# Test Definition: MTRNA

T.vaginalis, Misc, Amplified RNA

## Overview

### Useful For

Detection of *Trichomonas vaginalis* in urine and male patient specimens

### Method Name

Transcription Mediated Amplification

### NY State Available

Yes

## Specimen

### Specimen Type

Varies

### Necessary Information

**Specimen source is required.**

### Specimen Required

**Submit only 1 of the following specimens:**

**Specimen Type:** Urine

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

**Container/Tube:** Aptima Urine Specimen Transport Tube

**Specimen Volume:** 15 to 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.

**Specimen Type:** Urine (following prostatic massage)

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

**Container/Tube:** Aptima Urine Specimen Transport Tube

**Specimen Volume:** 15 to 20 mL

**Collection Instructions:**

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

2. Patient should void a small amount of urine prior to prostatic massage. Pre-massage urine can be discarded or submitted for other testing as applicable.

3. Patient then ceases voiding and a prostatic massage is performed by the urologist or other health care professional.

4. Collect post-massage urine into a sterile, plastic, preservative-free container.

5. Transfer 2 mL of post-massage urine specimen 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.

**Specimen Type:** Urethral

**Supplies:** Swab, Aptima Male/Female Collection (T583)

**Container/Tube:** Aptima Collection Unisex Swab

**Specimen Volume:** Swab

**Collection Instructions:**

1. **Urethral specimens must be collected** using an Aptima Collection Unisex Swab.

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

3. With a rotating movement, insert swab (blue shaft) 2 to 4 cm into urethra.

4. Once inserted, rotate swab gently at least 1 full rotation using sufficient pressure to ensure swab comes into contact with all urethral surfaces. Allow swab to remain inserted for 2 to 3 seconds.

5. Place swab in the Aptima transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.

6. Cap tube securely and label tube with patient's entire name and collection date and time.

## Forms

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

## Specimen Minimum Volume

See Specimen Required

## Reject Due To

| | |
|---|---|
| Midstream urine specimen<br>Over-filled or under-filled urine transport tubes<br>Transport tubes containing a cleaning swab or more than 1 swab | Reject |

## Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---|---|---|---|
| Varies | Refrigerated (preferred) | 30 days | APTIMA VIAL |
| | Ambient | 30 days | APTIMA VIAL |

## 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 infection (STI) agent, with an estimated 3.7 million 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 post-hysterectomy/post-abortion infection.(3)

Symptoms of *T vaginalis* overlap considerably with other sexually transmitted infections; 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 technically challenging and takes 5 to 7 days to complete. Molecular methods, such as the Aptima *T vaginalis* assay, offer high 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

This assay is not FDA approved for urine and specimens collected from male patients. However, the performance characteristics of this test have been established by Mayo Clinic in accordance with CLIA-guidelines.

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 *Trichomonas 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, pre-analytical 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*.

### Clinical Reference

1. Weinstock H, Berman S, Cates W Jr: Sexually transmitted diseases among American youth: incidence and prevalence estimates, 2000. Perspect Sex Reprod Health. 2004 Jan-Feb;36(1):6-10

2. Soper D: Trichomoniasis: under control or undercontrolled? Am J Obstet Gynecol. 2004 Jan;190(1):281-290

3. Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Trichomoniasis-CDC Fact Sheet. Centers for Disease Control and Prevention (CDC); Reviewed February 27, 2020. Accessed September 10, 2020. Available at www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm

4. Schwebke JR, Burgess D: Trichomoniasis. Clin Microbiol Rev. 2004 Oct;17(4):794-803

5. Wendel KA, Erbelding EJ, Gaydos CA, Rompalo AM: Trichomonas vaginalis polymerase chain reaction compared with standard diagnostic and therapeutic protocols for detection and treatment of vaginal trichomoniasis. Clin Infect Dis. 2002 Sep;35(5):576-580

## Performance

### Method Description

The APTIMA *Trichomonas vaginalis* Assay combines the technologies of target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) for detection of 16S rRNA from *T vaginalis*.(Package insert: Aptima *Trichomonas vaginalis* Assay. 503684 Hologic, Inc; Rev. 004 09/2018)

### PDF Report

No

### Day(s) Performed

Monday through Saturday

### Report Available

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

## Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

## CPT Code Information

87661

## LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---|---|---|
| MTRNA | T.vaginalis, Misc, Amplified RNA | 46154-1 |

| Result ID | Test Result Name | Result LOINC Value |
|---|---|---|
| SRC6 | SOURCE: | 31208-2 |
| 35034 | T.vaginalis, Misc, amplified RNA | 46154-1 |