

Sample, Report

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

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

Reason for Testing: Evaluation of suspicious lesion

Related info: Not Provided

Patient History: Not Provided


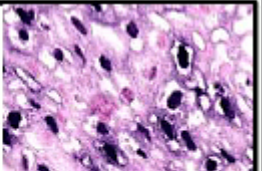
Lesion Size: 2mm x 1mm

Lesion Color: White

Lesion Location(s): Lip

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

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

Facts About Oropharyngeal HPV

- Swelling, lump or hoarse voice
- Contracted by direct contact
- Some infections protected by vaccine
- Most infections resolve
- Small % are persistent
- Fewer progress to dysplasia or cancer

Clinical photo of oral leukoplakia

Microscopic view of severe dysplasia in biopsy

Interpretation:

This sample is positive for HPV types 16 and 18 DNA. High risk (HR) HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 DNA were not detected. This infection is considered high risk for the 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.

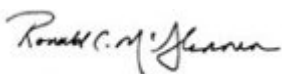
- **Risk:** The clinician's assessment of patient risk for a given HPV type involves several factors including the time duration of the infection, the patient's hormonal and immune status and whether there are coincident social habits or underlying disease that increase the general risk of malignancy. 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.

- **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: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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