OraLiva™

Provider Training Guide

Training Overview

Introduction

Workflow Review

Demo & Practice

Q&A

Next Steps

Oral Cancer

An Underdiagnosed Problem

54,000

new oral cancers annually in the U.S.[1]

<60%

5-year survival when detected late [2]

70%

new cases are diagnosed at a late stage [3]

[1]https://oralcancerfoundation.org/facts/
[2]*McRae MP, Cancer Cytopathol. 2020 Mar;128(3):207-220. PubMed Central PMCID: PMC7078980*
[3]Lingen MW, et al. "Evidence-based clinical practice guideline for the evaluation of potentially malignant disorders in the oral cavity." JADA 2017;148(10):712-727.e10.

Dental providers lack trusted tools

Visual Tactile Exam

Limitation

Hard to visually distinguish which lesions to refer

Limitation

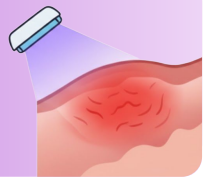
Over referrals

Missed cases

UV Light Tests

Limitation

Also flags inflammation and trauma



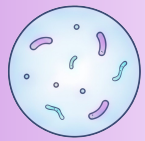
Limitation

Over referrals

Salivary Tests

Limitation

Early cancer doesn't shed enough biomarkers



Limitation

Missed cases

Visual screening is hard: In nearly **1-in-3** cases, **pathologists disagree** when evaluating dysplasia[1]

[1]Speight PM et al. Interobserver agreement in dysplasia grading. Oral Surg Oral Med Oral Pathol Oral Radiol. 2015;120:474-82, https://pubmed.ncbi.nlm.nih.gov/26216170/

OraLiva™

OraLiva's AI-enabled cytology test is one of the most accurate models for the accurate early detection and monitoring of oral cancer ever created.

Science based on
1,000 patient prospective study
13M cells classified by pathology [1]

Turns subjective visual-tactile exam into objective test to improve detection, documentation and trust.

- 97% Accurate[1]
- D7288 Covered by Many Plans†
- Soft Brush Collection
- Clinically Validated

[1]*Abram TJ et al. Oral Oncol. 2019;92:6-11.*
[2]*McRae, McDevitt, Journal of Dental Research, 2021, 100, 479-486*

OraLiva in Practice

Typical dental practice with 3,600 visits/year

- 360 lesions seen per year
- 90 oral potentially malignant disorders
- 9.5 high-risk cases[1]

Metric	Visual–Tactile	**OraLiva**	Impact with OraLiva
Sensitivity	65%[2]	94 %	**83%** reduction in missed high-risk lesions
Specificity	75%[2]	92%	**68%** fewer over-referrals / unnecessary biopsies

OraLiva improves diagnostic accuracy, strengthens patient trust, and adds measurable revenue with a 5 minute sample collection

[1]Psoter WJ et al. Prev Med. 2019;124:117–123.
[2]Lingen MW, et al. "Evidence-based clinical practice guideline for the evaluation of potentially malignant disorders in the oral cavity." JADA 2017;148(10):712-727.e10.

OraLiva™

Workflow Training

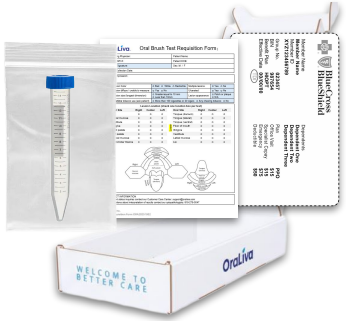
Workflow Overview

Sample Collection
by Provider
(billed by provider)

1 - Collect Sample

Collect sample from suspicious lesion with exfoliative brush

2 - Assemble Kit



Return kit components to sample box

3 - Return Kit

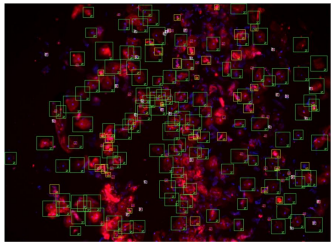
Use prepaid shipping label to return sample box

Sample Analysis
by OraLiva
(billed by OraLiva)

