

Press Inquiries

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Identafi™ 3000

Multi-Spectral, Oral Cancer Screening System

The deep penetrating power of Identafi™ 3000's multiple wavelengths is designed to enhance diagnostic efficacy as an adjunctive tool for early detection.

Trimira's™ new Identafi™ 3000 uses the Identafi™ Multi-Spectral Fluorescence and Reflectance technology to enhance visualization of mucosal abnormalities such as oral cancer or premalignant dysplasia that may not be apparent to the naked eye. Unlike other fluorescence technologies and dye systems, the Identafi™ 3000 is Multi-Spectral with three distinct color wavelengths, making it easier to distinguish lesion morphology and vasculature, potentially reducing false positives.

How It Works

The Identafi™ 3000 uses white, violet, and amber wavelengths of light to excite oral tissue in distinct and unique ways. As a result, biochemical changes can be monitored with fluorescence, while morphological changes can be monitored with reflectance. The combined system of fluorescence and reflectance uses the body's natural tissue properties as an adjunctive tool for oral mucosal examination.

Conventional examination of tissue is performed using a highly concentrated **White** light.

Wearing reusable Identafi™ 3000 filtered eyewear to enhance visual effects and allow transmission of reflected light, the health professional then switches to **Violet** for a second observation.

The clinician's filtered glasses block the violet excitation light and allow

the observation of the tissue's natural fluorescence. Violet light enhances normal tissue's natural fluorescence; however, suspect tissue appears dark because of its loss of fluorescence.

When suspect abnormalities are present the selector is switched to **Amber** light, which enhances normal tissue's reflectance properties so the clinician may directly observe the difference between normal and abnormal tissue vasculature. This can minimize the impact of confounders when screening for oral cancer.

Studies indicate abnormal tissue has a diffuse vasculature, whereas normal tissue vasculature is clearly defined. The combination of all three Multi-Spectral wavelengths provides the clinician with more visual information resulting in fewer false positives and increased confidence for recommending biopsies.



1. White



2. Violet



3. Amber

*Images courtesy of
Dr. Rebecca Richards-Kortum
& Dr. Ann M. Gillenwater*

ORAL CANCER - RISK FACTORS/CAUSES

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Oral Cancer – Risk Factors/Causes (in North America)

1. Tobacco & Alcohol – The most recognized and acknowledged is the use of tobacco (including smokeless) and alcohol.

2. Sexually Transmitted HPV-16 and -18 – Exposure to HPV-16 (human papilloma virus) is the fastest-growing risk factor for oral cancer. This is the same virus responsible for the vast majority of cervical cancers. The virus presents a fivefold increase in incidence under the age of 40, which means all patients over the age of 17 should be screened annually.

Why age 17? According to the CDC's Advisory Committee on Immunization Practices in recommending the new HPV vaccine "Gardasil" for cervical cancer prevention... "We chose 11 and 12 years because most girls have not had sex at that age." It added: "By 15 years of age, about 25% of American young people have become sexually active. And by age 17, 50% have already done so." – revolutionhealth.com

The HPV Connection – some startling statistics:

One of the most common virus groups in the world today – affecting the skin and mucosal areas of the body – is the human papilloma virus. More than 100 different types of HPV have been identified. Different types of HPV are known to infect different parts of the body. The most visible forms of the virus produce warts (papillomas) on the hands, arms, legs, and other areas of the skin. Most HPVs of this type are very common, harmless, noncancerous, and easily treatable. There are other forms of HPV which are sexually transmitted, and are a serious problem. The most common of these are; HPV- 16, -18, -31, and -45. These cancer-associated types of HPVs cause growths that usually appear flat and are nearly invisible, as compared with genital warts caused by HPV-6 and -11.

The FDA estimates that 70 percent of cervical cancers are associated with HPV-16 or -18. New studies have confirmed a significant link to oral cancer as well. In the oral environment, these manifest themselves primarily in the posterior regions, such as the base of the tongue, back of the throat (oropharynx), tonsils, and tonsillar pillars.

