

ORARISK[®] HPV

Identifies 50 types of oral HPV, a viral infection that could potentially lead to oral cancer

70% of oral cancers are linked to HPV

The Centers for Disease Control state that HPV is the leading cause of oral cancers.

Who Should Be Tested?

Patients who have:

- Traditional risk factors for oral cancer
- Been sexually active
- A family history of oral cancer
- Signs or symptoms of oral cancer
- Suspicious oral lesions

Why Test?

- Identify potential issues before symptoms develop
- Assess individual risk, even in asymptomatic patients
- Provide tailored care, including appropriate referrals and monitoring
- Support early detection and improved outcomes through risk-based evaluation

50 Types Identified

High Risk Genotypes: 16, 18, 26, 30, 31, 33, 34, 35, 39, 45, 51, 52, 53, 56, 58, 59, 64, 66, 67, 68, 69, 73, 82

Low Risk Genotypes: 2a, 6, 11, 32, 40, 42, 43, 44, 54, 55, 57, 61, 62, 70, 71, 72, 74, 77, 81, 83, 84, 89

Unknown Risk Genotypes: 41, 49, 60, 75, 80

* Risk categories are identified by the International Agency for Research on Cancer (IARC)



Free Patient Brochures Available

Perfect for patient education!

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Available in the state of New York

ORARISK® HPV Sample Report

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

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

Reason for Testing Related Info

Evaluation of suspicious lesion
 Not Provided

Lesion Size Color

3mm x 1mm
 Red

Lesion Location(s)

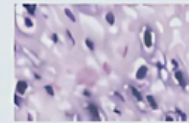
Hard Palate

MOLECULAR GENOTYPING OF HUMAN PAPILLOMAVIRUS (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

Report Includes:

FINAL REPORT

ORARISK® HPV

SAMPLE REPORT
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Cover

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Lesion Location(s) Hard Palate

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

Comments:
Significance: HPV of the oropharynx that is caused by person-to-person contact with implications for the development of cancers such as those involving the oral mucosa, the larynx, the base of tongue, and throat. The degree of dysplasia and cancer are based on the microscopic 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 concurrent social habits or underlying disease that increase the general risk of malignancy. The HPV type identified in this sample is high risk, meaning that the evidence has been associated with malignant changes in infected cells. HPV risk classification is derived from the IARC's evaluation of the carcinogenicity to humans (IARC, 2009. A review of Human Carcinogens Part 1: Biological Agents, IARC Monographs on the Evaluation of the Hazard of Human Carcinogens, IARC, Lyon, France: International Agency for Research on Cancer, 2010). Retrieved from: <http://monographs.iarc.fr/ViewArticle.aspx?pid=11654>
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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Result, Interpretation, & Comments (Significance, Risk, Considerations)

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References:
 1. Chaturvedi A, et al. Human papillomavirus in head and neck cancer: its role in pathogenesis and clinical implications. Clin Cancer Res. 2013;19(14):3701-13.
 2. Henson B, et al. Human papillomavirus and oral cancer: the International Agency for Research on Cancer multi-site study. Nat Rev Clin Oncol. 2017;13(1):59-71.

Methodology: Genomic DNA was extracted and amplified by polymerase chain reaction (PCR) using consensus oligonucleotide primers specific for the L region of the human papillomavirus (HPV) genome. Samples positive for HPV DNA were then subjected to genotyping with a series of restriction endonuclease enzymes. The resulting DNA fragments were analyzed by capillary electrophoresis microarray technology. A series of digital microarray patterns were generated, the results were used to identify the number of HPV DNA fragments in the restriction pattern of each HPV genotype. The HPV genotype was then determined by the restriction pattern. All results were confirmed by a second genotyping reaction. The analytical and performance characteristics of this laboratory developed test (LDT) was determined by the FDA. LDTs pursuant to Clinical Laboratory Improvement Amendments (CLIA) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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 Medical Director

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References & Methodology