4 - Sample Processing

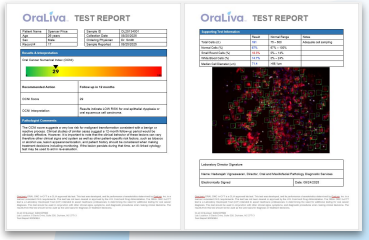
OraLiva receives and processes patient sample

5 - Sample Analysis



OraLiva AI analyzes cellular images based on 13M cell database

6 - Test Report



Easy to read actionable report digitally sent to ordering physician

Simple Billing and Reimbursement

Sample Collection

Conducted by	Provider
Billed By	Provider
Billed To	Dental Insurance
Code	D7288
Reimbursement by Delta Dental of MI & NC	$125
Average Reimbursement	~$55–$95

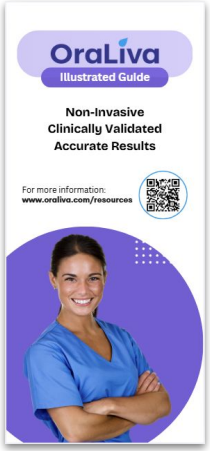
Sample Analysis

Conducted By	OraLiva Inc.
Billed By	OraLiva Inc.
Billed To	Medical Insurance
Code	88361 (balance billed)
Patient Out-of-Pocket Maximum	$99

OraLiva™ is a Proud Partner of DELTA DENTAL®

What's Included with the Test?

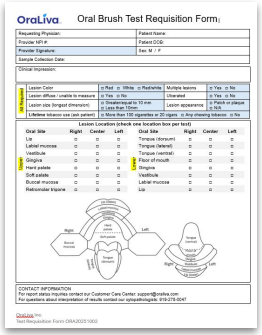
Illustrated Guide



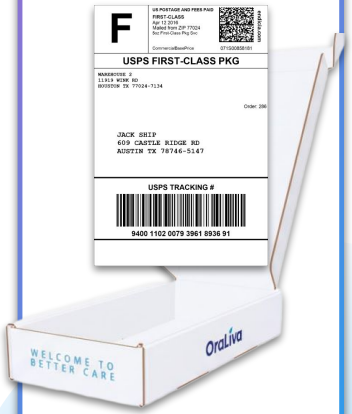
Sample Collection Tube

Orcellex® Brush

Test Requisition Form



Prepaid return box



Completing the Sample Kit: Sample Collection

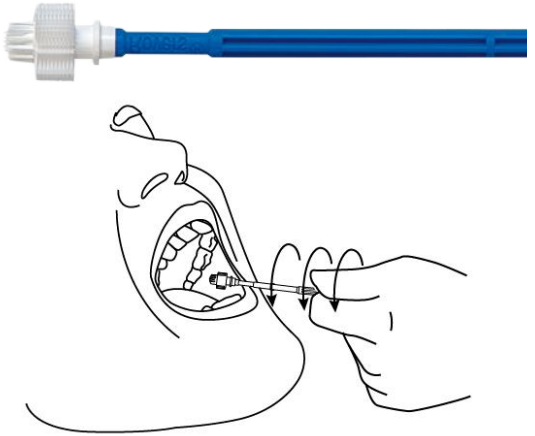
Which patients should I test?

If a patient presents with a lesion in the mouth, answering yes to any of the following questions should immediately confirm a test in indicated:

- Is the lesion larger than 10mm?
- Is the lesion red, or red and white in color?
- Is the patient a smoker?
- Is the patient over 60?