It has now been established that the path which brings people to oral cancer contains at least two distinct etiologies; one through tobacco and alcohol and another via HPV, particularly version 16, though other versions of the virus might be implicated as the research unravels further. There are further delineations that seem to be apparent between the two. In general, it appears that HPV-positive tumors occur most frequently in a younger group of individuals than tobacco-related malignancies. They also occur more frequently in white males, and in nonsmokers. The HPV group is the fastest-growing segment of the oral cancer population.

3. History of Oral Cancer – Patients who survive a first encounter with the disease have a 20 times higher risk of developing a second cancer; this increased risk can last for five to 10 years after the first occurrence.

4. Verrucous Leukoplakia – Approximately one-third become cancerous.

5. Erythroplakia – 91 percent show signs of dysplasia or malignancy.

6. Compromised Immune System – HIV

ORAL CANCER - DEFINITIONS / SIGNS AND SYMPTOMS

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Oral Cancer – Definitions / Signs and Symptoms

Oral cancer most commonly involves:

- the front two-thirds of the tongue
- the lining of the cheeks and lips (the buccal mucosa)
- the floor of mouth under the tongue
- the roof of the mouth (hard palate)
- the gums (gingiva)
- the small area behind the wisdom teeth (the retromolar trigone)
- the minor salivary glands.

Squamous Cell Carcinoma

Most oral cancers look very similar under the microscope and are called “squamous cell” carcinomas. These are malignant and tend to spread rapidly. Squamous epithelium is the tissue that lines the mouth, throat, tongue, and tonsils. These tissue cells are irregularly shaped and very flat. Squamous epithelium also lines other body cavities and capillaries to reduce friction, as well as lining the lungs to facilitate gas exchange.

Carcinoma is any malignant cancer that arises from epithelial cells. Carcinomas invade surrounding tissues and organs and may “metastasize,” or spread, to lymph nodes and other sites. Metastasis is the spread of a disease from one organ or body part to another nonadjacent organ or body part. Only malignant tumor cells and infections have the capacity to metastasize. Cancer cells can “break away,” “leak,” or “spill” from a primary tumor, enter lymphatic and blood vessels, circulate through the bloodstream, and settle down to grow within normal tissues elsewhere in the body.

Oral cancer is often detected late in development, when the possibility of metastasis is much greater. Like most cancers, cancer of the lip and oral cavity is best treated when found early — when cure rates are greater than 80 percent. Determination of the stage of cancer in the lip or oral cavity is important in order to plan the best course of treatment.

There are a number of stages:

- **Stage I.** The cancer is no more than 2 centimeters and has not spread to lymph nodes in the area.
- **Stage II.** The cancer is more than 2 centimeters but less than 4 centimeters and has not spread to lymph nodes in the area.
- **Stage III.** Either of the following may be true — the cancer is more than 4 centimeters; the cancer is any size but has spread to only one lymph node on the same side of the neck as the cancer.
- **Stage IV.** Any of the following may be true — the cancer has spread to tissues around the lip or oral cavity; the lymph nodes in the area may or may not contain cancer; the cancer is any size and has spread to more than one lymph node on the same side of the neck as the cancer, to lymph nodes on one or both sides of the neck, or to any lymph node that measures more than 6 centimeters.
- **Recurrent.** The cancer has returned after it has been treated. It may come back in the lip and oral cavity or in another part of the body.

The Most Common Symptoms of Oral Cancer include:

- A sore, lump or ulcer on the lip or in the mouth that does not heal
- A white or red patch on the gums, tongue or lining of the mouth
- Unusual bleeding, pain or numbness in the mouth
- Consistent oral pain or a feeling that something is caught in the throat
- Difficulty or pain with chewing or swallowing
- Swelling of the jaw causing dentures to fit poorly or uncomfortably
- Bad breath
- Abnormal taste in the mouth
- Tongue problems
- A lump in the neck
- Difficulty with jaw opening
- Tooth loosening
- Sensory loss of the face
- Difficulty swallowing