



HSV

HSV-1&2 DNA by PCR - Qualitative

GA Test Code	900
Method	Real-Time Polymerase Chain Reaction (rPCR) – Qualitative
Specimens	CSF, Serum: 1.0 mL (0.25 mL), refrigerated (7 days) or frozen (90 days). eSwab® Collect vaginal 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). 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). Swab: from any site, place in 1-2 mL viral transport medium, store and ship ambient or refrigerated (14 days). For longer storage, keep frozen (90 days). Whole Blood (EDTA or ACD): 5.0 mL (3.0 mL), ambient (4 days) or refrigerated (7 days). Fresh Tissue: 0.2 g (0.1 g), place in viral transport medium, store and ship ambient or refrigerated (up to 14 days).
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; whole blood in heparin.
Reference Range	HSV-1: Not Detected; HSV-2: Not Detected
Turnaround Time	Same or Next Day
CPT Codes	87529 (x 2)

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 uses real-time PCR to detect and differentiate between Herpes Simplex Virus (HSV) types 1 and 2. HSV-1 infections usually involve non-genital areas and HSV-2 infections are primarily found in genital areas, but there is overlap between the two types. The clinical courses of acute first-episode genital herpes among patients with HSV-1 and HSV-2 infections are similar and both can cause symptomatic or asymptomatic rectal and perianal infections. HSV infections may be unapparent because symptoms do not always follow a typical pattern or patients may be asymptomatic.

Clinical Utility

HSV DNA has been detected by PCR in asymptomatic patients on 28% of days tested vs. 8.1% by culture isolation. More importantly, on days when asymptomatic shedding of HSV DNA was detected by PCR, culture was positive just 60% of the time. Patients with ulcerative lesions had positive PCR results on 15 of 17 days (88.2%) versus positive cultures on 3 of 17 days (17.6%). Both immunologic analysis and culture isolation of HSV from cerebrospinal fluid (CSF) lack sensitivity/specificity and do not yield results quickly. PCR offers a rapid and sensitive way to test for HSV infections in CSF and has become the standard of care for patients with suspected CNS infection. Studies have shown the HSV PCR sensitivity to be from 75% to 100% with a specificity of 100%. In conclusion, the detection of HSV DNA by PCR has been proven to be the most specific, rapid, and sensitive means to diagnose anogenital and CNS infections.

Marchant J, Roe A. Genital herpes: recognizing and addressing patients' needs. *Herpes J* 1997; 4:36-41.

Wald A. Subclinical shedding of herpes simplex virus in the genital tract: implications from transmission. *Herpes J* 1997; 4:30-35.

Cone RW, et al. Extended duration of HSV DNA in genital lesions detected by the polymerase chain reaction. *J Infect Dis* 1991 Oct; 164(4): 757-60.

Guffond T, et al. Significance and clinical relevance of the detection of HSV by PCR in CSF from patients with presumed encephalitis. *Clin Infect Dis* 1994 May; 18(5): 744-9.

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