When in doubt, test

Orcellex® Brush



How to collect a sample

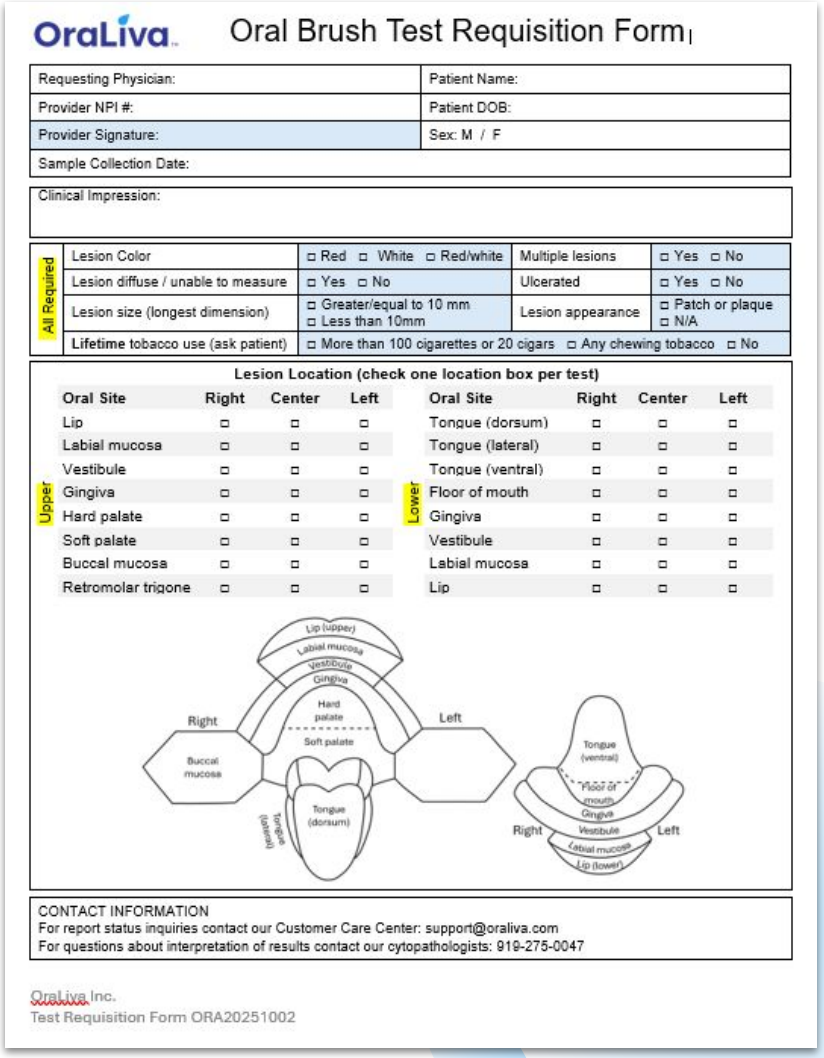
-Apply firm pressure
-15x turns
-If the lesion has heavy plaque or is thick layer, sample around the edge of the lesion.

Completing the Sample Kit: Requisition Form

Complete all sections of the **Test Requisition Form (TRF)** including:

- Patient information
- Clinical impression (single line of text describing the lesion)
- Check boxes for lesion characteristics
- Check one box for the lesion location

Ensure ordering physician signs the TRF



OraLiva Oral Brush Test Requisition Form

Requesting Physician:	Patient Name:
Provider NPI #:	Patient DOB:
Provider Signature:	Sex: M / F
Sample Collection Date:	

Clinical Impression:

All Required

Lesion Color	◻ Red ◻ White ◻ Red/white	Multiple lesions	◻ Yes ◻ No
Lesion diffuse / unable to measure	◻ Yes ◻ No	Ulcerated	◻ Yes ◻ No
Lesion size (longest dimension)	◻ Greater/equal to 10 mm ◻ Less than 10mm	Lesion appearance	◻ Patch or plaque ◻ N/A
Lifetime tobacco use (ask patient)	◻ More than 100 cigarettes or 20 cigars ◻ Any chewing tobacco ◻ No		

Lesion Location (check one location box per test)

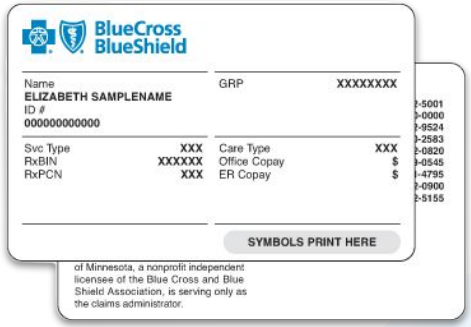
Upper — Oral Site	Right	Center	Left	Lower — Oral Site	Right	Center	Left
Lip	◻	◻	◻	Tongue (dorsum)	◻	◻	◻
Labial mucosa	◻	◻	◻	Tongue (lateral)	◻	◻	◻
Vestibule	◻	◻	◻	Tongue (ventral)	◻	◻	◻
Gingiva	◻	◻	◻	Floor of mouth	◻	◻	◻
Hard palate	◻	◻	◻	Gingiva	◻	◻	◻
Soft palate	◻	◻	◻	Vestibule	◻	◻	◻
Buccal mucosa	◻	◻	◻	Labial mucosa	◻	◻	◻
Retromolar trigone	◻	◻	◻	Lip	◻	◻	◻

CONTACT INFORMATION
For report status inquiries contact our Customer Care Center: support@oraliva.com
For questions about interpretation of results contact our cytopathologists: 919-275-0047

OraLiva Inc.
Test Requisition Form ORA20251002

Completing the Sample Kit: Medical Insurance

- ➔ Scan and print a copy of the patient's medical insurance card **(front and back)**
- ➔ Include a copy in the sample return box
- ➔ Patient will be balance billed by OraLiva with a maximum out-of-pocket of $99

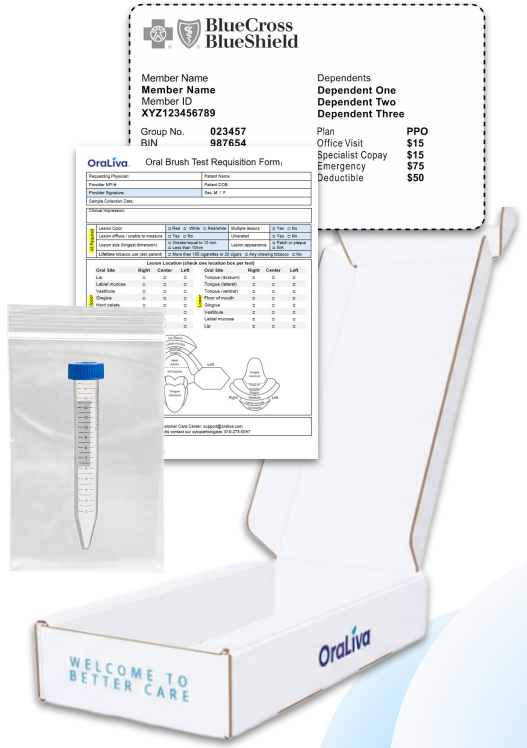


Completed Sample Return Box

- ✓ Test tube with brush head. Tube is returned to plastic bag
- ✓ Completed Test Requisition Form
- ✓ A scan of patient's medical insurance card

Close the Sample Return Box and return with prepaid shipping label

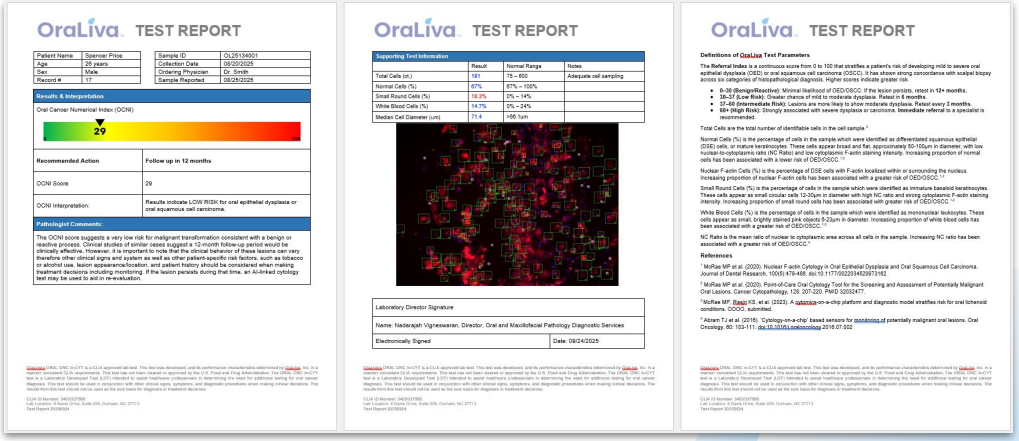
- Schedule pickup or drop off at any FedEx location



Understanding the Report

Once the Sample Return Box is sent to OraLiva's lab:

1. The lab will run a test of the sample, within 10 days.
2. OraLiva's lab will return the results to the provider via HIPAA-secure online portal.
3. The Test Report details OraLiva's findings and clinical recommendations
4. Provider discusses results with patient



OraLiva TEST REPORT

Patient Name	Spencer Price	Sample ID	OL26134001
Age	26 years	Collection Date	08/20/2025
Sex	Male	Ordering Physician	Dr. Smith
Record #	17	Sample Reported	08/25/2025

Results & Interpretation

Oral Cancer Numerical Index (OCNI)

29

Recommended Action	Follow up in 12 months
OCNI Score	29
OCNI Interpretation:	Results indicate LOW RISK for oral epithelial dysplasia or oral squamous cell carcinoma.

Pathologist Comments:

The OCNI score suggests a very low risk for malignant transformation consistent with a benign or reactive process. Clinical studies of similar cases suggest a 12-month follow-up period would be clinically effective. However, it is important to note that the clinical behavior of these lesions can vary therefore other clinical signs and system as well as other patient-specific risk factors, such as tobacco or alcohol use, lesion appearance/location, and patient history should be considered when making treatment decisions including monitoring. If the lesion persists during that time, an AI-linked cytology test may be used to aid in re-evaluation.

OraLiva TEST REPORT

Supporting Test Information

	Result	Normal Range	Notes
Total Cells (dc)	181	75 – 600	Adequate cell sampling
Normal Cells (%)	67%	67% – 100%	
Small Round Cells (%)	18.3%	0% – 14%	
White Blood Cells (%)	14.7%	0% – 24%	
Median Cell Diameter (um)	71.4	>66.1um	

Laboratory Director Signature	
Name: Nadarajah Vigneswaran, Director, Oral and Maxillofacial Pathology Diagnostic Services	
Electronically Signed	Date: 09/24/2025

OraLiva TEST REPORT

Definitions of OraLiva Test Parameters

The **Referral Index** is a continuous score from 0 to 100 that stratifies a patient's risk of developing mild to severe oral epithelial dysplasia (OED) or oral squamous cell carcinoma (OSCC). It has shown strong concordance with scalpel biopsy across six categories of histopathological diagnosis. Higher scores indicate greater risk.

- **0–36 (Benign/Reactive):** Minimal likelihood of OED/OSCC. If the lesion persists, retest in **12+ months**.
- **36–37 (Low Risk):** Greater chance of mild to moderate dysplasia. Retest in **6 months**.
- **37–60 (Intermediate Risk):** Lesions are more likely to show moderate dysplasia. Retest every **3 months**.
- **60+ (High Risk):** Strongly associated with severe dysplasia or carcinoma. **Immediate referral** to a specialist is recommended.

Total Cells are the total number of identifiable cells in the cell sample.[3]

Normal Cells (%) is the percentage of cells in the sample which were identified as differentiated squamous epithelial (DSE) cells, or mature keratinocytes. These cells appear broad and flat, approximately 50-100µm in diameter, with low nuclear-to-cytoplasmic ratio (NC Ratio) and low cytoplasmic F-actin staining intensity. Increasing proportion of normal cells has been associated with a lower risk of OED/OSCC.[1,2]

Nuclear F-actin Cells (%) is the percentage of DSE cells with F-actin localized within or surrounding the nucleus. Increasing proportion of nuclear F-actin cells has been associated with a greater risk of OED/OSCC.[1,2]

Small Round Cells (%) is the percentage of cells in the sample which were identified as immature basaloid keratinocytes. These cells appear as small circular cells 12-30µm in diameter with high NC ratio and strong cytoplasmic F-actin staining intensity. Increasing proportion of small round cells has been associated with greater risk of OED/OSCC.[1,2]

White Blood Cells (%) is the percentage of cells in the sample which were identified as mononuclear leukocytes. These cells appear as small, brightly stained pink objects 6-23µm in diameter. Increasing proportion of white blood cells has been associated with a greater risk of OED/OSCC.[1,2]

NC Ratio is the mean ratio of nuclear to cytoplasmic area across all cells in the sample. Increasing NC ratio has been associated with a greater risk of OED/OSCC.[1]

References

[1] McRae MP et al. (2020). Nuclear F-actin Cytology in Oral Epithelial Dysplasia and Oral Squamous Cell Carcinoma. Journal of Dental Research. 100(5):478-486. doi:10.1177/0022034520972182

[2] McRae MP et al. (2020). Point-of-Care Oral Cytology Tool for the Screening and Assessment of Potentially Malignant Oral Lesions. Cancer Cytopathology, 128: 207-220. PMID 32052477.

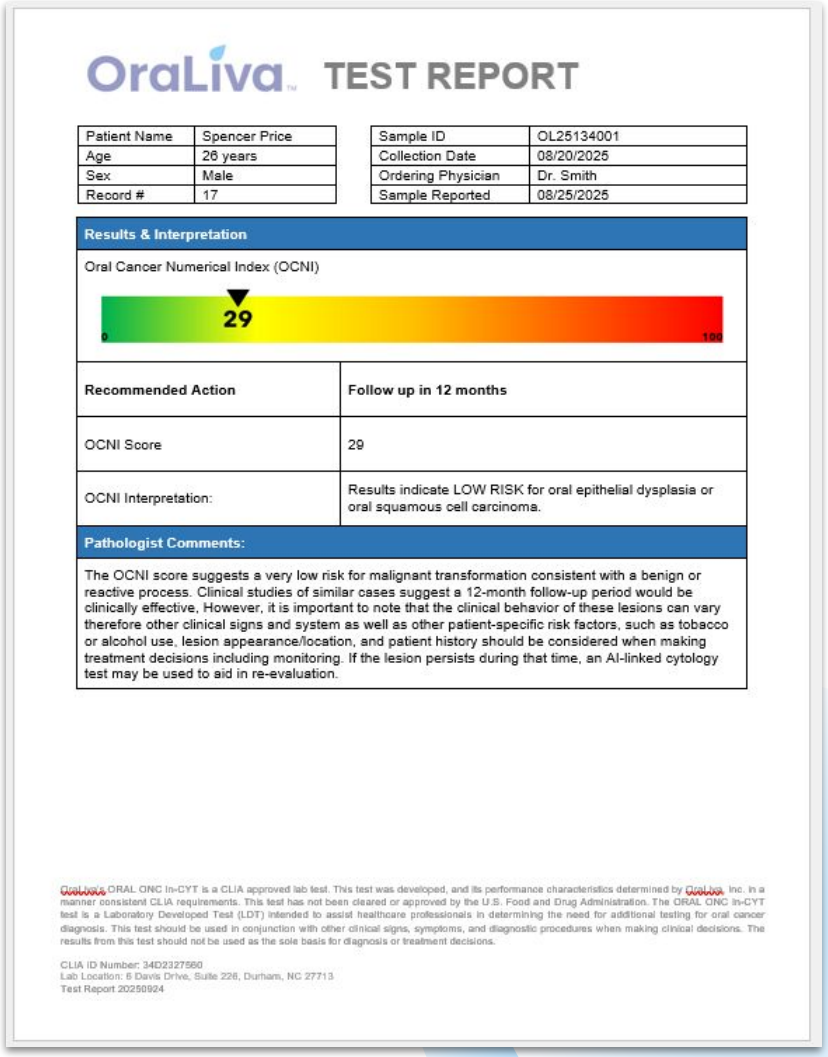
[3] McRae MP, Patel KS, et al. (2023). A cytology-on-a-chip platform and diagnostic model stratifies risk for oral lichenoid conditions. OOOO, submitted.

[4] Akram TJ et al. (2018). "Cytology-on-a-chip" based sensors for monitoring of potentially malignant oral lesions. Oral Oncology, 80: 103-111. doi:10.1016/j.oraloncology.2018.07.002

Understanding the Report: Page 1

Intended User: GP Dentist, OMS, Oral Pathologist

1. Oral Cancer Numerical Index (ONCI™). ONCI is an index quantifying the risk of the lesion in question.
2. Actionable Recommendation
3. Pathologist Comments



OraLiva™ TEST REPORT

Patient Name	Spencer Price
Age	26 years
Sex	Male
Record #	17

Sample ID	OL25134001
Collection Date	08/20/2025
Ordering Physician	Dr. Smith
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0 100

