KNOWING EARLIER TO GIVE THEM A LATER®

Introducing the First and Only Tests to Aid in the Diagnosis of Oral Cancer by Detecting a Tumor-Initiating and Stem Cell-Associated Biomarker

The OncAlert® Oral Cancer product line is comprised of proprietary tests that detect CD44 and total protein. These tests are optimized for easy use by collecting samples via an oral saline rinse. The test results, along with other clinical factors, can aid in the early detection of oral cancer (including oral and oropharyngeal cancer).
Oral cancer is a global challenge with more than 529,000 cases and nearly 292,000 deaths each year.¹

**Worldwide 5-year survival rate is only 50%** due to delayed intervention with more than half of diagnoses at stage III and IV.²

Earlier detection (stage I and II) yields **survival rates up to 80%-90%**.²

**WHO IS AT RISK FOR ORAL CANCER?**

Oral cancer is common in both developed and developing countries.

- Prevalence is substantially higher among men
- Key risk factors are linked to preventable causes
  - Tobacco use: smoking or smokeless
  - Excessive alcohol use
  - Infection with human papillomavirus (HPV)

**MORE THAN HALF OF ORAL CANCER IS DETECTED IN STAGE III AND IV – OFTEN TOO LATE²**
THE FIRST AND ONLY TESTS TO IDENTIFY A TUMOR-INITIATING AND STEM CELL-ASSOCIATED BIOMARKER FOR ORAL CANCER

The OncAlert® Oral Cancer RAPID Test and OncAlert® Oral Cancer LAB Test are technologically advanced and highly accurate methods to aid in the early detection of oral cancer through the unprecedented detection of CD44 and total protein levels collected in an oral rinse.

CD44 is significantly overexpressed in oral cancer even in early stages.

The qualitative biomarker assay (OncAlert RAPID), with a negative predictive value (NPV) of over 90%, performs well in ruling out oral / oropharyngeal cancer when a reasonable suspicion exists.

ONCALERT: IMPROVING THE STANDARD OF CARE

<table>
<thead>
<tr>
<th>EXAMINATION TYPE</th>
<th>SENSITIVITY</th>
<th>SPECIFICITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional</td>
<td>64</td>
<td>31-76</td>
</tr>
<tr>
<td>OncAlert RAPID</td>
<td>71-84*</td>
<td>30-50*</td>
</tr>
<tr>
<td>OncAlert LAB</td>
<td>80**</td>
<td>93**</td>
</tr>
</tbody>
</table>

*Sensitivity or Specificity is dependent upon selected biomarker threshold.

**Without clinical variables the OncAlert LAB Test will yield a false negative rate of 15% while the false positive rate is 52%. The biomarker assay performs well in confirming when there is a reasonable suspicion of cancer, but will not effectively assist in the discrimination of more benign processes.

OncAlert LAB, a quantitative algorithm which incorporates clinical variables with biomarker levels, provides better discrimination of cancer vs. benign processes.
Timely diagnosis of oral cancer has been challenging.

- Early lesions are often not visible, or they mimic other conditions
- Traditional palpation and visual examination cannot identify occult lesions
- Current testing options can be cumbersome, costly, and difficult to interpret

The fast, simple, and accurate OncAlert Oral Cancer tests can help aid diagnosis at an early stage.
The OncAlert Oral Cancer tests can easily be integrated into your practice for your at-risk patients.

- Requires no special training or equipment
- Can be easily administered by clinicians
- Combines with a visual and physical exam as part of a regular check-up
  - Is simple and painless for patients
  - Provides easy-to-interpret test results
  - Identifies patients who may need additional follow-up

The accurate, cost-effective tests can benefit nearly every adult, with particular emphasis on at-risk populations for oral cancer (i.e. current and former tobacco users, those who consume excessive alcohol, or those who may be infected with human papillomavirus).
ONCALERT
ORAL CANCER RAPID TEST
A SIMPLE, NON-INVASIVE TEST THAT DELIVERS ONSITE RESULTS IN 20 MINUTES

The OncAlert Oral Cancer RAPID Test provides a qualitative result, reporting either elevated or normal levels of oral cancer biomarkers.

