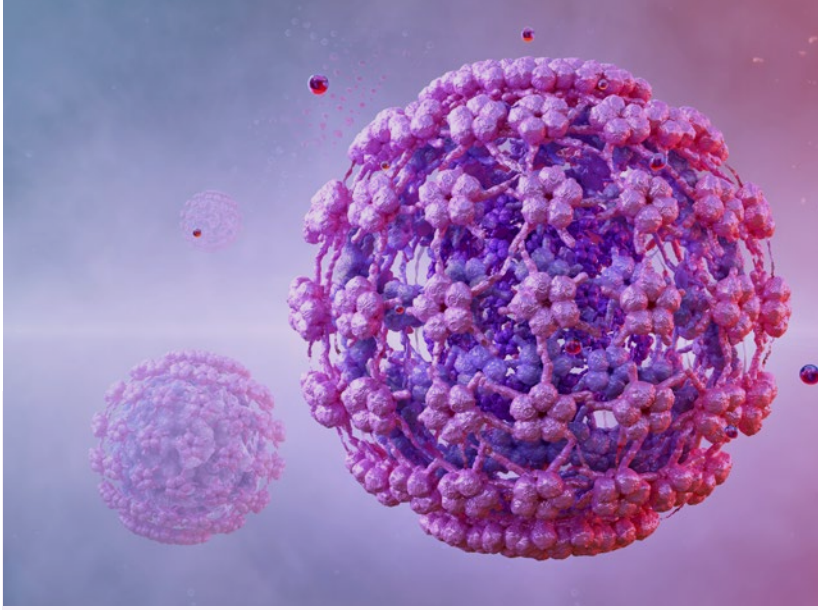
SIMPLYTEST®

ORAL HEALTH

By Spectrum Health Science

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]

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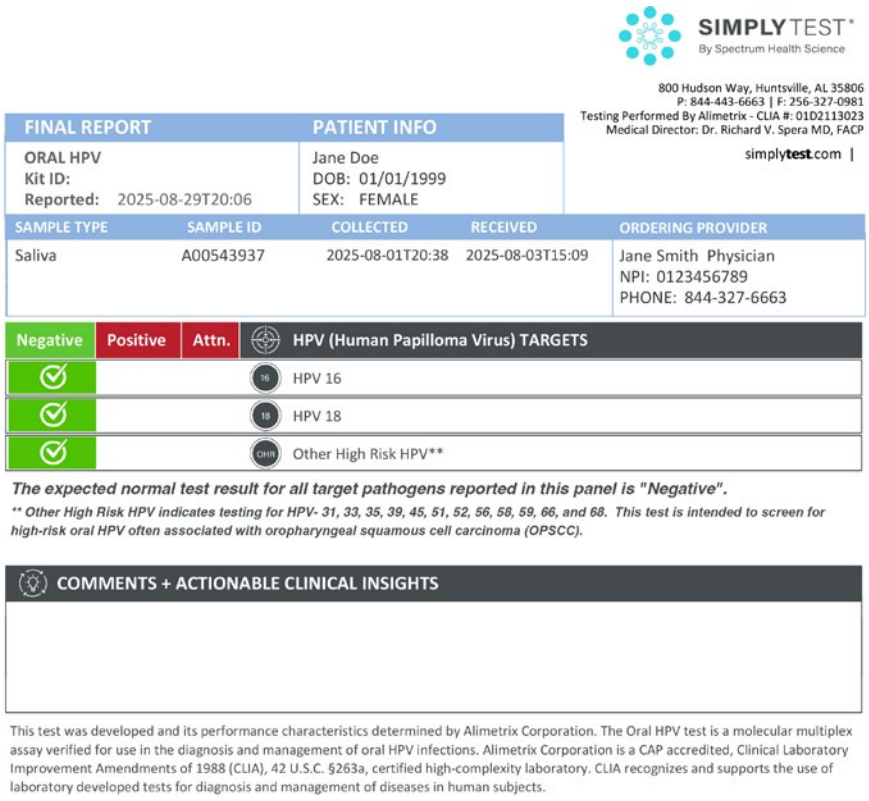
ORAL HPV REPORT



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P: 844-443-6663 | F: 256-327-0981
Testing Performed By Alimetrix - CLIA #: 01D2113023
Medical Director: Dr. Richard V. Spera MD, FACP
simplytest.com |

FINAL REPORT	PATIENT INFO
ORAL HPV Kit ID: Reported: 2025-08-29T20:06	Jane Doe DOB: 01/01/1999 SEX: FEMALE

SAMPLE TYPE	SAMPLE ID	COLLECTED	RECEIVED	ORDERING PROVIDER
Saliva	A00543937	2025-08-01T20:38	2025-08-03T15:09	Jane Smith Physician NPI: 0123456789 PHONE: 844-327-6663

Negative	Positive	Attn.	HPV (Human Papilloma Virus) TARGETS
✓			HPV 16
✓			HPV 18
✓			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 Alimetrix Corporation. The Oral HPV test is a molecular multiplex assay verified for use in the diagnosis and management of oral HPV infections. Alimetrix 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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Fakhry, C., et al. (2023). JCO Global Oncology, 9, e2300464. https://ascopubs.org/doi/full/10.1200/GO.23.00464
3. Bandala-Jacques, A., Saldanha, I. J., & D'Souza, G. (2025). BMC Cancer, 25, 1441. https://doi.org/10.1186/s12885-025-14904-4
4. Viens L.J., et al. (2016). Human Papillomavirus–Associated Cancers — United States, 2008–2012. MMWR.
5. Gillison M.L., et al. (2015). Epidemiology of Human Papillomavirus–Positive Head and Neck Squamous Cell Carcinoma. Oral Oncology.
6. D'Souza G., et al. (2009). Oral Human Papillomavirus Infection in Men Who Have Sex With Men. PLoS ONE.
7. Kreimer A.R., et al. (2013). Human papillomavirus types in head and neck squamous cell carcinomas worldwide: a systematic review. Cancer Epidemiol Biomarkers Prev.
8. Mazul A.L., et al. (2023). Salivary HPV testing for oropharyngeal cancer detection: a meta-analysis. Oral Oncology. https://doi.org/10.1016/j.oraloncology.2023.106315

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