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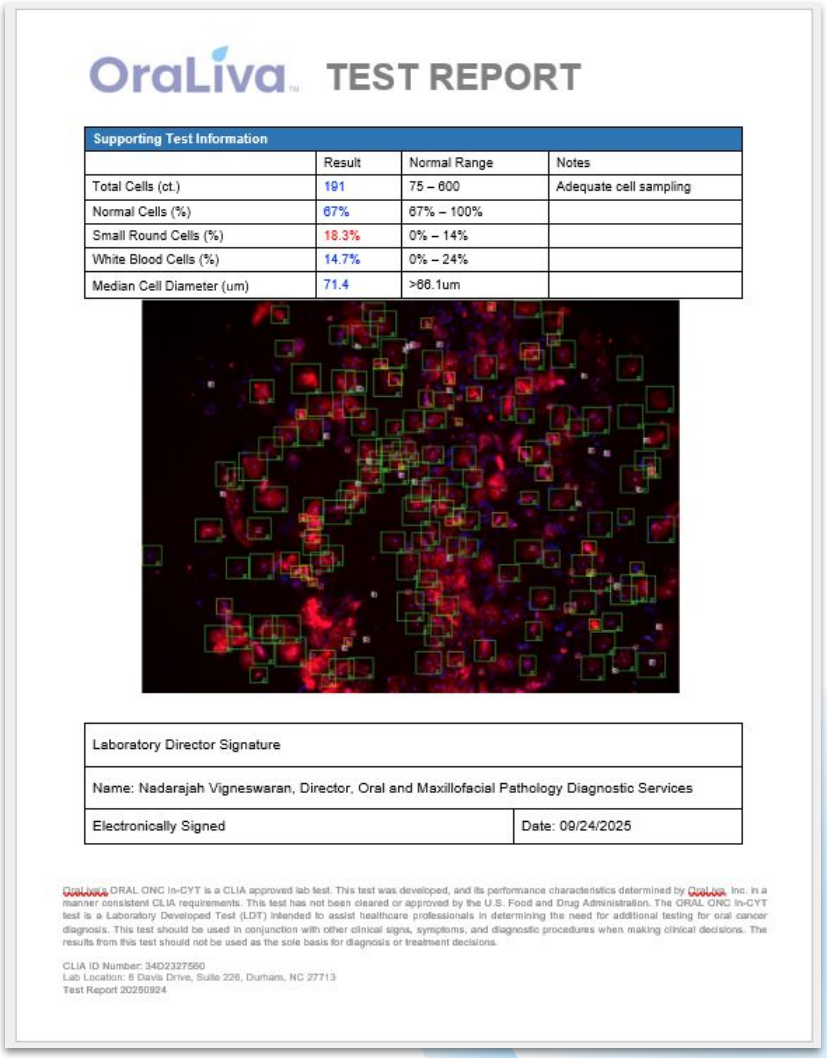
OraLiva ORAL ONC In-CYT is a CLIA approved lab test. This test was developed, and its performance characteristics determined by OraLiva, Inc. in a manner consistent CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. The ORAL ONC In-CYT test is a Laboratory Developed Test (LDT) intended to assist healthcare professionals in determining the need for additional testing for oral cancer diagnosis. This test should be used in conjunction with other clinical signs, symptoms, and diagnostic procedures when making clinical decisions. The results from this test should not be used as the sole basis for diagnosis or treatment decisions.

CLIA ID Number: 34D2327560
Lab Location: 6 Davis Drive, Suite 226, Durham, NC 27713
Test Report 20250924

