OraRisk® HSV

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Sample, Report

Date Of Birth: 09/25/1980 (35 yrs)
Gender: Female
Patient Id:
Patient Location:

Ordering Provider

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Sample Information

Specimen#: 99999712
Accession#: 201509-10052
Specimen: Oral Rinse

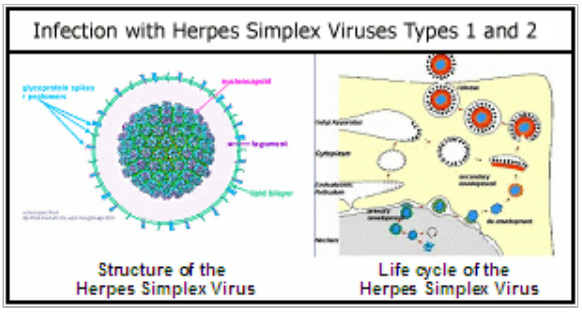
Collected: 09/16/2015 09:21
Received: 09/18/2015 09:21
Reported: 09/20/2015 09:29

Reason for Testing: Evaluation of suspicious lesion
Related info: Not Provided
Patient History: Not Provided

Lesion Size: 2mm x 1mm
Lesion Color: Mixed
Lesion Location(s): Hard Palate

MOLECULAR DETECTION OF HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2 IN THE OROPHARYNX

Test Results	
HSV Type 1	Positive
HSV Type 2	Positive



Interpretation:

This sample is positive for HSV-1 and HSV-2 DNA. See comments.

Comments:

- Significance: HSV-1 and HSV-2 in the oropharyngeal tract is transmitted by direct contact with body fluids or lesions of an infected individual. The current positive result demonstrates evidence of HSV-1 and HSV-2 infection and the presence of shed virus in the tested oral rinse sample.

- Risk: Oropharyngeal herpes (inclusive of herpes labialis, herpes stomatitis, herpes glossitis, herpes pharyngitis) are common infections of the ororespiratory tract. Such conditions are most frequently caused by primary or recurrent shedding of herpes simplex virus type 1 (HSV-1), but numerous reports of herpes simplex virus type 2 (HSV-2) infection are described. Infections by both types of HSV are the result of transmission by person-to-person contact, including kissing, oral sex, and other means to transmit the virus from vesicular or ulcerative lesions. Following a primary infection, the herpes viruses usually becomes latent in the nerve tissues, principally in the root of the trigeminal ganglion. These infections frequently recur causing small, painful vesicles commonly called cold sores or fever blisters. Herpes infections may also lead to severe and dangerous consequences: if they occur in or near the eye, where herpes keratitis is a leading cause of blindness. Other complications of oral herpes most typically cause "aphthous ulcers" or canker sores, but may rarely include involvement of the central nervous system (encephalitis) or a form of hepatitis. In each of those conditions, herpes infections may be life threatening and should be met with the evaluation of conditions that predispose a person to such serious outcomes including reasons for a weakened immune system, undetected malignant disease or other viral diseases such as HIV/AIDS.

- Consider: Currently, there are no standard recommendations for the use of tests for HSV infections in either the ororespiratory or genital tracts. However, molecular testing for HSV-1 and HSV-2 for samples from the oropharynx can confirm a clinical impression of HSV infection, or as an adjunct to cytologic assessment of a vesicular or ulcerative lesion. Mild outbreaks of herpes simplex lesions typically require no treatment, but may require management of localized pain and or fever. Severe infections, and in particular in immunocompromised persons, may require treatment with an antiviral agent. Oral antiviral drugs include acyclovir (Zovirax), valacyclovir (Valtrex) and famciclovir (Famvir). Topical acyclovir or penciclovir (Denavir) creams may shorten attacks of recurrent HSV-1 if it is applied early, usually before clinically obvious lesions. Specific recommendations for the frequency and management consequence of these DNA based tests can be reviewed at http://www.cdc.gov/mmwr/pdf/rr/rr6403.pdf

Methodology: Genomic DNA was extracted and amplified by a multiplex polymerase chain reaction (PCR) using primers specific for the Herpes Simplex Virus. Concurrently, the integrity of the extracted DNA was evaluated by the amplification of apolipoprotein B, a common housekeeping gene. Result interpretation is performed by analysis of peak height and size data generated through fluorescence detection by automated electrophoresis. The analytical and performance characteristics of this laboratory-developed test (LDT) were determined by OralDNA Labs, A Service of Access Genetics, LLC pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not a requirement prior to use for clinical purposes.

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