



Your Patients May Have an
Increased Risk for Oral Cancer...
Be Certain with OraRiskSM HPV

OraRiskSM 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 HPV in cancers of the head and neck is unquestioned:

- 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 OraRiskSM 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

For more information, contact: **877-577-9055** or visit www.OralDNA.com/training,
www.cdc.gov or www.oralcancerfoundation.org.

To order OraRiskSM HPV
testing supplies, contact your
Henry Schein[®] representative:
800-372-4346

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DENTAL



Item # 325-8317

Each box contains 12 OraRiskSM HPV
salivary testing supplies.

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.

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104588-HPV 3-10

OraRiskSM HPV Result Report

ORARISKSM HPV
FINAL REPORT

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

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 HPV type 16 is a high risk HPV type. The HPV type 16 is associated with an increased risk for the development of dysplasia or neoplasia of the ororespiratory tract. The HPV type 16 is associated with an increased risk for the development of dysplasia or neoplasia of the ororespiratory tract.

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 then 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 **on:** UsingOralDNA.com

Patient Communication: PossibleOfficeWorkflow.com

OralDNA Labs, Inc., 214 Overlook Circle, Suite 120, Brentwood, TN 37027 6155779055; Fax: 6156272826 www.oraldna.com
Medical Director: Ronald McGlennen, MD
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.

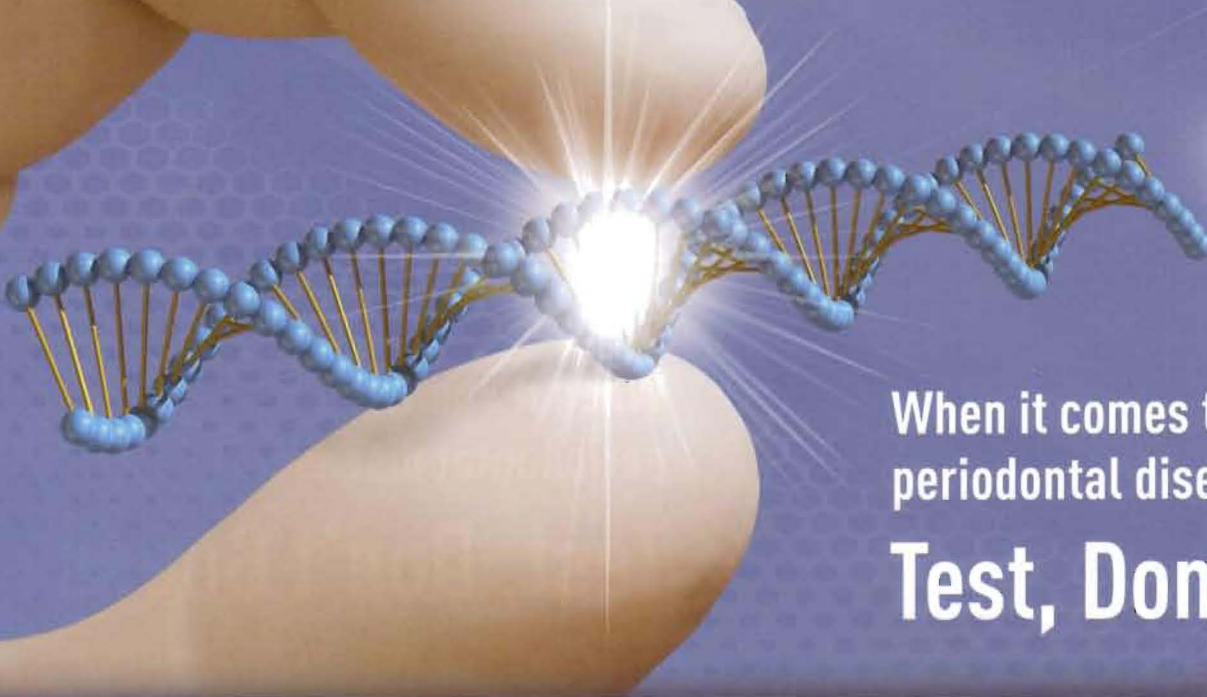
How to Administer the Test:

1. Patient vigorously swishes and **gargles** 3 ml of 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 Brentwood, Tennessee, OralDNA[®] Labs is a specialty diagnostics company focused on advancing wellness through salivary diagnostic testing. In May 2009, OralDNA[®] Labs was acquired by Quest Diagnostics[®] 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.

