GENETRACK Diagnostics

Trichomoniasis

WHAT IS TRICHOMONIASIS?

Trichomoniasis is a common sexually transmitted disease (STD) caused by infection with a protozoan parasite called *Trichomonas vaginalis*. Trichomoniasis is transmitted through sexual contact with the penis or vagina of an infected individual.

T. vaginalis is an anaerobic, flagellated protozoan parasite, and is the most common pathogenic protozoan infection of humans in industrialized countries. Although it does not have a cyst form, but can still survive for up to 24 hours in urine, semen, or even water samples (1).

SYMPTOMS

Most individuals infected with trichomoniasis remain asymptomatic, with only approximately 30% of infected individuals showing symptoms (2). However, asymptomatic individuals can still pass the infection on to any sexual partners. The severity of symptoms can vary significantly, ranging from just mild irritation to severe inflammation. The onset of symptoms also varies, with some individuals showing symptoms 5 to 28 days post-exposure, while symptoms occur in others much later, or symptoms may disappear then reappear (2).

Symptomatic males may experience itching or irritation inside the penis, painful burning sensation after urination or ejaculation, increased urination, and abnormal discharge from the penis (3). Symptoms in females include itching and irritation of the vagina, painful and more frequent urination, endocervical bleeding, and abnormal vaginal discharge with an unpleasant odour (2,3).

Trichomoniasis infections can cause discomfort during sexual intercourse, and are associated with an increased risk of contracting other STDs, including a two to three-fold increased risk of HIV (2,4).

Trichomoniasis during pregnancy also increases the risk of premature rupture of membranes, preterm delivery, and low birth weight (4), and is associated with an increased risk of the transmission of HIV from an HIV-positive mother to her child (5).

PREVALENCE

Any sexually active individual is at risk of trichomoniasis. There are estimated to be 3.7 million infected individuals in the United States (3), with higher rates among females aged 14-59 years (2.1%) compared to males (0.5%) (4,6). Trichomoniasis prevalence is significantly higher among African American females (9.6-13%), compared to Hispanic (1.4%) and non-Hispanic white females (0.8-1.8%) (6,7).

Factors that are associated with a higher prevalence of trichomoniasis infection in the United States include increased poverty level, lower educational level, and unmarried status (4). There is also a particularly high prevalence among STD clinic patients (26% of symptomatic women and 6.5% asymptomatic women tested) (8).

DIAGNOSIS

Traditional culture methods for the detection of *T. vaginalis* are technically challenging and require up to 7 days. “Wet-mount” preparations have also previously been used but can have low sensitivity. Nowadays, trichomoniasis is diagnosed with nucleic acid amplification testing (NAAT) to provide the most sensitivity and specificity.

TREATMENT

Prescription antibiotics are an effective treatment for trichomoniasis. However, reinfection is common through sexual contact with an infected partner; hence treatment of all sexual partners should occur at the same time. Abstaining from sexual contact for 7 to 10 days after the completion of the antibiotic course and all symptoms have ceased is important to prevent passing the infection to any sexual partners.

Retesting is recommended for all sexually active females within three months of treatment (4). Condom use reduces, but does not eliminate, the risk of trichomoniasis (9). Douching is not recommended as it can increase the risk of vaginal infections, including trichomoniasis (10).

TESTING RECOMMENDATIONS

Diagnostic testing for trichomoniasis should be performed in females with abnormal vaginal discharge. It should also be considered in patients receiving care in high-prevalence settings (e.g. STD clinics and correctional institutions) and in individuals with a high risk of infection (e.g. multiple sex partners, history of STD) (4).

Routine screening in HIV-positive females is recommended, due to the increased risk of pelvic inflammatory disease (PID) associated with trichomoniasis infection in HIV-positive females (11). Furthermore, the effective treatment of trichomoniasis in HIV-positive individuals significantly reduces genital tract HIV viral load and viral shedding (12).

TEST PROCEDURE

Correct specimen collection and handling is required for optimal assay performance.

This test requires a first-void urine specimen collected at least 1 hour after previous urination. All supplies for sample collection are provided in this kit.

Collect 20-30 mL of first-void urine in the sterile urine collection container and transfer 2 mL to the urine specimen transport container using the disposable pipette provided. Transfer to the urine transport container must occur within 24 hours of collection, and liquid level must fall between the two black indicator lines on the tube label. Re-cap the urine transport container tightly. Seal in the transport bag and return to the laboratory in the provided prepaid return shipping envelope.

