OrisDX | Oro Lesion Saliva DNA Test

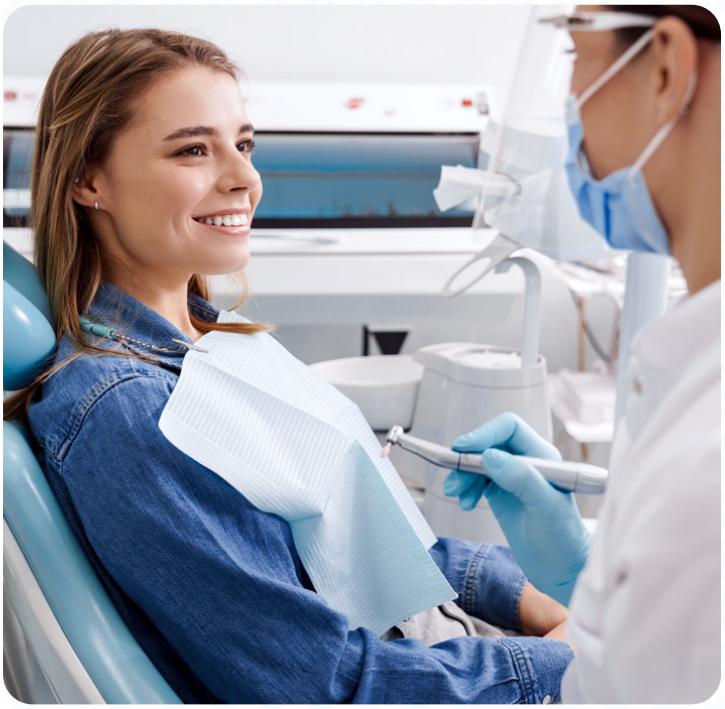
Detect Early, Live Fully.

Prevalence of Oral Cancer

Oral cancer is the sixth most common cancer in the U.S., and the type most often identified by dentists during routine care. An estimated 58,000 new cases were diagnosed in 2024 with a 21% mortality rate[1], primarily among adults over 40 who smoke, drink heavily, or have HPV infections. Since the mid-2000s, incidence rates have risen by 1% annually.[2]

Challenges in Detecting Oral Cancer

Early detection of oral cancer is difficult because it is often symptomless, painless, and frequently misdiagnosed. Traditional methods lack the sensitivity to detect early molecular changes, leading to missed diagnoses, unnecessary biopsies, and delayed intervention. Closing these gaps is essential to improving survival rates and patient outcomes.



Oral Cancer Survival Rates by Stage

Stages I & II (Early Detection)



OVER 80% 5-year survival

Stages III & IV (Late Detection)



DROPS TO 40% OR LESS 5-year survival

Approximately 70% of cases are diagnosed at later stages, reducing the 5-year survival rate from 83.7% at a localized stage to 38.5% when metastasized.[3]

Benefits of Early & Accurate Detection

Detecting oral cancer at its earliest stages is critical. Early and accurate detection offers:



Improved Survival Rates

Timely intervention significantly enhances treatment outcomes.



Curative Potential

Early-stage cancers can often be effectively treated with minor surgical procedures.



Reduced Costs

Early detection lowers financial burdens for patients and healthcare systems.

Limitations of Traditional Diagnostics for Oral Cancer

False Positives
Systematic visual inspection and palpation of the oral cavity often leads to high false positive rates, causing unnecessary anxiety.

Unnecessary Biopsies
Invasive procedures often target benign lesions, causing discomfort and increased costs - despite 80% of biopsies being

No Established Guidelines
Neither the American Medical Association (AMA) nor the American Dental Association (ADA) has published screening guidelines, leaving practitioners without clear protocols.

Limited Sensitivity
Standard visual methods often miss early molecular changes, leading to delayed diagnoses.

These challenges highlight the urgent need for precise, non-invasive diagnostic solutions to improve early detection and outcomes.

Advancements in Precision Diagnostic Technologies



Next-Generation Sequencing (NGS) has revolutionized early-stage oral cancer detection with its superior sensitivity compared to traditional visual inspection and palpation methods.[4] By identifying even minute traces of tumor DNA, NGS offers a fast, cost-effective, and patient-friendly diagnostic tool that enables

OrisDX

OrisDX is bringing the power of advanced medical diagnostics to dental clinics, revolutionizing early detection of oral cancer with an innovative and non-invasive test. By harnessing cutting-edge science, OrisDX empowers dental professionals to play a critical role in early intervention, ultimately improving patient outcomes.

The OrisDX Solution

OrisDX uses NGS and a proprietary seven-biomarker panel for precise early-stage oral cancer detection. Hygienists collect a pain-free saliva sample, which is sent to the OrisDX central lab, avoiding in-office processing. Unique molecular identifiers and ultra-deep sequencing ensure accurate, low-frequency mutation detection with minimal false positives. A digital health portal streamlines care with surgeon referrals for positive

Oris Bridge Digital Health Patient Navigator

To create the most patient-oriented process possible, OrisDX developed the Oris Bridge. This proprietary technology allows clinicians and patients to order test kits, track the process, navigate insurance reimbursement, and effectively plan care

A recent study published in CANCER demonstrated the panel's 93% sensitivity and 99% specificity in detecting oral

93%
Sensitivity

Sensitivity measures a test's ability to correctly identify individuals with a disease, minimizing missed cases (false negatives).

99%
Specificity

Specificity reflects how well a test identifies individuals without a disease, minimizing incorrect diagnoses

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4. Morandi, L., et al. Clin Epigenet 9, 85 (2017). https://doi.org/10.1186/s13148-017-0386-7