Test Definition: MTRNA

T.vaginalis, Misc, Amplified RNA

Overview

Useful For

Detection of *Trichomonas vaginalis* in male 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 male patients.

Submit only 1 of the following specimens:

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.

Specimen Type: Urine (following prostatic massage)

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 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 (T583)

Specimen Volume: Swab

Collection Instructions:

1. **Urethral specimens must be collected** using an APTIMA Collection Unisex Swab (T583)..

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 date and time of collection.

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

Other	Female patient Midstream urine specimen Over-filled or under-filled urine transport tubes Transport tubes containing a cleaning swab or more than 1 swab

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 disease (STD) 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, 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 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 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;36(1):6-10

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

3. Centers for Disease Control and Prevention (CDC) Trichomoniasis-CDC Fact Sheet. Available at http://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm Accessed August 2012

4. Schwebke JR, Burgess D: Trichomoniasis. Clin Microbiol Rev 2004;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;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, Gen-Probe Incorporated, San Diego, CA, 502246 Rev. B 2011-05)

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.
- 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 U.S. 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