OraRisk® HPV 16/18/HR

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Sample, Report

Date Of Birth: 03/18/1980 (35 yrs)
Gender: Female
Patient Id:
Patient Location:

Reason for Testing: Not Provided
Related info: Not Provided
Patient History: Not Provided

Ordering Provider

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Sample Information

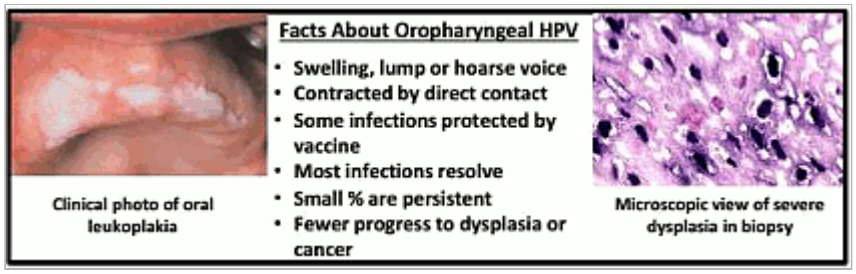
Specimen#: 99997713
Accession#: 201509-10806
Specimen: Oral Rinse
Body Site: Oropharyngeal

Collected: 09/16/2015 05:25
Received: 09/18/2015 15:25
Reported: 09/20/2015 09:16

Lesion Size: Not Provided
Lesion Color: Not Provided
Lesion Location(s): Not Provided

MOLECULAR DETECTION OF HUMAN PAPILLOMAVIRUS (HPV)16/18/HR IN THE OROPHARYNX

Test Results	
HPV 16	Negative
HPV 18	Negative
HPV High Risk	Negative



Interpretation:

This sample is negative for high risk (HR) HPV DNA from the following HPV types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. These results do not exclude the possibility of HR 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: The Cobas HPV Test contains two major processes 1)automated extraction of nucleic acids including HPV and cellular DNA and 2)simultaneous PCR amplification of target DNA sequences using both HPV (polymorphic L1 region) and Beta-globin specific primer pairs and the real-time detection of these cleaved fluorescent-labeled detection probes. PCR amplification of target DNA sequences uses HPV specific complementary primer pairs designed to amplify HPV DNA from 14 high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) as well as Beta-globin. Results are generated by the cobas 4800 software. Limitations: This test does not detect low-risk HPV types. A negative high-risk HPV result does not exclude the possibility of future cytologic HSIL or underlying CIN 2-3 or cancer. Only clinician collected cervical specimens using the ThinPrep Pap Test(tm) PreservCyt have been approved by the FDA for testing. All other acceptable sample types were validated by OralDNA Labs, A Service of Access Genetics, LLC pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. The FDA has determined that such clearance or approval is not a requirement prior to off-label use for clinical purposes.

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.
- Kerr DA, Pitman MB, Sweeney B, Arpin RN, 3rd, Wilbur DC, Faquin WC. Performance of the Roche cobas 4800 high-risk human papillomavirus test in cytologic preparations of squamous cell carcinoma of the head and neck. Cancer Cytopathol 2014;122:167-74.
- Hubbers CU, Akgul B. HPV and cancer of the oral cavity. Virulence 2015;6:244-8.
- Morbini P, Dal Bello B, Alberizzi P, et al. Oral HPV infection and persistence in patients with head and neck cancer. Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116:474-84.
- Smith EM, Ritchie JM, Summersgill KF, et al. Age, sexual behavior and human papillomavirus infection in oral cavity and oropharyngeal cancers. Int J Cancer 2004;108:766-72.

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