OraRisk® HPV

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Sample, Report

Date Of Birth: 07/03/1980 (35 yrs)
Gender: Female
Patient Id: 123456
Patient Location: ABC Clinic

Ordering Provider

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855-672-5362

Sample Information

Specimen#: 39136880
Accession#: 201509-02784
Specimen: Oral Rinse
Body Site: Oropharyngeal

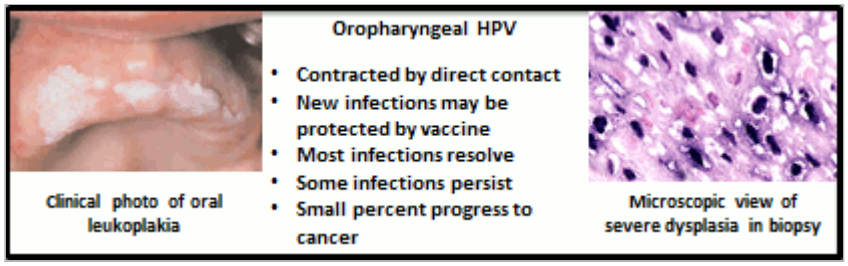
Collected: 08/30/2015 09:26
Received: 09/01/2015 12:37
Reported: 09/03/2015 13:19

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

Lesion Size: 2mm x 4mm
Lesion Color: Mixed
Lesion Location(s): Soft Palate

MOLECULAR DETECTION OF HUMAN PAPILLOMAVIRUS (HPV) IN THE OROPHARYNX

Test Results	
HPV Detection	Negative



Interpretation:

This sample is negative for HPV DNA. These results do not exclude the possibility of HPV not detected due to sampling or assay sensitivity. See comments.

Comments:

- Significance: The presence of HPV in the oropharyngeal tract is considered a precursor for the development of squamous epithelial dysplasia or neoplasia. In the absence of this risk factor other causes of oral cancer should be considered including the use of tobacco, alcohol and the individual's immune status. The diagnosis of dysplasia and cancer are based on the morphologic assessment of a specimen obtained from biopsy.

- Risk: Based on this result, HPV does not contribute to an increased risk of the development of cancers of the oropharyngeal tract.

- Consider: No specific recommendations are sanctioned at this time. However, if the clinical history or observations suggest residual risk, repeat testing may be indicated in the future.

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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