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When it comes to
periodontal disease...
Test, Don't Guess

MyPerioPath®

Salivary DNA test that determines the cause of periodontal infections

The test report will tell you:

- The type and concentration of disease-causing bacteria
- The bacterial information necessary to help classify high-risk versus low-risk cases
- Targeted treatment considerations designed to help you provide personalized therapy

Treat the cause, not the symptoms:

- Create a highly personalized treatment approach
- Enable better risk assessment for more predictable outcomes
- Establish a systematic way to track patient oral health progress
- Increase patient acceptance of recommended treatment plans

Each box contains 12 Periodontal Testing Supplies, which can be used to run the MyPerioPath® and/or MyPerioID® PST® tests. **Item # 325-9748**

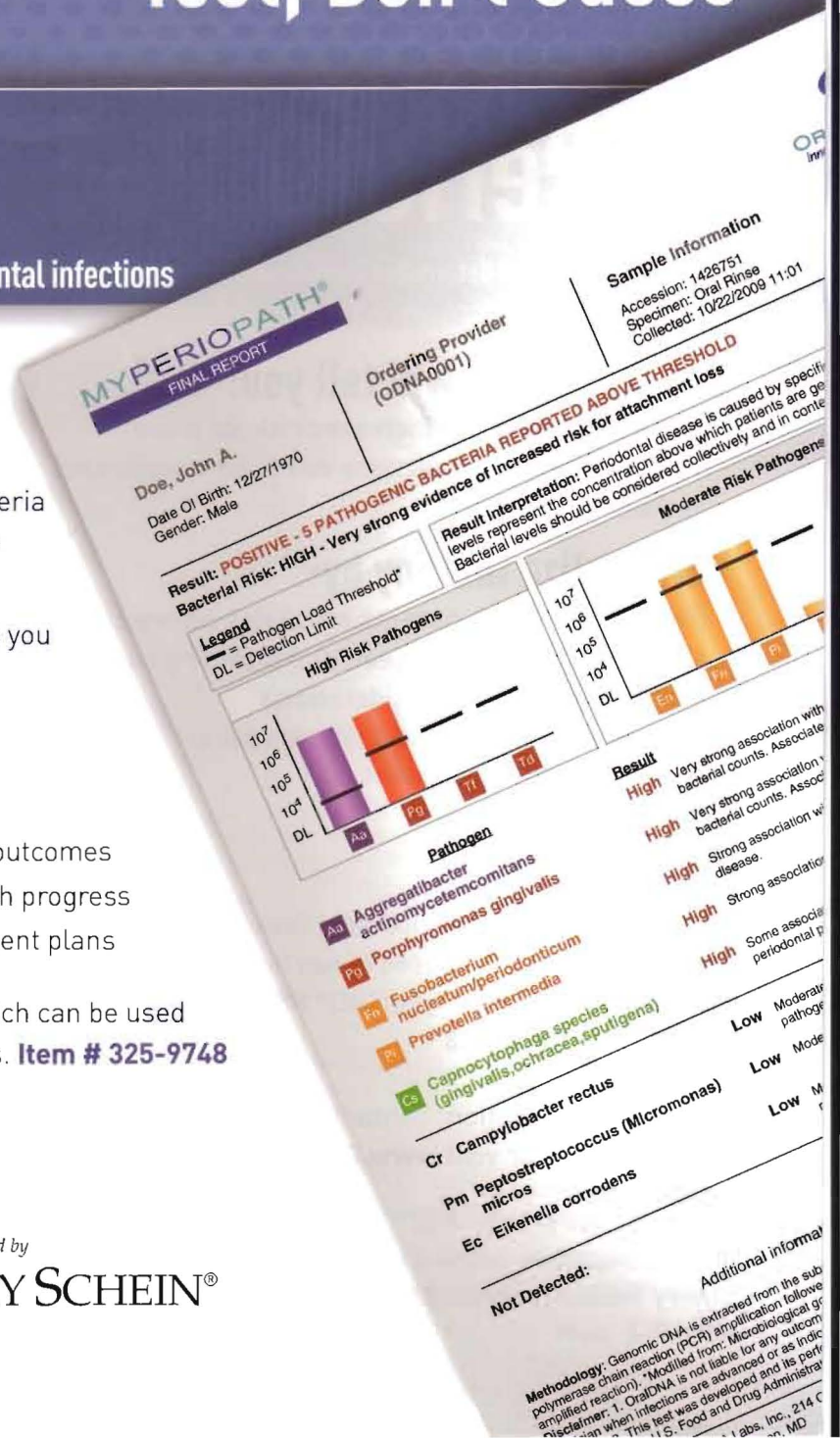
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When it comes to
periodontal disease...
Test, Don't Guess

