Test Definition: TVRNA

Trichomonas vaginalis, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Trichomonas vaginalis* in urine, cervical/endocervical or vaginal specimen types

This test is **not intended for use** in medico-legal applications.

Method Name

Transcription-Mediated Amplification

NY State Available

No

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Endocervix/Cervix
Supplies: Aptima Unisex Swab Collection Kit (T583)
Container/Tube: Aptima Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. **Specimens must be collected using the Aptima Unisex Swab Collection Kit**.
2. Use cleaning swab (white shaft) to remove excess mucus from endocervix/cervix.
Discard the cleaning swab.
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 blue swab into Aptima transport tube provided in collection kit.
5. Snap off blue swab at score line so it fits into closed tube.
7. Cap tube securely and label tube with patient's entire name and collection date and time.
8. Maintain swab container at 2 to 30 degrees C (refrigerate temperature is preferred), transport within 60 days of collection.

Specimen Type: Vaginal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. **Specimens must be collected using the Aptima Multitest Swab Collection Kit**.
2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
3. Place pink swab into Aptima transport tube provided in collection kit.
4. Snap off pink swab at score line so it fits into closed tube.
5. Cap tube securely and label tube with patient's entire name and collection date and time.
6. Maintain swab container at 2 to 30 degrees C (refrigerate temperature is preferred), transport within 60 days of collection.

Specimen Type: ThinPrep Specimen (Endocervix/Cervix)
Supplies: Aptima Specimen Transfer Kit (T652)
Container/Tube: Aptima specimen transfer tube
Specimen Volume: 1 mL
Collection Instructions:
1. Collect ThinPrep sample as per normal collection process.
2. **ThinPrep specimen must be aliquoted (as outlined below) before it is processed/tested for Papanicolaou testing (Pap smear)**.
3. Vortex ThinPrep/PreservCyt vial 3 to 10 seconds.
4. Within 1 minute of vortexing:
a. Transfer 1 mL of specimen into the Aptima specimen transfer tube 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.
4. Label Aptima transfer tube with appropriate label.
5. Use remainder of ThinPrep specimen for Pap testing.
6. Maintain specimen transport tube at 2 to 30 degrees C (refrigerate temperature is preferred), transport within 30 days of collection when stored at 2 to 14 degrees C or within 14 days when stored at 15 to 30 degrees C.

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. Within 24 hours of collection, transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the Aptima urine transport tube.
4. Maintain Aptima urine specimen transport tube at 2 to 30 degrees C (refrigerate temperature is preferred), transport

within 30 days of collection.

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	Reject
Clean catch urine specimen	Reject
Over-filled or under-filled urine transport tubes	Reject
Specimen collected into a SurePath device	Reject
Transport tubes containing a cleaning swab or more than 1 swab	Reject
Multiple sources on single tube	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)		APTIMA VIAL
	Ambient		APTIMA VIAL
	Frozen	180 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

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.

Vaginal swab and PreservCyt Solution liquid Papanicolaou (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 US Food and Drug Administration 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 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* RNA.

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 girls younger than 14 years.

This report is intended for clinical monitoring or management of patients; it is not intended for use in medico-legal applications.

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):866-9. 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):668-70. 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
Mayo Clinic Jacksonville Clinical Lab

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 cleared, approved, or is exempt by the US 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

Test ID	Test Order Name	Order LOINC® Value
TVRNA	Trichomonas vaginalis Amplified RNA	46154-1

Result ID	Test Result Name	Result LOINC® Value
34810	Trichomonas vaginalis amplified RNA	46154-1
SRC29	SOURCE:	31208-2