STD5 — STD5 Panel by PCR - Qualitative (CT/NG, HSV-1&2, and *Trichomonas vaginalis*)

GA Test Code	**501**
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). *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
	HSV-1	Not Detected
	HSV-2	Not Detected
	Trichomonas vaginalis	Not Detected
Turnaround Time	24-48 hours	
CPT Code	***Chlamydia trachomatis***	87491
	Neisseria gonorrhoeae	87591
	HSV-1	87529
	HSV-2	87529
	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*, Herpes Simplex Virus 1&2, 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.