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TEST UPDATE: Herpes Simplex Virus 1 and 2

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Effective March 5, 2018, PathGroup has transitioned Herpes Simplex Virus 1 and 2 (HSV 1 & 2) detection from a laboratory developed Polymerase Chain Reaction (PCR) methodology to the FDA-approved Aptima HSV 1 & 2 Assay. The Aptima assay is a real time transcription-mediated amplification (TMA) for the qualitative detection and differentiation of HSV-1 and HSV-2 messenger RNA (mRNA) in clinician-collected swab specimens from anogenital skin lesions. Compared to culture, this platform provides excellent sensitivity and specificity for the detection of HSV-1 and 2 in patient lesion swab specimens (clinical sensitivities of 98.2% and 99.4%, and clinical specificity of 97.8% and 94.5%, respectively. Based on internal studies, it is also 2-3 times more sensitive than the currently used PCR test.[i]

HSV causes superficial and systemic infections within every major organ system of the body in both normal and immunocompromised patients. It is estimated that 500,000 to 1 million people acquire HSV infection each year, and at least 50 million individuals in the United States have a genital herpes infection, which has become the most common sexually transmitted disease among women. Two distinct HSV genotypes exist, HSV type 1 and HSV type 2. HSV type 1 is considered to be primarily associated with ocular and oral infection, while HSV type 2 is associated with genital infection. However, these distinctions have blurred and either strain of HSV may be isolated from herpetic lesions, and can cause genital herpes. Genotyping of the virus is necessary for proper treatment of infected neonates and immunocompromised individuals, adequate management of pregnant women and effective STD counseling.

Test codes, test specifications and pricing will remain the same. No action is required of PathGroup accounts or providers.

ORDERING:

PATHGROUP TEST CODE	PATHGROUP TEST NAME	CPT
0HSV	Herpes Simplex Virus Type 1 and 2, Aptima	87529 X 2

PATHGROUP TEST METHODOLOGY:

Transcription Mediated Amplification (TMA) on the Aptima™ Panther ™system.

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SPECIMEN COLLECTION AND STORAGE:

SPECIMEN CONTAINER:

Acceptable specimen collection devices include the following:

- PreserveCyt (ThinPrep) - collected cervical and vaginal specimen
- APTIMA Unisex Swab Specimen Collection Kit - Endocervical and Male Urethral Swab Specimens
- APTIMA Vaginal Swab Specimen Collection Kit
- APTIMA Urine Specimen Collection Kit
- Urine in sterile container
- BD Universal Swab

SPECIMEN STABILITY: 21 Days after receipt of sample

UNACCEPTABLE CONDITIONS:

- Specimens collected in media other than the recommended ThinPrep Vial, BD Universal Swab, Aptima Swabs, Aptima Urine collection tubes or urine in sterile container.
- Specimen vials with less than recommended volumes.
- Frozen specimens
- Serum

TEST PERFORMED: Monday - Friday

TURNAROUND TIME: 48 hours

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227.

[i] [i]*Paul D. Swenson, Azza El-Sabaeny, Vanessa Thomas-Moricz, Megan Allen, Anabel Groskopf, Alice Jiang, Damon Getman.* Evaluation of a transcription mediated amplification assay for detection of herpes simplex virus types 1 and 2 mRNA in clinical specimens. Journal of Clinical Virology. 80 (2016): 62 – 67