

# Good News. Great Science.

A routine diagnostic test  
that can help you save lives



# A routine test that can help you prevent a devastating cancer

## Oral cancer rising in low risk groups<sup>1,2,3</sup>

- Oral cancer kills about as many Americans as melanoma and twice as many as cervical cancer
- Oral cancer is rising in women<sup>1</sup>, young people<sup>2</sup> and non-smokers<sup>2</sup>
- At least 25% of oral cancer victims have no known risk factors<sup>3</sup>

## Finding cancer is too late

- By the time a lesion appears suspicious for cancer, it is generally dangerous, often life-threatening
- **Mortality rates have not decreased in 50 years due to late detection<sup>4</sup>**

<sup>1</sup> American Dental Association. Oral Cancer. Available at [www.ada.org/public/topics/cancer\\_all.asp](http://www.ada.org/public/topics/cancer_all.asp). Accessed Feb 17, 2010

<sup>2</sup> Llewellyn CD, Johnson NW, Warnakulasuriya KA. Risk factors for squamous cell carcinoma of the oral cavity in young people--a comprehensive literature review. *Oral Oncol.* Jul 2001;37(5):401-418.

<sup>3</sup> <http://www.ada.org/2607.aspx>

<sup>4</sup> Neville BW, Day TA. Oral Cancer and Pre-Cancerous Lesions. *CA Cancer J Clin.* 2002;52 (4):195-215.



# Finding dysplasia while still harmless is the key to preventing oral cancer

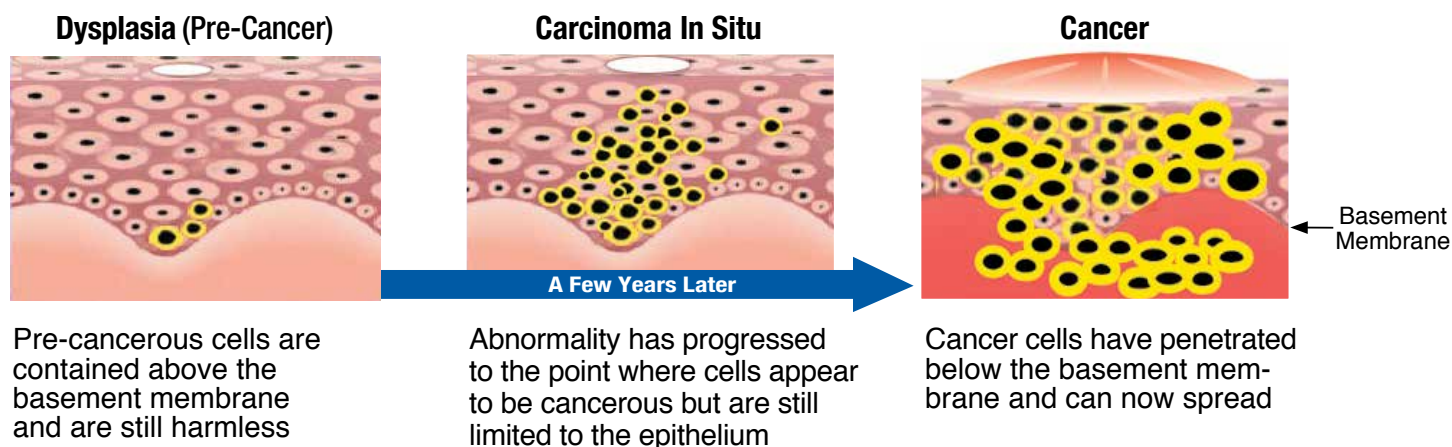
**Dysplasia (pre-cancer) first presents as a red or white spot in the mouth that looks identical to common tissue changes.**



All of these examples were confirmed dysplasias

- Small spots are routinely seen in the mouth. Approximately 4% are dysplastic.<sup>5</sup>
- OralCDx, a laboratory tissue test, allows you to painlessly differentiate between healthy and abnormal tissue to rule out dysplasia.

**If not detected, dysplasia may progress to become invasive oral cancer**



**Painlessly rule out dysplasia**



<sup>5</sup> Christian DC. Computer-assisted analysis of oral brush biopsies at an oral cancer screening program. J Am Dent Assoc 2002;133:357-362

# Preventing oral cancer starts by examining all areas of your patient's mouth

## How to find dysplasia



Studies have shown that **10% of patients have a white or red tissue change or spot of unknown cause<sup>5,6</sup>**

Visually examine all areas of your patients' oral mucosa for red or white spots. Include the lips, cheeks, all sides of the tongue, top of the mouth, floor of the mouth.



**When indicated, perform the OralCDx Brush Biopsy to help rule out dysplasia.**

The patented biopsy brush allows the doctor to collect a full tissue sample down to the basement membrane.

<sup>5</sup> Christian DC. Computer-assisted analysis of oral brush biopsies at an oral cancer screening program. J Am Dent Assoc 2002;133:357-362

<sup>6</sup> Lingen, M.W., et al., Critical evaluation of diagnostic aids for the detection of oral cancer. Oral Oncol, 2007.

## OralCDx: the dysplasia experts



Once the sample has been collected, the specimen is sent to CDx to be analyzed by specially trained pathologists aided by a proprietary computer network.

