVRNA**

Trichomonas vaginalis Amplified RNA

**Supplies:** Swab, Aptima Multitest Swab Specimen Collection Kit (T584)

**Specimen Volume:** Adequate amount

**Collection Instructions:**

1. **Vaginal specimens must be collected** using the APTIMA Multitest Swab Specimen Collection Kit (T584), formerly called Aptima Vaginal Swab Specimen Collection Kit.

2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.

3. Place swab into APTIMA transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.

4. Cap tube securely, and label tube with patient's entire name, and date and time of collection.

**Specimen Stability Information:** Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 180 days.

**Specimen Type:** Urine

**Supplies:** Aptima Urine Transport Tube (T582)

**Container/Tube:** APTIMA Urine Specimen Transport Tube (T582)

**Specimen Volume:** 15-20 mL

**Collection Instructions:**

1. Patient should not have urinated for at least 1 hour prior to specimen collection.

2. Patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.

3. Transfer 2 mL of urine into the APTIMA urine specimen transport tube using the disposable pipette provided within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the APTIMA urine transport tube. Place the labels on the transport tube so the black fill lines are still visible for volume confirmation.

**Specimen Stability Information:** Transport and store urine specimen transport tube at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 180 days.

**Specimen Type:** ThinPrep Specimen (Endocervix)

**Supplies:** Aptima Thin Prep Transport Tube (T652)

**Container/Tube:** ThinPrep (also called PreservCyt) Collection Kit

**Specimen Volume:** 1 mL
Collection Instructions:

1. Aliquot ThinPrep specimen for Trichomonas and/or Chlamydia and/or Neisseria testing before processing for Pap smear. For each specimen, use a new pair of clean gloves.

2. Vortex ThinPrep/PreservCyt vial 3 to 10 seconds. Within 1 minute of vortexing:

   A. Transfer 1 mL of specimen into the APTIMA Specimen Transfer Tube (T652) using a disposable transfer pipette or a pipette tip containing a filter (aerosol barrier or hydrophobic plug).

   B. Process only 1 ThinPrep and transfer tube set at a time.

   C. Recap APTIMA Specimen Transfer Tube tightly and gently invert 3 times to mix.

3. Label APTIMA transfer tube with appropriate label.

4. Use remainder of ThinPrep specimen for Pap testing.

Specimen Stability Information: Transport and store urine specimen transport tube at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 180 days.

Forms
If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume
The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube.

Reject Due To

<table>
<thead>
<tr>
<th>Other</th>
<th>Male patient Midstream urine specimen Overfilled or underfilled urine transport tubes Specimen collected into a SurePath device Transport tubes containing a cleaning swab or more than 1 swab</th>
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Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
<td></td>
<td>APTIMA VIAL</td>
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<td></td>
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<tr>
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Clinical and Interpretive

Clinical Information

Trichomonas vaginalis (TV) is a protozoan parasite that commonly infects the genital tract of men and women. It is now considered to be the most common curable sexually transmitted disease (STD) agent, with an estimated 3.7
millon infected individuals in the United States.(1-4) Although up to 70% of infected individuals are asymptomatic, infections may be associated with vaginitis, urethritis, and cervicitis in women, and urethritis and prostatitis in men.(3) Patients that are infected with *T. vaginalis* have an increased risk of acquiring other sexually transmitted infections such as HIV, while infections in pregnant women are associated with premature labor, low-birth-weight offspring, premature rupture of membranes, and posthysterectomy/postabortion infection.(3)

Symptoms of *T. vaginalis* overlap considerably with other sexually transmitted infections and, therefore, laboratory diagnosis is required for definitive diagnosis. The most commonly used method for detection is microscopic examination of a wet-mount preparation of vaginal secretions. However, this method has only 35% to 80% sensitivity compared with culture.(5) Culture also suffers from relatively low sensitivity (38%-82%) when compared to molecular methods.(5) Culture is also technically challenging and takes 5 to 7 days to complete. Molecular methods, such as the APTIMA *T. vaginalis* assay, offer the highest sensitivity and specificity for detection of trichomoniasis. The APTIMA test utilizes target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) technologies for detection of *T. vaginalis* ribosomal RNA (rRNA).

**Reference Values**

**Negative**

**Interpretation**

A positive result is considered indicative of current or recent *Trichomonas vaginalis* infection (trichomoniasis).

**Cautions**

The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of *Trichomonas vaginalis*.

To ensure proper endocervical sampling, excess mucus should first be removed.

Urine, vaginal swab, and PreservCyt Solution liquid Pap specimen sampling is not designed to replace cervical exams and endocervical specimens for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.

This assay has only been approved by the FDA for the specimen types indicated. Performance with other specimen types has not been evaluated by the manufacturer.

Reliable results are dependent on adequate specimen collection. Because the transport system used for this assay does not permit microscopic assessment of specimen adequacy, training of clinicians in proper specimen collection techniques is necessary.

Therapeutic failure or success cannot be determined with the APTIMA *T. vaginalis* assay since nucleic acid may persist following appropriate antimicrobial therapy.

Results from the APTIMA *T. vaginalis* assay should be interpreted in conjunction with other clinical data and symptoms.

A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, preanalytical errors, technical errors, or target levels below the assay limit of detection. Furthermore, a negative result does not preclude a possible infection because the presence of *Trichomonas tenax* or *Pentatrichomonas hominis* in a specimen may affect the ability to detect *T. vaginalis* rRNA.

Assay performance of the APTIMA *T. vaginalis* assay has not been evaluated in the presence of *Dientamoeba fragilis*. 
The APTIMA T vaginalis assay has not been validated for use with vaginal swab specimens collected by patients.

Performance of the vaginal swab specimen has not been evaluated in pregnant women or in women less than 14 years of age.

Clinical Reference


Performance

Method Description

The APTIMA Trichomonas vaginalis assay combines the technologies of target capture, transcription-mediated amplification, and hybridization protection assay for detection of 16S rRNA from T vaginalis. (Package insert: APTIMA Trichomonas vaginalis Assay, Gen-Probe Incorporated, San Diego, CA, 502246 Rev. C 8/2012)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Saturday; Varies

Analytic Time

1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
Test Definition: TVRNA
Trichomonas vaginalis Amplified RNA

- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87661

LOINC® Information

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