MyPerioID® PST®

Salivary DNA test that determines increased risk for severe periodontal infections

The test report will tell you:

- Which patients are at increased risk for more severe periodontal infections due to an exaggerated immune response

Personalize therapy by:

- Establishing which patients are at risk before clinical signs and symptoms appear, and providing customized periodontal therapy considerations
- Determining which patients may require more aggressive treatment
- Optimizing preventive recare appointments

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104588-PST 3-10

MYPERIOD PST
FINAL REPORT

1, Patient
Date Of Birth: 12/27/1970
Gender: Male

Ordering Provider
John A. Doe
214 Overlook Circle, Suite 120
Brentwood, TN 37027

Sample Information
Accession: 1426752
Specimen: Oral Rinse
Collected: 10/22/2009 11:01

Received:
Reported:
Printed:

Result:
POSITIVE

Genotype **G/T**
Genotype **C/T**

IL-1B (+3954)

Interpretation:
The results of the PST test indicate that your patient is **POSITIVE** for more severe periodontal disease due to the genetic variations in the IL-1A and IL-1B genes. PST-positive patients may require more aggressive treatment.

Comments:
• **Significance:** This individual has the "PST-positive" genotype, which indicates an increased risk for severe periodontal disease. The PST test assesses one of the genetic variations in the IL-1A and IL-1B genes, which are known to be involved in the inflammatory response. The presence of a "T" at both IL-1A and IL-1B predisposes an individual to more severe periodontal disease and may require more aggressive treatment.

• **Risk:** Prevalence of the PST-positive genotype is higher in populations with a higher prevalence of periodontal disease. Whenever the PST-positive genotype is present, the frequency of periodontal disease is increased, and additional risk factors in the oral hygiene have an amplifying effect on the disease.

• **Consider:** The PST test assesses one of the genetic variations in the IL-1A and IL-1B genes, which are known to be involved in the inflammatory response. The presence of a "T" at both IL-1A and IL-1B predisposes an individual to more severe periodontal disease and may require more aggressive treatment.

Methodology: Genomic DNA is extracted and tested for two Interleukin-1 (IL-1) gene polymorphisms (IL-1A and IL-1B) using a single base extension detection method.

Disclaimer: 1. OralDNA is not liable for any outcomes arising from the use of the PST test. 2. The PST test is not intended to be used as a diagnostic tool for periodontal disease. 3. This test was developed and its performance is not guaranteed by the U.S. Food and Drug Administration. The FDA has determined that this test is a laboratory-developed test (LDT).

Test performed by: Interleukin
214 Overlook Circle
Brentwood, TN, MD