Herpes Simplex Viruses (HSV-1 & HSV-2)

DNA Detection by RT-PCR

WOMEN'S HEALTH

Pathology, Inc.

Welcome to Excellence

OVERVIEW

Herpes simplex viruses (HSV) can cause superficial and systemic infections. Infection sites may include the skin, lips, oral cavity, eyes, genital tract, and central nervous system. Severity of infection can range from mild to severe.[1] In the newborn, infection with HSV-1 or -2 can be life threatening, particularly when it affects the central nervous system or becomes disseminated.[2]

HSV-1 and HSV-2 are distinct types but often overlap in clinical presentation. HSV-1 is primarily related to the development of ocular and oral infections, whereas, HSV-2 is the primary cause of genital herpes. According to the Centers for Disease Control (CDC), the prevalence of Herpes infection in people ages 12 and older is at least 45 million.[3] Genital HSV-2 affects approximately 1:4 women and 1:8 men.[3] It is estimated that 1.6 million new HSV-2 infections occur each year in the United States.[4]

Most people infected with HSV-2 are unaware of their infection or may have mild symptoms that they mistake for other skin conditions. Genital HSV can cause recurrent painful genital sores in many adults and can be severe in people with compromised immune systems. Genital HSV can also lead to potentially fatal infections in newborns when the mother develops an infection during pregnancy. About 2% of women acquire genital HSV during pregnancy.[2] The risk of infecting a baby is 30 to 50% when a woman is newly infected late in pregnancy.[5] ACOG guidelines for pregnant women recommend 1) the offering of suppressive viral therapy at or beyond 36 weeks of gestation in women who have active recurrent disease, and 2) cesarean delivery in women with active disease or prodromal symptoms which may preclude an impending outbreak.[2]

TESTING FOR HSV INFECTION

Traditionally, laboratory diagnosis of HSV infection has relied on viral cell culture, serological testing, or antigen testing. In primary infection, viral cultures can be insensitive and have a false-negative rate of 25%.[1] With recurrent disease, the rate of viral isolation is less than 50%.[1] False-negative rates can also be attributed to quality of specimen, transport conditions, or bacterial growth.

Serology testing will not indicate the site or stage of infection nor will it differentiate between a current or past infection. False-negative results can occur if testing is performed too early.[1,6] Antigen detection tests are comparable in performance to viral culture, but do not distinguish between HSV-1 and HSV-2 infection.[6]

Traditional technologies are being replaced with highly sensitive and specific real-time polymerase chain reaction (RT-PCR)-based assays, which can detect the virus even during low viral shedding. A comparison study between PCR and viral culture in HSV-infected patients demonstrated positivity by PCR to be between 4 to 8 times that of viral culture.[7] The range of sensitivity and specificity of PCR detection for HSV DNA has been shown to be between 98 to 100%.[8] PCR detection is higher in early as well as late stages of infection and in both first and recurrent episodes.[9] PCR can distinguish HSV-1 from HSV-2 and provides faster turnaround time than viral cultures.

CLINICAL UTILITY

- Highly sensitive and specific identification of HSV-1 and HSV-2 by PCR
- Rapid turnaround time: 48 to 72 hours
- Higher frequency of detection of HSV DNA by PCR compared to culture[7]
- Convenient 5-in-1 option allows testing for HPV, CT, NG, HSV-1, and HSV-2 from a single ThinPrep® specimen

This test was developed and its performance characteristics determined by Pathology, Inc. in Torrance, California. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

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SAMPLE TYPE AND COLLECTION

ThinPrep® Liquid-based Pap. Please use cervical brush, spatula, or broom to collect Pap. (SurePath™ Paps and Swabs are not acceptable at this time).

METHODOLOGY

Real-Time Polymerase Chain Reaction (RT-PCR)

ORDERING INFORMATION

Test Code	Test Name
522	Herpes Simplex Virus Types 1 & 2 (HSV-1 and HSV-2)
520	Herpes Simplex Virus Type 1 (HSV-1)
521	Herpes Simplex Virus Type 2 (HSV-2)
528	ThinPrep® 5-in-1 Liquid-based Pap (HPV reflex, NG, CT, HSV-1 / HSV- 2)

Specimen/Stability	ThinPrep® Liquid Pap: Ambient temperature for 14 days
Collection Instructions	Cervical brush, spatula, broom (No Swabs)
Report	48 to 72 hours

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3. Genital Herpes – CDC Fact Sheet http://www.cdc.gov/std/Herpes/STDFact-Herpes.htm (accessed February 2010)
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8. Schmutzhard J, et al. Detection of herpes simplex virus type 1, herpes simplex virus type 2 and varicella-zoster virus in skin lesions. Comparison of real-time PCR, nested PCR and virus location. *Journal Clinical Virology 2004; 29:120-26.*
9. Ramaswamy M, et al. Diagnosis of genital herpes by real time PCR in routine clinical practice. *Sex Transm Infect 2004; 80:406-10.*

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