Test Definition: TVRNA

Trichomonas vaginalis Amplified RNA

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.

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 collection date and time.

6. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection.

Specimen Type: Vaginal

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, 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 collection date and time.

5. Transport and store swab container at 2 to 30 degrees C (refrigerate is preferred temperature) within 60 days of collection.

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* 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 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.

5. Transport and store specimen transport tube at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection.

Forms

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

Reject Due To

Male patient	Reject
Urine specimen	
Specimen collected into a SurePath device	
Transport tubes containing a cleaning swab or more than 1 swab	

Specimen Minimum Volume

See Specimen Required

Specimen Stability Information

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

Clinical & 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 posthysterectomy/postabortion 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 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.

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

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. 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;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, and hybridization protection assay for detection of 16S rRNA from *T vaginalis*.(Package insert: APTIMA *Trichomonas vaginalis* Assay. 503684 Hologic, Inc; Rev. 004 09/2018)

PDF Report

No

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees & Codes

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	Reporting Name	LOINC®
34810	Trichomonas vaginalis amplified RNA	46154-1
SRC29	SOURCE:	31208-2