



SIMPLY TEST[®]
ORAL HEALTH

ORAL HPV

Saliva Screening for High-Risk HPV

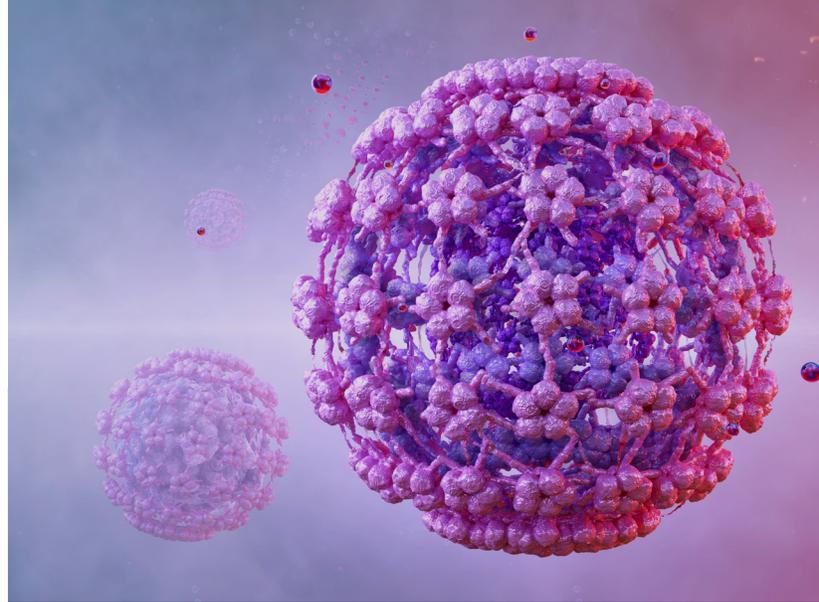
WHY TEST?

High-risk human papillomavirus (HPV), particularly HPV-16, is a well-established cause of oropharyngeal squamous cell carcinoma (OPSCC). Unlike tobacco and alcohol related cancers, HPV-positive OPSCC often presents in younger, non-smoking adults and is often asymptomatic until advanced stages, contributing to delayed diagnosis.

SimplyTest[®] screening enables earlier identification of high-risk HPV types, assessment of persistence, and timely referral, supporting improved clinical outcomes through proactive intervention.

WHY IT MATTERS

- OPSCC is now the most common HPV associated cancer in the U.S., surpassing cervical cancer.⁴
- Often asymptomatic early on, contributing to delayed diagnosis and treatment.⁵
- Disproportionately affects men aged 40-60, with oral HPV detected in ~10.1% of men vs. 3.6% of women.⁶
- Persistent high-risk HPV infection may precede oropharyngeal cancer by 4-6 years, making regular screening critical.⁷
- Validated saliva-based HPV-16 testing demonstrates ~81% sensitivity and ~94% specificity for detecting risk of HPV-16 linked to OPSCC.⁸



LINK TO OROPHARYNGEAL CANCER

The burden of HPV-attributable oropharyngeal cancer continues to grow and is now the most common HPV-associated malignancy in the U.S., surpassing cervical cancer. Persistent high-risk oral HPV infection, particularly in men aged 40-60, significantly increases the likelihood of malignant transformation. Screening in routine clinical settings allows for early identification, monitoring, and timely referral of at-risk individuals.

- HPV accounts for 4.5% of global cancer cases (~690,000 annually), with HPV-OPSCC forming a distinct and growing subset that differs clinically and prognostically from tobacco and alcohol related cancers.¹
- Globally, 30.8-42.7% of OPSCC cases are HPV-positive, with a meta-analysis reporting an overall positivity rate of 45.8%.²
- Men 50-79 are the highest-risk group for oropharyngeal cancer in the U.S., peaking at 32.4 per 100,000 in men 60-79 (SEER 2011-2022).³

SIMPLYTEST® ORAL HPV REPORT



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Testing Performed By Alimetrics - CLIA #: 01D2113023
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FINAL REPORT		
ORAL HPV		
Sample Type: Saliva		
Reported: 2026-01-30T18:17		
PATIENT INFO		
Name: John Doe	SAMPLE INFO	ORDERING PROVIDER
DOB: 01/01/1999	Specimen #: TEST0130202602	Name: Test Org Admin And Provider
Sex: M	Collected: 2026-01-30T22:26	NPI: 0123456789
	Received: 2026-01-30T16:34	Phone: 6153367534

Negative	Positive	Attention	HPV (Human Papilloma Virus) TARGETS
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HPV 16
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HPV 18
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other High Risk HPV

The expected normal test result for all target pathogens reported in this panel is "Negative".

** Other High Risk HPV indicates testing for HPV- 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. This test is intended to screen for high-risk oral HPV often associated with oropharyngeal squamous cell carcinoma (OPSCC).

COMMENTS + ACTIONABLE CLINICAL INSIGHTS

This test was developed and its performance characteristics determined by Alimetrics Corporation. The Oral HPV test is a molecular multiplex assay verified for use in the diagnosis and management of oral HPV infections. Alimetrics Corporation is a CAP accredited, Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, certified high-complexity laboratory. CLIA recognizes and supports the use of laboratory developed tests for diagnosis and management of diseases in human subjects.

ORAL HPV HOW TO TEST

- Collect**
Collect 1 mL of patient saliva, place in postage paid box and send sample off to the lab.
- Review**
Review results on secure HIPPA compliant web portal including option to share with patients. Review findings with the patient and outline next steps.
- Monitor**
If high-risk HPV is detected, schedule a follow-up saliva test in approximately 6 months to assess for persistence. If the infection persists or clinical signs are present, consider referral to ENT or OMFS as part of a coordinated care plan.

WHEN TO TEST

HPV-related oropharyngeal cancer is rising, especially in men 40–60. Persistence, not one-time exposure, is the key. Saliva testing enables longitudinal monitoring to guide counselling and referral.

WHO TO TEST

Adults 30–65 with a history of oral sex or deep kissing and >2 lifetime partners, plus smokers and immunocompromised individuals are higher risk. Also test anyone with signs suggestive of OPSCC, such as a persistent sore throat, unilateral tonsillar swelling, or a neck mass.

Sources:

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