MAYO CLINIC LABORATORIES

Test Definition: MTRNA

Trichomonas vaginalis, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Trichomonas vaginalis* in prosthetic massage (VBIII) fluid or male urethral swabs

Method Name

Transcription-Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

This test should only be performed in men.

Submit only 1 of the following specimens:

Specimen Type: Post-prostatic massage fluid (VBIII)
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 fluid into a sterile, plastic, preservative-free container.
5. Transfer 2 mL of post-massage fluid specimen into the Aptima urine specimen transport tube using the disposable pipette provided within 24 hours of collection. The correct volume of fluid has been added when the fluid level is between the black fill lines on the Aptima urine transport tube.

Specimen Type: Urethral (male only)
Supplies: Aptima Unisex Swab Collection Kit (T583)

Container/Tube: Aptima Unisex Swab
Specimen Volume: Swab
Collection Instructions:
1. **Urethral specimens must be collected** using an Aptima Unisex Swab Collection kit.
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

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 & Interpretive

Clinical Information
Trichomonas vaginalis is a protozoan parasite that commonly infects the genital tract of men and women. It is considered to be the most common nonviral sexually transmitted infection (STI), with an estimated 2.6 million cases documented in 2020 in the United States. 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. Patients that are infected with *T vaginalis* have an increased risk of acquiring other STIs 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.

Symptoms of *T vaginalis* overlap considerably with other STIs; therefore, laboratory diagnosis is required for definitive diagnosis. The most frequently 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. Culture also suffers from relatively low sensitivity (38%-82%) when compared to molecular methods. 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, and hybridization protection assay technologies for detection of *T vaginalis* ribosomal RNA.

Reference Values

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Trichomonas vaginalis* and is strongly supportive of a diagnosis of trichomoniasis.

A negative result indicates the absence of nucleic acid from *T vaginalis*.

A negative result does not exclude the possibility of infection. If clinical indications strongly suggest gonococcal or chlamydial infection, additional specimens should be collected for testing.

A result of inconclusive indicates that a new specimen should be collected.

The predictive value of an assay depends on the prevalence of the disease in any specific population. In settings with a high prevalence of sexually transmitted infections, positive assay results have a high likelihood of being true-positive results. In settings with a low prevalence of sexually transmitted infections or in any setting in which a patient's clinical signs and symptoms or risk factors are inconsistent with infection, positive results should be carefully assessed, and the patient retested by other methods if appropriate.

Cautions

This assay is not US Food and Drug Administration approved for prosthetic massage (VBIII) fluid or male urethral samples. 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* RNA.

Assay performance of the APTIMA *T vaginalis* assay has not been evaluated in the presence of *Dientamoeba fragilis*.

Clinical Reference

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187
2. Andrea SB, Chapin KC. Comparison of Aptima *Trichomonas vaginalis* transcription-mediated amplification assay and BD Affirm VPIII for detection of *T. vaginalis* in symptomatic women: Performance parameters and epidemiological implications. J Clin Microbiol. 2011;49(3):866-869. doi:10.1128/JCM.02367-10
3. Chernesky M, Jang D, Gilchrist J, et al. Ease and comfort of cervical and vaginal sampling for Chlamydia trachomatis and Trichomonas vaginalis with a new Aptima specimen collection and transportation kit. J Clin Microbiol. 2014;52(2):668-670. doi:10.1128/JCM.02923-13

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 ribosomal RNA from *T vaginalis*.(Package insert: Aptima *Trichomonas vaginalis* Assay. Hologic, Inc; Rev. 003, 06/2023

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

1 to 4 days

Specimen Retention Time

14 days

Performing Laboratory Location

Jacksonville

Fees & 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 account representative. 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