

TRICH *Trichomonas vaginalis* DNA by PCR - Qualitative

GA Test Code	101 <i>Note:</i> For comprehensive STD testing, GA recommends ordering Test #501 STD Panel by PCR (CT/NG, HSV-1&2, <i>Trichomonas vaginalis</i>).
Method	Real-Time Polymerase Chain Reaction (rPCR) – Qualitative
Specimens	ThinPrep: 2.0 mL (1.0 mL), store and ship ambient (up to 3 months). SurePath: 1.0 mL (0.5 mL), store and ship ambient (14 days). eSwab® Collect cervical, vaginal or urethral specimen with swab and place in tube with liquid media. Break-off swab (pre-scored) and seal tube for transport. Sample is stable for 90 days at room temperature (15-30°C). eSwab® - Urine: G Swab kits include a urine collection pipette. Use pipette to add 1.0 mL only of first catch urine to red fill line on media tube. Sample is stable for 90 days at room temperature (15-30°C). Swab: from any site, place in 1-2 mL viral transport medium, store/ship ambient or refrigerated (14 days). If longer storage is needed, store frozen (90 days). Urine: 10.0 mL (5.0 mL). Collect first-catch (not mid-stream) urine in sterile, leakproof container. The patient should not have urinated for 2 hours prior to collection. Immediately refrigerate urine and ship within 24 hours on cold pack. <i>Note:</i> The presence of blood, mucus, some spermicidal agents, feminine powder sprays, and treatments for vaginal conditions such as yeast infection may interfere with nucleic acid test based assays.
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed.
Reference Range	Not Detected
Turnaround Time	24-48 hours
CPT Code	87661

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing. This assay involves testing by real-time polymerase chain reaction (rPCR) amplification and detection of *Trichomonas vaginalis* DNA.

Clinical Utility

Trichomonas vaginalis (TV) is a protozoan parasite and an etiological agent for trichomoniasis, a sexually transmitted infection (STI). It is the most prevalent STI and often goes untreated as a significant percentage ($\geq 50\%$) of men and women are asymptomatic. TV infections left untreated can cause cervicitis, vaginitis, pelvic inflammatory disease, pre-term delivery, urethritis and infertility. Infected individuals are at a higher risk of contracting other STIs, especially HIV. The prevalence of TV increases with age and is most common in women ages 35-45.

<http://www.cdc.gov/std/trichomonas/STDFact-Trichomoniasis.htm>.

Hardick A, Hardick J, Wood BJ, et al. Comparison between the Gen-Probe transcription-mediated amplification *Trichomonas vaginalis* research assay and real-time PCR for *Trichomonas vaginalis* detection using a Roche LightCycler instrument with female self-obtained vaginal swab samples and male urine samples. J Clin Microbiol. 2006;44:4197-4199.

Genetic Assays, Inc.