ORARISK® HPV
FINAL REPORT

ORALDNA® LABS
Innovations in Salivary Diagnostics

Doe, Jane P.
Date Of Birth: 01/01/1999
Gender: Female

Ordering Provider

Sample Information
Accession: 0123456
Specimen: Oral Rinse
Collected: 05/14/2014 10:22
Received: 05/14/2014 10:22
Reported: 05/17/2014 10:38
Printed: 05/17/2014 11:06

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. See interpretation.
18	This HPV Type is classified as being of **high** risk. See interpretation.

Clinical Information	
Reason(s) for test:	Presence of Lesion
Lesion Size:	3mm x 4mm
Lesion Color:	Red
Lesion Location(s):	Soft Palate
Additional Clinical Information:	None Reported

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, 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 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) has 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 the polymerase chain reaction (PCR) using consensus oligonucleotide primers specific for the L1 region of the human papillomavirus (HPV) genome. Samples positive for the presence of 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.
Disclaimer: 1. OralDNA is not liable for any outcomes arising from clinician's treatment protocols and decisions. Dentists should consult with an ENT or oral surgeon 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 OralDNA.com on:

Patient Communication	Possible Office Workflow	Using OralDNA

OralDNA Labs, A Service of Access Genetics, LLC, 7400 Flying Cloud Drive, Eden Prairie, MN 55344 855-ORALDNA; Fax: 952-767-0446 www.oraldna.com

Medical Director: