

OralAdvance™ Overview

When a dental health provider finds a suspicious oral lesion, PMI Labs' OralAdvance™ provides an easy and informative way to assess these lesions without waiting or sending patients for a biopsy.

OralAdvance™ helps dentists assess the malignant potential of suspicious oral lesions. It is a virtually painless, chair-side test where cells are collected via a soft brush from the lesion in question and sent to our lab for analysis. We perform a quantitative analysis on the amount of DNA in the cells collected to determine whether a lesion has features indicative of precancerous or cancerous changes.

The test consists of a sample collection kit containing a soft cytology brush for sample collection and proprietary quantitative cytology laboratory analysis conducted at PMI Labs in Vancouver, Canada. The turn-around time from PMI Labs receipt of sample to issue of electronic report is 2-3 working days. The cost of OralAdvance™ analysis is CAD\$150 and is the subject of whole or partial coverage from some dental insurance plans in Canada.

Performance

Multiple clinical studies of OralAdvance™ are underway and three projects are currently being written for publication. At this point, test performance in detecting moderate, severe dysplasia and cancer has been demonstrated in the range of 80-92% sensitivity (ability to find abnormality when present), 98-100% specificity (ability to confirm normal when normal).

Interpretation

OralAdvance™ is complementary to current care. The test is used once a suspicious lesion is found during a screening exam to determine malignant potential prior to biopsy.

Test results should be interpreted using clinical judgment in correlation with all relevant clinical information. If DNA abnormality is detected by OralAdvance™, the malignant potential of the lesion is very likely: the test is very specific for pre-malignant and malignant changes; thus, a thorough diagnostic workup is recommended. However, not all lesions with malignant potential display gross DNA abnormality and on rare occasion the brush may not collect representative material. Therefore, if the test result is negative (no DNA abnormality is detected) and the lesion persists after 3-4 weeks, it should be re-evaluated.

Technology

OralAdvance™ analysis combines advanced image cytometry technology and expert cytopathology assessment. PMI Labs has developed a proprietary cytometer ClearCyte™ that has received Canadian and European market approvals. This technology was developed in partnership with the BC Cancer Agency.

Cancer is a disease characterized by abnormal DNA. Measurement of the relative DNA content of cells (DNA ploidy) has long been recognized as a practical way of detecting extensive DNA abnormalities. These abnormalities are often signatures of cancer cells. DNA ploidy can be measured by image cytometry (computer-controlled high-resolution microscopy) of slide-based cytological specimens specifically stained for DNA.

ClearCyte™ makes measurements of thousands of cell nuclei and sort them according to their DNA content. DNA content provides the cytopathologist with an objective measure of large-scale DNA abnormality and can indicate precancerous or cancerous changes in the tissue area sampled. Furthermore, gross DNA abnormality (aneuploidy) has been shown to strongly correlate with lesion progression to cancer and poor prognosis.

About Oral Cancer

In Canada, an estimated 3500 people will be diagnosed with and 1200 will die of oral cancer each year.(i) This mortality rate is so high because most oral cancers are diagnosed after they have progressed to symptomatic late-stage disease, with at least 50% revealing regional metastases. Only 36% of all oral cancers are detected in their early stage – the same rate as cancer of the colon.

The main reason for this is that only in recent years has it been established that examination of oral soft tissue is the responsibility of a dentist. In fact, in British Columbia a comprehensive annual oral exam is now recommended for everyone over the age of 40.(ii)

(i) Canadian Cancer Statistics, Canadian Cancer Society.

(ii) Recommended by the BC Oral Cancer Prevention Program and the College of Dental Surgeons of BC.