



Your Patients May Have an  
Increased Risk for Oral Cancer...  
Be Certain with OraRisk<sup>®</sup> HPV

# OraRisk<sup>®</sup> HPV

Salivary DNA test that determines who is at increased risk for HPV-related oral cancers

## About oral HPV and oral cancer

The role of oral HPV in cancers of the head and neck is unquestioned:

- Oral HPV is now known to be an independent risk factor for oral and throat cancers
- The incidence of oral HPV-associated oral and throat cancers is estimated at 50-65%<sup>1</sup>

## The OraRisk<sup>®</sup> HPV test report:

- A non-invasive, easy-to-use screening tool to identify the type(s) of oral HPV present, as well as the associated risk profile for each type detected
- Lists oral HPV types as high, low or unknown risk based on the virus's association with malignant changes in HPV-infected cells
- Enables the clinician to establish increased risk for oral cancer and determine appropriate referral and monitoring conditions

## Who should be tested?

- Patients with traditional risk factors for oral cancer
- Patients who are sexually active
- Patients with a family history of oral cancer
- Patients with signs and symptoms of oral cancer
- Patients with suspicious oral lesions



# OraRisk<sup>®</sup> HPV Result Report

**ORARISK<sup>®</sup> HPV**  
FINAL REPORT

Doe, John (Id: 123456)  
Date Of Birth: 01/01/0001  
Gender: Male

Ordering Provider

Sample Information  
Accession: SAMPLE001  
Specimen: Oral Rinse  
Collected: 01/01/2009 01:01

Received: 01/01/2009  
Reported: 01/01/2009  
Printed: 01/01/2009

**Result: POSITIVE - HIGH RISK HPV IDENTIFIED**

HPV Type(s) Identified	Patient Risk
16	High

Clinical Information	
Reason(s) for test:	Presence
Lesion Size:	8mm
Lesion Color:	
Lesion Location(s):	
Additional Clinical Information:	

Interpretation:  
This sample is positive for the following HPV type(s) (16). This HPV infection is associated with an increased risk for the development of dysplasia or neoplasia of the ororespiratory tract. The morphologic assessment of a specimen obtained from the biopsy.

- Risk:** The clinician's assessment of patient risk for a given HPV type involves several factors including the time 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) have been associated with malignant changes in infected cells.
- 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.

Methodology: Genomic DNA was extracted from the submitted specimen and amplified by Polymerase Chain Reaction (PCR) using primers specific for the human papilloma virus (HPV) genome. HPV DNA positive PCR products were subjected to digestion by restriction enzymes. Digested DNA fragments were then separated on a polyacrylamide gel, visualized by aid of ethidium bromide and HPV genotype determined by matching the fragment pattern to that of known HPV restriction fragment patterns.

Disclaimer: 1. OralDNA is not liable for any outcomes arising from clinician's treatment protocols and decisions. Dentists should consult with a periodontist or patient's physician when infections are advanced or as indicated by patient's medical condition. 2. OralDNA is not responsible for inaccurate test results due to poor sample collection. 3. This test was developed and its performance characteristics determined by OralDNA Labs, Inc pursuant to CLIA requirements. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

Additional information is available from [MyOralDNA.com](http://MyOralDNA.com) or: [UsingOralDNA@questdiagnostics.com](mailto:UsingOralDNA@questdiagnostics.com)

Patient Communication: \_\_\_\_\_ Possible Office Workflow: \_\_\_\_\_

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Chief Dental Officer: Thomas W. Nabors, DDS

Test results are reported as positive high-risk, positive low-risk, positive risk-unknown or negative—no HPV detected.

## How to Administer the Test:

1. Patient vigorously swishes and **gargles** saline solution for 30 seconds
2. Patient expectorates into funneled collection tube
3. Funnel is removed, cap is secured to top of collection tube
4. Samples are sent via pre-paid FedEx<sup>®</sup> envelope to OralDNA<sup>®</sup> Labs for DNA-PCR analysis
5. E-mail notification is sent to clinician when electronic result report is available

## About OralDNA<sup>®</sup> Labs

Located in Brentwood, Tennessee, OralDNA<sup>®</sup> Labs is a specialty diagnostics company focused on advancing wellness through salivary diagnostic testing. In May 2009, OralDNA<sup>®</sup> Labs was acquired by Quest Diagnostics<sup>®</sup> Incorporated (NYSE: DGX), the world's leading provider of diagnostic testing, information, and services. Our goal is to help bridge the gap between dentistry and medicine, and more specifically, the mouth and body.