

ORARISK[®] HPV

SAMPLE, REPORT

Date of Birth: 01/01/1975 (48 yrs)

Gender: Female

Patient ID: 920-I

Patient Location: Test Site A

ORDERING PROVIDER

Ronald McGlennen MD
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Suite 150
Eden Prairie, MN 55344
855-672-5362

SAMPLE INFORMATION

Specimen#: 5981002002

Accession#: 202305-03264

Specimen: Oral Rinse(P)

Collected: 06/03/2023

Received: 06/03/2023 23:00

Reported: 06/05/2023 09:53



ORALDNA[®] LABS

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CLIA#: 24D1033809
CAP#: 7190878

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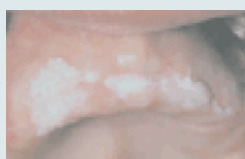
Specimen#: 5981002002
Accession#: 2023O5-O3264
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Reason for Testing Evaluation of suspicious lesion
Related Info Not Provided

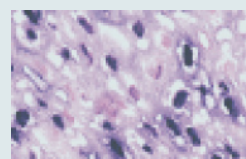
Lesion Size 3mm x 1mm
Color Red
Lesion Location(s) Hard Palate

MOLECULAR GENOTYPING OF HUMAN PAPILOMAVIRUS (HPV) IN THE OROPHARYNX

HPV Type	Risk
16	High



Clinical photo of oral leukoplakia



Microscopic view of severe dysplasia in biopsy

Oropharyngeal HPV

- Contracted by direct contact
- Most infections resolve
- New infections may be protected by vaccine
- Some infections persist
- Small percent progress to cancer

Interpretation:

This sample is positive for the following HPV type(s): 16. This HPV infection is considered high risk for development of dysplasia or neoplasia of the oropharyngeal tract. These results do not exclude the possibility of HPV not detected due to improper specimen collection or assay sensitivity. See comments.

Comments:

Significance: HPV of the oropharyngeal tract is caused by person-to-person contact with implications for the development of cancers such as those involving the oral mucosa, the tonsils, the base of tongue, and throat. The diagnosis of dysplasia and cancer are based on the morphologic assessment of a specimen obtained from biopsy.

Risk: The clinician's assessment of patient risk for a given HPV type involves several factors including the duration of the infection, the patient's hormonal and immune status, and whether there are coincident social habits or underlying disease that increase the general risk of malignancy. The HPV type identified in this sample is listed as high risk, meaning that the virus(es) has been associated with malignant changes in infected cells. HPV risk classifications are derived from the IARC's evaluation of the carcinogenicity to humans. (IARC. 2009. A Review of Human Carcinogens Part B: Biological Agents. IARC Monogr Eval Carcinog Risks Hum, 100b. Retrieved from <http://monographs.iarc.fr/index.php>)

Consider: Office protocols for patient follow-up (e.g. more frequent exam intervals, use of adjunctive early detection methods, referral to oral surgeon or ENT for further evaluation) and repeat HPV testing as necessary to determine if HPV infection is persistent or has resolved.



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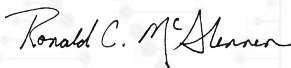
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References:

- 1 Chung CH, Gillison ML. Human papillomavirus in head and neck cancer: its role in pathogenesis and clinical implications. Clin Cancer Res 2009;15:6758-62.
- 2 Herrero R, Castellsague X, Pawlita M, et al. Human papillomavirus and oral cancer: the International Agency for Research on Cancer multicenter study. J Natl Cancer Inst 2003;95:1772-83.

Methodology: Genomic DNA was extracted and amplified by polymerase chain reaction (PCR) using consensus oligonucleotide primers specific for the L1 region of the human papillomavirus (HPV) genome. Samples positive for HPV DNA were then subjected to digestion with a series of restriction endonuclease enzymes. The resulting DNA fragments were analyzed by methods of automated microcapillary electrophoresis. A series of digital electropherograms and rendered gel images were generated, the results interpreted by matching of resulting display of DNA fragments to the restriction patterns of known and validated HPV types. The analytic sensitivity of this assay for the detection of HPV has been validated to be 37.1 genome copies/reaction. 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.



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Medical Director

