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**Lab Dept:** Microbiology/Virology

**Test Name:** TRICHOMONAS VAGINALIS AMPLIFIED RNA ASSAY (MALES)

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**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*.

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**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#: MTRNA)

**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 urethral 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:** Urethral swabs, the first portion of voided urine specimens

**Container:**

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

Urethra (Males)

Supply T583 – Aptima Unisex swab specimen collection system



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:**

**Urethral swab (Male) specimens – Supply T583:**

- a. Patient should not have urinated for at least 1 hour prior to collection.
- b. With rotating movement, insert swab (blue shaft) 2 to 4 cm into urethra.
- c. Once inserted, rotate swab gently at least 1 full rotation using sufficient pressure to ensure swab comes in contact with all urethral surfaces. Allow swab to remain inserted 2-3 seconds.
- d. Place the swab in the APTIMA transport tube provided in collection kit.

Snap off swab at score line so swab fits into closed tube.

**e.** Cap tube securely, and label tube with patient's entire name, and date and time of collection.

**Urine specimens – Screw-capped urine cup:**

**a.** The patient should not have urinated for at least one hour prior to sampling.

**b.** 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.

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

**d.** Send sample to the laboratory.

**Urine specimens (following prostatic massage) – Screw-capped urine cup:**

**a.** The patient should not have urinated for at least one hour prior to sampling.

**b.** 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.

**c.** Patient then ceases voiding and a prostatic massage is performed by the urologist or other health care professional.

**d.** Collect post-massage urine into a urine collection cup.

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

**f.** 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.

**Urethral 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.

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**Interpretive**

**Reference Range:**

Negative for *Trichomonas vaginalis*

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

**Limitations:**

- 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*.

**Methodology:**

Transcription Mediated Amplification (Gen-Probe)

**References:**

[Mayo Medical Laboratories](#) August 2015