Maintain specimen at temperatures between 2°C and 30°C during storage and transport.

Upon receipt at the laboratory, the urine sample is analyzed by a fully automated nucleic acid amplification testing procedure. *T. vaginalis* rRNA is detected using nucleic acid hybridization, where single-stranded chemiluminescent DNA probes are combined with the rRNA amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer.

SPECIAL INSTRUCTIONS

- Repeat urine collection (at least 1 hour after previous urination) if more than 60ml of first-void urine is collected.
- Females should not clean the labial area prior to urine collection.
- Do not apply the transport medium directly to skin or mucous membranes or take internally.

TEST INTERPRETATION

- A positive result indicates that *T. vaginalis* nucleic acid (rRNA) is present in the specimen tested and strongly supports a trichomoniasis diagnosis.

- A negative result indicates that *T. vaginalis* nucleic acid (rRNA) was not detected in the specimen tested.

- An indeterminate result indicates that a new specimen should be tested.

DISCLAIMERS/LIMITATIONS

This report is not intended for use in medico-legal applications. These results are intended for screening and monitoring for trichomoniasis and should be interpreted in conjunction with other laboratory and clinical information.

Correct specimen collection and handling is required for optimal assay performance. Blood, lubricants, and spermicides are not expected to cause interference in this assay.

The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of *T. vaginalis*.

A negative result does not exclude the possibility of infection. False-negative test results may occur due to improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or organism levels below the sensitivity of this assay. The presence of *Trichomonas tenax* or *Pentatrichomonas hominis* in a specimen may also affect the ability to detect *T. vaginalis* rRNA.

False-positive results are rare, but may be more frequent in low-prevalence populations. A false-positive result may also occur directly after successful antimicrobial therapy, as *T. vaginalis* nucleic acids may persist for 3 weeks or more.

The performance of this assay has not been evaluated in adolescents less than 14 years of age.

REFERENCES

(1) Soper D (2004). "Trichomoniasis: under control or undercontrolled?" *Am J Obstet Gynecol.* 190 (1), 281–90.

(2) Trichomoniasis Fact Sheet. *CDC.* [Online] February 2020.

(3) Satterwhite CL, et al. (2013). Sexually transmitted infections among US women and men: Prevalence and incidence estimates, 2008. *Sex Transm Dis,* 40 (3), 187-193.

(4) 2015 Sexually Transmitted Diseases Treatment Guidelines, Trichomoniasis. *CDC.* [Online] June 4, 2015.

(5) Gumbo FZ, et al. (2010) Risk factors of HIV vertical transmission in a cohort of women under a PMTCT program at three peri-urban clinics in a resource-poor setting. *J Perinatol,* 67 (2), 717-723.

(6) Patel EU, et al. (2018) Prevalence and Correlates of Trichomonas vaginalis Infection Among Men and Women in the United States. *Clin Infect Dis,* 67 (2), 211-217.

(7) Trichomoniasis Statistics. *CDC.* [Online] February 27, 2020.

(8) Flagg EW, et al. (2019) Prevalence of Trichomonas vaginalis Among Civilian, Noninstitutionalized Male and Female Population Aged 14 to 59 Years: United States, 2013 to 2016. *Sex Transm Dis,* 46 (10), e93-e96.

(9) Crosby R, et al. (2012) Condom Effectiveness against Non-Viral Sexually Transmitted Infections: A Prospective Study Using Electronic Daily Diaries. *Sex Transm Infect,* 88 (7), 484-489.

(10) Tsai CS, Shepherd BE & Vermund SH. (2009) Does Douching Increase Risk for Sexually Transmitted Infections? A Prospective Study in High-Risk Adolescents. *Am J Obstet Gynecol,* 200 (1), 38.e1-e8.e8.

(11) Moodley P, et al. (2002) Trichomonas vaginalis is associated with pelvic inflammatory disease in women infected with human immunodeficiency virus. *Clin Infect Dis,* 34 (4), 519-522.

(12) Anderson BL, et al. (2012) Effect of trichomoniasis therapy on genital HIV viral burden among African women. *Sex Trans Dis,* 39 (8), 638-642.