



ORARISK[®] HSV

SAMPLE, REPORT

Date of Birth: 09/20/1980 (42 yrs)

Gender: Male

Patient ID: 920-G

Patient Location: Test Site A

ORDERING PROVIDER

Ronald McGlennen MD
7400 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344
855-672-5362

SAMPLE INFORMATION

Specimen#: 5989009003

Accession#: 202306-O3363

Specimen: Oral Rinse(P)

Collected: 06/05/2023

Received: 06/06/2023 14:29

Reported: 06/07/2023 09:20



ORALDNA[®] LABS

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oraldna.com

CLIA#: 24D1033809
CAP#: 7190878

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| | | | |
|---------------------------|---------------------------------|---------------------------|-------------|
| Reason for Testing | Evaluation of suspicious lesion | Lesion Size | 2mm x 1mm |
| Related Info | Not Provided | Color | Mixed |
| | | Lesion Location(s) | Hard Palate |

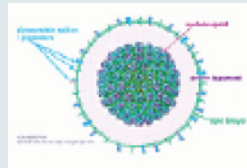
MOLECULAR DETECTION OF HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2 IN THE OROPHARYNX

Test Results

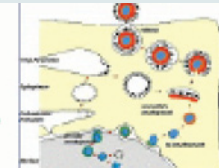
| | |
|------------|----------|
| HSV Type 1 | Positive |
| HSV Type 2 | Positive |

Infection with Herpes Simplex Viruses Types 1 and 2

Structure of the Herpes Simplex Virus



Lifecycle of the Herpes Simplex Virus



Interpretation:

This sample is positive for HSV-1 DNA 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 a 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 oro-respiratory 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 become 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.

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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: Roche Cobas(R) 4800 intended for external anogenital lesion specimens from symptomatic male and female patients as an aid in diagnosis of anogenital HSV-1 and HSV-2 infections in symptomatic patients. The analytical and performance characteristics of this laboratory-developed test (LDT) was determined by OralDNA Labs pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. Warning: The Cobas(R) HSV 1 and 2 Test is not FDA cleared for use with cerebrospinal fluid (CSF) and is not intended to be used for prenatal screening or for individuals under the age of 18 years.

Ronald C. McGlennen

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Medical Director