Every cell on the slide is evaluated.

# Rely on CDx<sup>®</sup>, the world's largest specialized oral pathology lab

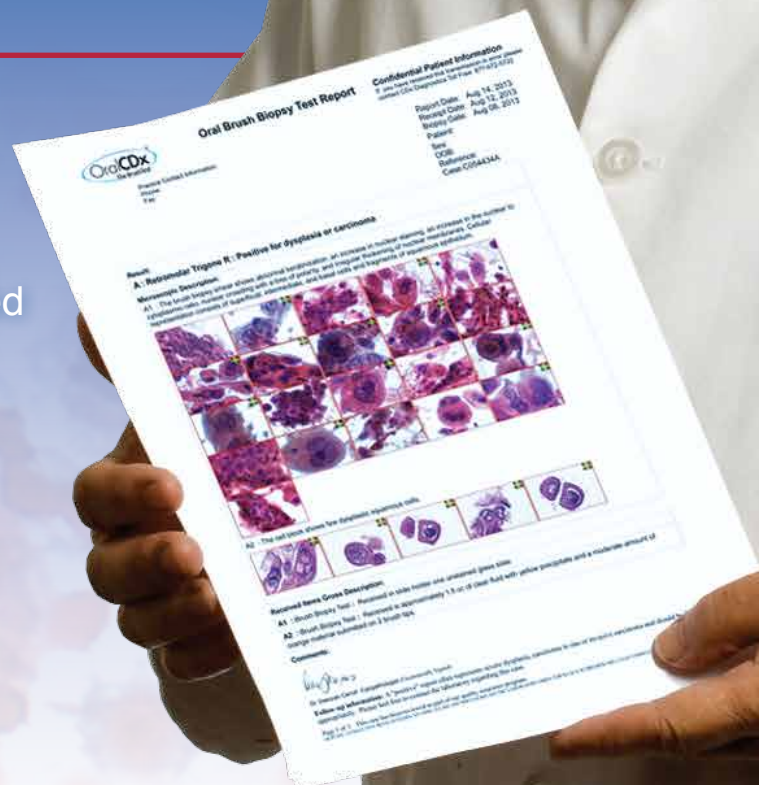


Over **10,000**  
oral pre-cancers detected

- Advanced pathology and missile defense computer science are used to analyze each specimen
- OralCDx provides you with a definitive lab report and personalized follow-up suggestions



THE POWER TO PREVENT™



# OralCDx®

## An important advance for your patients...

### Excellent Patient Acceptance:

- OralCDx® is an easy-to-perform, minimally-invasive, in-office procedure
- Cancer prevention message is well-received by patients

**Only OralCDx allows you to provide every patient with the peace of mind that comes from painlessly detecting dysplasia to help stop the progression to oral cancer.**



# and your practice

## Easy Practice Implementation:

- Takes only minutes to perform
- Mouth map available to document examination
- Patient communication materials provided
- Pathology report with representative cellular images
- Clinical support team provides you with patient specific follow-up suggestions



THE POWER TO PREVENT™



## Testing routine tissue changes in your patients' oral mucosa can help prevent a major cancer that is rapidly increasing in low risk groups

- Every oral carcinoma starts as a small white (leukoplakia) or red (erythroplakia) harmless-appearing tissue change
- Studies show that, upon examination, 10% of patients have a white or red tissue change or spot of unknown cause<sup>5,6</sup>
- Although most spots are harmless, OralCDx<sup>®</sup> is the only painless way to know that none of these tissue changes contains pre-cancerous cells

## 2 Simple Steps that give you "The Power to Prevent"

- 1** Examine all areas of your patients mouth for red or white changes
- 2** Perform an OralCDx Brush Biopsy when indicated to help rule out dysplasia while it is still harmless.

## 10 Years of Demonstrated Clinical Efficacy

In every study in which the same tissue was simultaneously tested by both OralCDx and a scalpel biopsy, the OralCDx Brush Biopsy was found to be at least as sensitive in ruling out dysplasia and cancer.<sup>7,8,9</sup>

Measured False Negative Rate = 0%.  
Statistical False Negative Rate < 4%, p<.05  
Measured False Positive Rate (OralCDx "Positive" Result) = 0%.  
Statistical False Positive Rate (OralCDx "Positive" Result) <3%, p<.05  
J Am Dent Assoc 1999;130:1445-1457

<sup>7</sup> Sciubba JJ and the U.S. Collaborative OralCDx Study Group. Improving detection of precancerous and cancerous oral lesions: Computer-assisted analysis of the oral brush biopsy. U.S. Collaborative OralCDx Study Group.; J Am Dent Assoc 1999; 130:1445-1457.

<sup>8</sup> Scheifele C, Schmidt-Westhausen AM, Dietrich T, Reichart PA. The sensitivity and specificity of the OralCDx technique: evaluation of 103 cases. Oral Oncol. Sep 2004; 40(8):824-828.

<sup>9</sup> Mehrotra R, Hullmann M, Smeets R, Reichert TE, Driemel O. Oral Cytology Revisited. Journal of Oral Pathology and Medicine 2009; 38(2):161-166.