FINAL REPORT

ORARISK® HPV

SAMPLE, REPORT

Date of Birth: 02/14/2000 (23 yrs)
Gender: Female
Patient ID: 920-J
Patient Location: Test Site A

ORDERING PROVIDER

Ronald McGlennen MD
7400 Flying Cloud Drive
Suite 150
Eden Prairie, MN 55344
855-672-5362

SAMPLE INFORMATION

Specimen#: 5981003001
Accession#: 202305-03263
Specimen: Oral Rinse(P)

Collected: 05/30/2023
Received: 05/30/2023 23:00
Reported: 06/01/2023 10:47

ORALDNA® LABS

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CLIA#: 24D1033809
CAP#: 7190878

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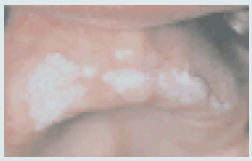
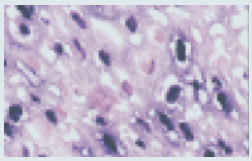
Reason for Testing	Screening test
Related Info	Not Provided

MOLECULAR GENOTYPING OF HUMAN PAPILLOMAVIRUS (HPV) IN THE OROPHARYNX

Test Results	
HPV Detection	Negative



Clinical photo of oral leukoplakia



Microscopic view of severe dysplasia in biopsy

Oropharyngeal HPV

- Contracted by direct contact
- Most infections resolve
- New infections may be protected by vaccine
- Some infections persist
- Small percent progress to cancer

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 suggested at this time. However, if the clinical history or observations suggest residual risk, repeat testing may be indicated in the future.

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References:

1 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.

2 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.

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. The analytical and performance characteristics of this laboratory-developed test (LDT) was determined by OralDNA Labs pursuant to Clinical Laboratory Improvement Amendments (CLIA 88) requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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