GENETIC ASSAYS
A Molecular Diagnostics Laboratory

STD3 STD3 Panel by PCR - Qualitative (CT/NG and *Trichomonas vaginalis*)

GA Test Code	**301**
Method	Real-Time Polymerase Chain Reaction (rPCR) – Qualitative
Specimens	**ThinPrep**: 4.0 mL (2.0 mL), store and ship ambient (up to 3 months). **SurePath**: 2.0 mL (1.0 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 30 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 30 days at room temperature (15-30°C). **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. *Note*: 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	***Chlamydia trachomatis*** Not Detected ***Neisseria gonorrhoeae*** Not Detected ***Trichomonas vaginalis*** Not Detected
Turnaround Time	24-48 hours
CPT Code	***Chlamydia trachomatis*** 87491 ***Neisseria gonorrhoeae*** 87591 ***Trichomonas vaginalis*** 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 the simultaneous and multiplex amplification and detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA by real-time polymerase chain reaction (rPCR).

Clinical Utility

A positive PCR result for any 1 of the specific targets indicates the presence of the respective organism in the specimen. A negative result indicates the absence of detectable DNA in the specimen, but does not rule out infection with these or other enteric pathogens. False-negative results may occur due to inhibition of PCR (known inhibition rate of <1%).

Sexually transmitted diseases treatment guidelines, 2010. *MMWR*, December 17, 2010/Vol. 59/No. RR-12, 44-55.

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

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