OraRisk® HPV

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Sample, Report

Date Of Birth: 07/03/1981 (34 yrs)
Gender: Female
Patient Id: 123456
Patient Location: ABC Clinic

Ordering Provider

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Sample Information

Specimen#: 39136881
Accession#: 201509-02785
Specimen: Oral Rinse
Body Site: Oropharyngeal

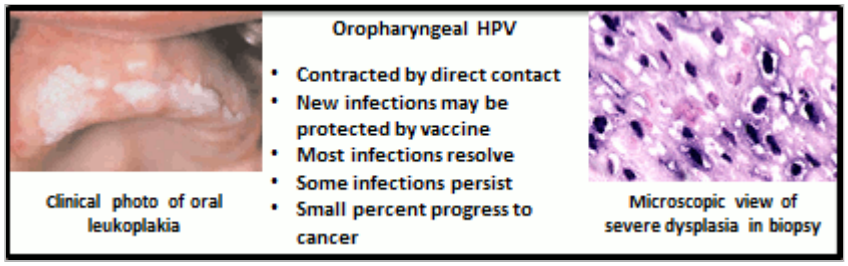
Collected: 08/29/2015 07:10
Received: 09/01/2015 12:40
Reported: 09/03/2015 13:23

Reason for Testing: Evaluation of suspicious lesion
Related info: Not Provided
Patient History: Not Provided

Lesion Size: 1mm x 3mm
Lesion Color: Red
Lesion Location(s): Hard Palate

MOLECULAR GENOTYPING OF HUMAN PAPILLOMAVIRUS (HPV) IN THE OROPHARYNX

HPV Type	Risk
16	High



Interpretation:

This sample is positive for the following HPV type(s) 16. This HPV infection is considered high risk for development of dysplasia or neoplasia of the oropharyngeal tract. These results do not exclude the possibility of HPV not detected due to sampling or assay sensitivity. See comments.

Comments:

- Significance: HPV of the oropharyngeal 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. HPV risk classifications are derived from the IARC's evaluation of the carcinogenicity to humans. (IARC. 2009. A Review of Human Carcinogens Part B: Biological Agents. IARC Monogr Eval Carcinog Risks Hum, 100b. Retrieved from http://monographs.iarc.fr/index.php.)

- 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 and amplified by polymerase chain reaction (PCR) using consensus oligonucleotide primers specific for the L1 region of the human papillomavirus (HPV) genome. Samples positive for 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.

References:

- Chung CH, Gillison ML. Human papillomavirus in head and neck cancer: its role in pathogenesis and clinical implications. Clin Cancer Res 2009;15:6758-62.
- Herrero R, Castellsague X, Pawlita M, et al. Human papillomavirus and oral cancer: the International Agency for Research on Cancer multicenter study. J Natl Cancer Inst 2003;95:1772-83.

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