Understanding the Report: Page 2

Intended User: OMS, Oral Pathologist

1. Cytologic test data
2. Cytologic image and AI overlay
3. Lab director signature



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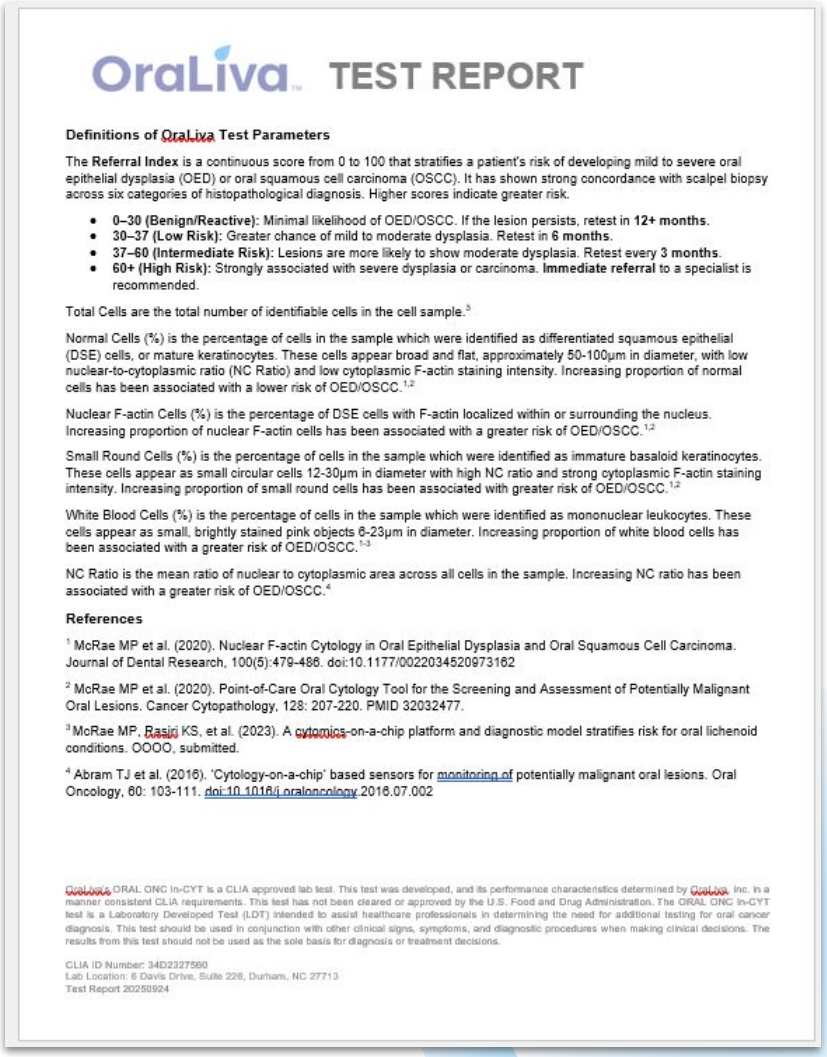
Test Report 20250924

Understanding the Report: Page 3

Intended User: GP Dentist, OMS, Oral Pathologist

1. Supporting test information
2. Citations and reference



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[3] McRae MP, Basiri KS, et al. (2023). A cytomics-on-a-chip platform and diagnostic model stratifies risk for oral lichenoid conditions. OOOO, submitted.

[4] Abram TJ et al. (2016). 'Cytology-on-a-chip' based sensors for monitoring of potentially malignant oral lesions. Oral Oncology, 60: 103-111. doi:10.1016/j.oraloncology.2016.07.002

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CLIA ID Number: 34D2327560
Lab Location: 6 Davis Drive, Suite 226, Durham, NC 27713
Test Report 20250924

Common FAQs

Who can collect the sample?
Any dental or medical provider — however hygienists should coordinate care with the dentist as the dentist will ultimately order the test.

When should I collect the sample?
Samples can be collected any time during a patient visit. Samples are not contaminated by use of cleaning products or any topical anesthetic. Patients can eat/drink prior to their visit.

Who reviews the test?
All samples are reviewed by a board-certified pathologist.

Does OraLiva increase my liability risk?
No — OraLiva reduces risk. Each test adds a pathologist reviewed, CLIA-certified report documenting diligence and improving defensibility.

Is the OraLiva test FDA-approved?
No, OraLiva has not yet received FDA clearance, but it is fully authorized for commercial use as a CLIA-validated Laboratory Developed Test (LDT)—the same regulatory pathway used for many routine medical diagnostics. LDTs are widely used, clinically validated, reimbursable, and trusted across healthcare.

Sample Collection Demo

(conducted with OraLiva rep)

OraLiva

Additional Resources
www.oraliva.com/resources/

Contact
support@oraliva.com