QUICK RESULTS IN JUST 3 STEPS

SWISH
Patient swishes and gargles a sterile saline solution in mouth for 10 seconds

SPIT
Sample is collected in the specimen cup

SET
Test cassette is inserted into the specimen cup. Results should be read at 20 minutes

The OncAlert RAPID Test helps you easily identify the presence of biomarkers associated with oral and oropharyngeal cancer.

Discard test after use. Results may not be valid after 20 minutes.

Patients should not smoke, eat, drink or brush their teeth at least one hour prior to testing.
DISCUSSING ONCALERT RAPID TEST RESULTS WITH YOUR PATIENTS

*If control line does not appear, discard the test and do not use the results.*

(A positive test is read when either the CD44 OR total protein test strip shows a positive result.)

**TOTAL PROTEIN**

![Gradient Scale Image]

**CD44**

![Gradient Scale Image]

Test results should be assigned based on either the CD44 or Total Protein gradient scales.

**A healthcare professional may do one or more of these things:**

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Test Result</th>
<th>Test Positive</th>
<th>Test Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Lesion</td>
<td>+</td>
<td>- Take appropriate clinical action</td>
<td>- Based on clinical feature of lesion may watch and re-examine or biopsy</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Counsel patient that they have elevated markers</td>
<td>- Routine follow-up</td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Educate that lifestyle changes may decrease marker levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Order OncAlert LAB Test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-</td>
<td>Repeat RAPID Test</td>
<td></td>
</tr>
<tr>
<td>Without Lesion</td>
<td>-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This test and suggested guidance is not designed to take the place of clinical findings or healthcare provider judgment. It should only be used as an aid in diagnosis.
ONCALERT
ORAL CANCER
LAB TEST
QUANTITATIVE RESULTS THAT SUPPORT CONFIDENT DECISION-MAKING

The OncAlert Oral Cancer LAB Test delivers an accurate measure of oral cancer biomarkers

- Provides a quantitative, personalized result using an algorithm that incorporates important factors such as sex, age, race and tobacco use history
- Helps support decisions about further diagnostic tests, monitoring, and possible interventions

EASY TO USE AND UNDERSTAND

Samples are collected in office or clinic for testing at a reference laboratory

- Point-of-care, patient friendly sample collection
- Easy administration that fits into your office workflow
- Quantitative and objective results to aid in the diagnosis of oral cancer
HOW THE ONCALERT ORAL CANCER LAB TEST WORKS

This unique test is highly specific and sensitive, with high intra- and inter-assay reproducibility

- Quantitatively detects all CD44 isoforms and total protein
- Creates historical, longitudinal profile of patient’s oral/oropharyngeal cavity CD44 and total protein levels when incorporated in a follow-up
- The measurements are reported back to the clinician for use as an aid in diagnosis
- May reduce the incidence of false negatives compared to a conventional oral exam alone
- Incorporates clinical variables (e.g. age, sex, race, smoking history) for improved performance
- May be used following a positive RAPID test to improve discrimination between benign and malignant processes

DISCUSSING ONCALERT LAB TEST RESULTS WITH YOUR PATIENTS

A healthcare professional may do one or more of these things:

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<td>- Take appropriate clinical action</td>
<td>- Based on clinical feature of lesion may watch and re-examine or biopsy</td>
</tr>
<tr>
<td>Without Lesion</td>
<td>- Additional testing and follow-up</td>
<td>- Routine follow-up</td>
</tr>
<tr>
<td>- Repeat LAB Test</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This test and suggested guidance is not designed to take the place of clinical findings or healthcare provider judgment. It should only be used as an aid in diagnosis.
EARLY FRONTLINE IDENTIFICATION — enabling earlier intervention when outcomes are likely to be better

ACCURATE — the only product line that detects the tumor-initiating and stem cell-associated biomarker CD44 and total protein

NON-INVASIVE — in-office collection of oral rinse sample for the OncAlert Oral Cancer RAPID Test and the OncAlert Oral Cancer LAB Test

COST-EFFECTIVE — applicable for a broad range of patients

FAST — easy-to-interpret results in 20 minutes with OncAlert Oral Cancer RAPID Test

Give patients a better later, with the OncAlert Oral Cancer product line.

Order today through your local OncAlert Oral Cancer distributor or at www.oncalert.com

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Sources:
1 WHO 2014-2015 World Cancer Report

References:


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