
Lab Dept: Microbiology/Virology

Test Name: TRICHOMONAS VAGINALIS AMPLIFIED RNA ASSAY (FEMALES)

General Information

Lab Order Codes: TVRNA

Synonyms: Trichomonas vaginalis by Nucleic Acid Amplification (Gen-Probe);
Trichomonas rRNA

CPT Codes: 87661 – Trichomonas vaginalis, amplified probe technique

Test Includes: Target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) for the detection of 16S rRNA from *Trichomonas vaginalis*.

Logistics

Test Indications: *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. Although up to 70% of infected individuals are asymptomatic, infections may be associated with vaginitis, urethritis, and cervicitis in women, and urethritis in men. Patients that are infected with *Trichomonas 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.

Symptoms of *Trichomonas 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 35-85% sensitivity compared with culture. Culture also suffers from relatively low sensitivity (38-82%) when compared to molecular methods. Culture is also technically challenging and takes 5-7 days to complete. Molecular methods offer the highest sensitivity and specificity for detection of trichomoniasis.

Lab Testing Sections: Virology - Sendouts

Referred to: Mayo Medical Laboratories (MML Test#: TVRNA)

Phone Numbers: MIN Lab: 612-813-5806

STP Lab: 651-220-6555

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 3 days, performed daily

- Special Instructions:**
- This test is approved for endocervical swabs, vaginal swabs, and urine utilizing special collection kits.
 - **Obtain special collection supplies based on type of specimen to be collected. Supplies are available through Materials Management.**
 - For urine specimens: Patient should not have urinated for at least 1 hour prior to specimen collection. The first portion of voided urine is used because it has the highest concentration of organisms, midstream urine is unacceptable.
 - **Specimen site and date/time of collection** are required for processing.
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Specimen

Specimen Type: Endocervical swabs, vaginal swabs, the first portion of voided urine specimens


Container:

Obtain one of the following (stocked on patient units):

Endocervix (Females)

Supply T583 – Aptima Unisex swab specimen collection system



Vaginal (Females)	<p>Supply T584 – Aptima Vaginal swab specimen collection system</p> 
Urine	Collect in standard sterile screw-cap urine cup.

Volume: 15 - 20 mL of urine or 1 swab based on supply kit for specimen type

Collection:

Endocervical swab (Female) specimens – Supply T583:

- Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft). Discard this Swab.
- Insert the specimen collection swab (blue shaft) 1 to 1.5 cm into the endocervical canal.
- Gently rotate the swab clockwise for 30 seconds in the endocervical canal to ensure adequate sampling.
- Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
- Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
- Re-cap the swab specimen transport tube tightly.
- Label tube with patient identifiers, specimen type and date and time of collection.

Vaginal Swab specimens – Supply T584:

- Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
- Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
- Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
- Re-cap the swab specimen transport tube tightly.
- Label tube with patient identifiers, specimen type and date and time of collection.

Urine specimens – Screw-capped urine cup:

- The patient should not have urinated for at least one hour prior to sampling.
- Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup. Minimum amount is 2 mL urine. Collection of larger volumes of urine may reduce test sensitivity.

Female patients should not cleanse the labial area prior to providing the specimen.

c. Label the urine sample with patient identifiers and date and time of collection.

d. Send sample to the laboratory.

Transport/Storage:

Transport swabs at 2-27°C to the Laboratory. Once in the lab, refrigerate swab and forward to Mayo.

Transport urine at 2-8°C to the Laboratory for processing.

Special Processing:

Lab staff:



Urine specimens – Supply T582:

a. Transfer 2 mL of urine into the urine specimen transport tube from Supply T582 using the disposable pipette provided within 24 hours of collection. The correct volume has been added when the fluid level is between the black fill lines on the urine transport tube.

b. Label with patient identifiers and date and time of collection.

c. Store at refrigerated temperatures.

d. Forward to Mayo for testing.

Endocervical and Vaginal swab specimens: Store at refrigerated temperatures and forward to Mayo for testing.

Sample Rejection:

Specimen not submitted in appropriate transport container; improperly labeled specimen; midstream urine; insufficient volume; external contamination. If an unacceptable specimen is received, the physician or nursing station will be notified and another specimen requested before the specimen is discarded.

Interpretive

Reference Range:

Negative for *Trichomonas vaginalis*

Interpretation: A positive result is considered indicative of current or recent *Trichomonas vaginalis* infection.

Limitations:

- 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 be removed first.
- Urine and vaginal swab 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 *Trichomonas vaginalis* assay since nucleic acid may persist following appropriate antimicrobial therapy.
- Results from the APTIMA *Trichomonas 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 *Trichomonas vaginalis* rRNA.
- Assay performance of the APTIMA *Trichomonas vaginalis* assay has not been evaluated in the presence of *Dientamoeba fragilis*.
- The APTIMA *Trichomonas vaginalis* assay has not been validated for the use with vaginal swab specimens collected by patients.
- Performance of the vaginal swab specimen has not been evaluated in pregnant women or in women <14 years of age.

Methodology:

Transcription Mediated Amplification (Gen-Probe)

References:

[Mayo Medical Laboratories](#) January 2018