OraRisk® 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%[1]

The OraRisk® 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


ORARISK® HPV
FINAL REPORT

ORALDNA® LABS

Doe, Jane P.
Date Of Birth: 01/01/1988
Gender: Female

Ordering Provider

Sample Information
Accession: 8508831
Specimen: Oral Rinse
Collected: 11/26/2009 19:39

Received: 11/30/2009 19:28
Reported: 12/01/2009 21:12
Printed: 12/01/2009 21:12

Result: POSITIVE - HIGH RISK HPV IDENTIFIED

16 18

HPV Type(s) Identified	Patient Risk
Mixed Types	High

Type	Clinical Significance
16	This HPV Type is classified as being of high risk for the development of cancer.
18	This HPV Type is classified as being of high risk for the development of cancer.

Test Information	
Reason for test:	Presence of Lesion
Lesion Size:	40mm x 50mm
Lesion Color:	Red
Lesion Location:	Soft Palate
Additional Clinical Information:	

Interpretation:
This sample is positive for the following HPV type(s) (16,18). This HPV infection is considered a high risk for development of dysplasia or neoplasia of the ororespiratory tract. See comment.

Comment:

- **Significance:** HPV of the ororespiratory tract is caused by person to person contact with implications for the development of cancers such as those involving the oral mucosa, the tonsils and the base of tongue. The diagnosis of dysplasia and cancer are based on the morphologic assessment of a cytology or tissue specimen obtained from biopsy.
- **Risk:** The assignment of risk of 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 these viruses have been associated with malignant changes in infected cells.
- **Consider:** A current recommendation following the result of a high risk HPV infection is close observation and repeat testing for persistent HPV one year (12 months) later.

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 physician'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. 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 on:

Patient Communication	Sample Office Protocol	Using OralDNA

OralDNA Labs
Medical Director: Ronald McGlennen, MD

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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

For more information, call 855-ORALDNA or visit **www.OralDNA.com/professionals**, www.cdc.gov or www.oralcancerfoundation.org.

ORALDNA® LABS
Innovations in Salivary Diagnostics

Reference:
1. D'Souza G, Kreimer AR, Viscidi R, et al. Case-control study of human papillomavirus and oropharyngeal cancer. *N Engl J Med.* 2007; 356:1944-56.

OraRisk® HPV Result Report

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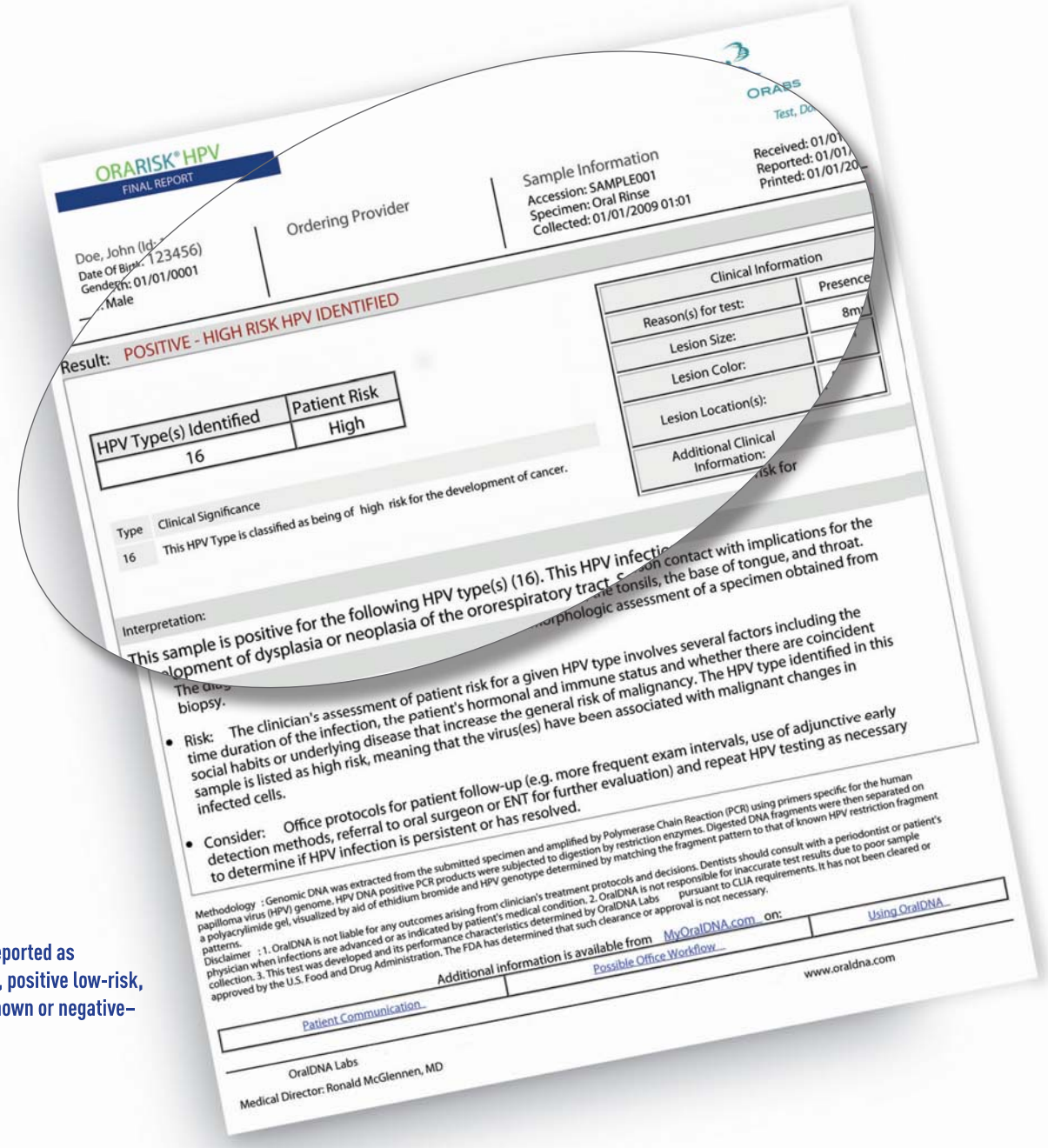
Innovations in Salivary Diagnostics


ORARISK® HPV
FINAL REPORT

Ordering Provider

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

Result: POSITIVE - HIGH RISK HPV IDENTIFIED

HPV Type(s) Identified	Patient Risk
16	High

Type	Clinical Significance
16	This HPV Type is classified as being of high risk for the development of cancer.

Clinical Information

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

Interpretation:
This sample is positive for the following HPV type(s) (16). This HPV infection ... development of dysplasia or neoplasia of the ororespiratory tract ... contact with implications for the ... tonsils, the base of tongue, and throat. ... 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 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 polyacrylimide 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 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 on:
Patient Communication
Possible Office Workflow
Using OralDNA

OralDNA Labs
Medical Director: Ronald McGlennen, MD
www.oraldna.com

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 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® envelope to OralDNA® Labs for DNA-PCR analysis
5. E-mail notification is sent to clinician when electronic result report is available

About OralDNA® Labs

Located in Eden Prairie, MN, OralDNA® Labs is a specialty diagnostics company focused on advancing wellness through salivary diagnostic testing. In December 2012, OralDNA® Labs was acquired by Access Genetics, LLC, a leading national CLIA and CAP-certified reference laboratory with advanced molecular diagnostics and IT capabilities.