

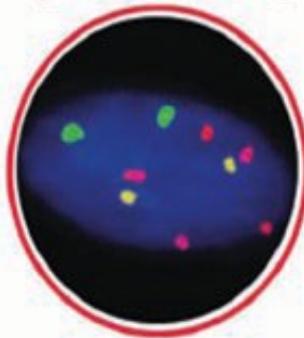
ORA-GEN-DTEST™

A New Genomic tool for
identifying early carcinogenesis
in squamous neoplasia

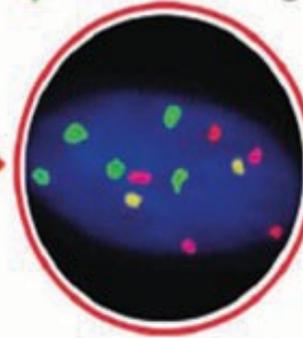
Based on biomarkers discovered at the

NATIONAL
CANCER
INSTITUTE

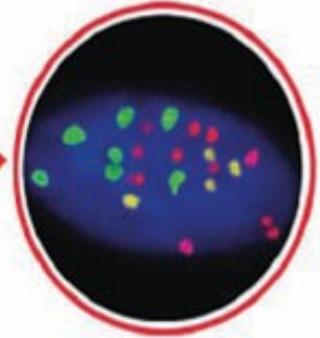
3q26 DNA Damage



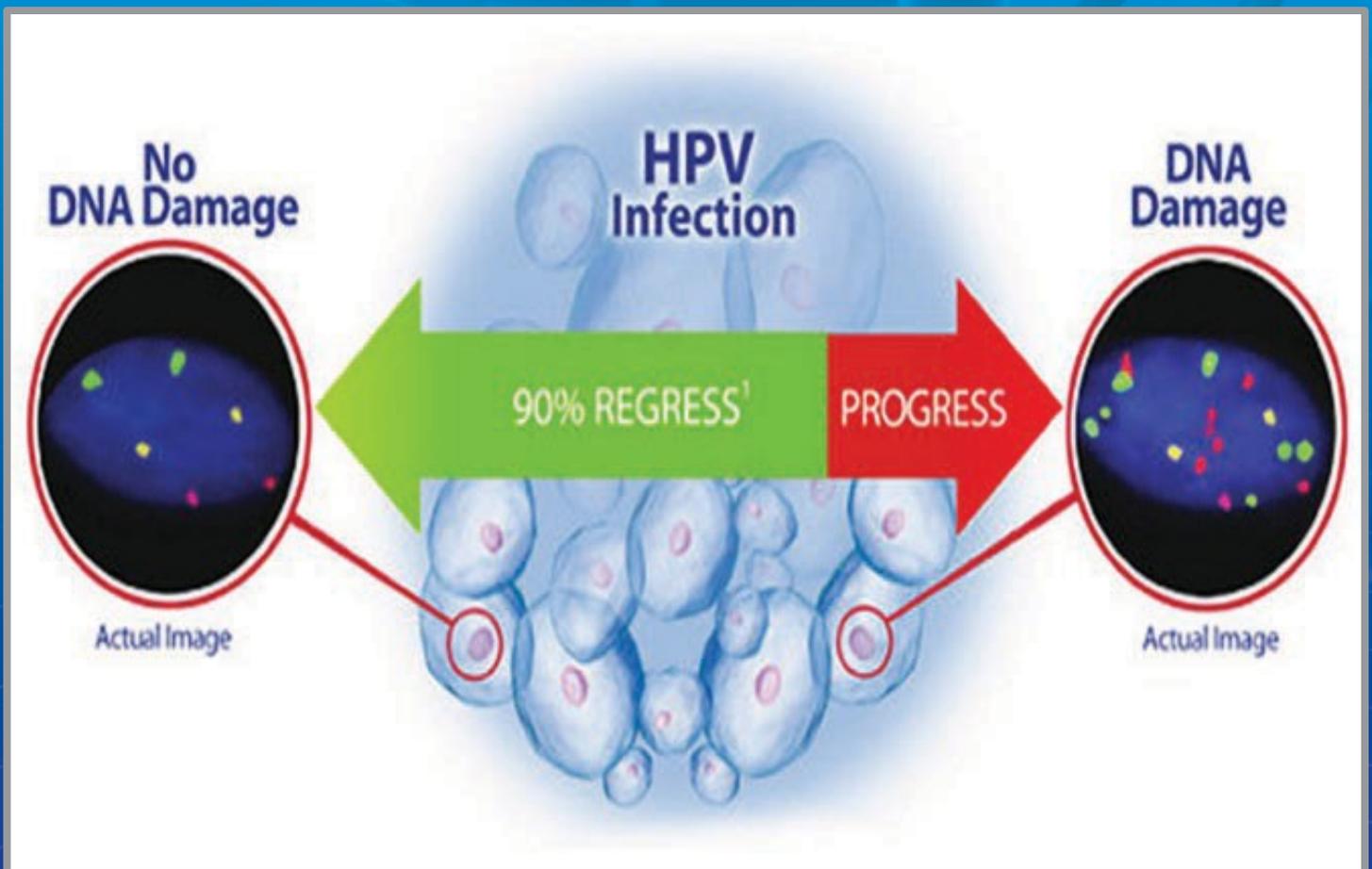
5p15 DNA Damage



Carcinoma



SQUAMOUS CANCER PROGRESSION



ONLY TECHNOLOGY THAT COMBINES HISTOLOGIC, MOLECULAR AND CLINICAL PARAMETERS TO PREDICT DISEASE PROGRESSION

HISTOLOGIC

- Quantitatively captures and analyzes cellular features
- Pathologist selects the most representative tumor area for analysis

MOLECULAR

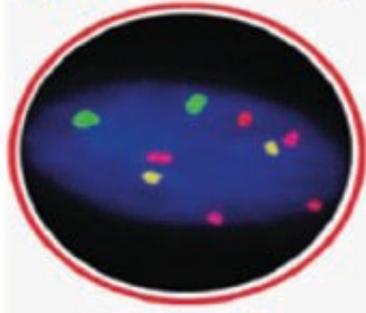
- Fluorescent in-situ hybridization captures loss, translocation or duplication of a gene.
- Computer digital imaging quantifies and captures biologic results.

CLINICAL

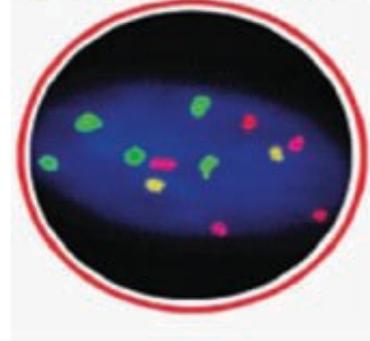
- Clinician incorporates clinical features to complete patient analysis.

3q26 and 5p15

3q26 DNA Damage



5p15 DNA Damage



ORA-GEN-DTEST™ is a fluorescent–in-situ hybridization (FISH) test for determining the acquisition of specific chromosomal aneuploidies (within the 3q26 and 5p15 regions). The test is performed on oral biopsies or oral cytology specimens. It assesses amplification of the 3q26 and 5p15 regions by the two fish probes and a control probe on chromosome 7. The results obtained are to be used with other clinical findings for further evaluation and monitoring of squamous neoplasia.

Diagnostic Applications

We have used multiple scientific disciplines to predict disease progression at the time of diagnosis.

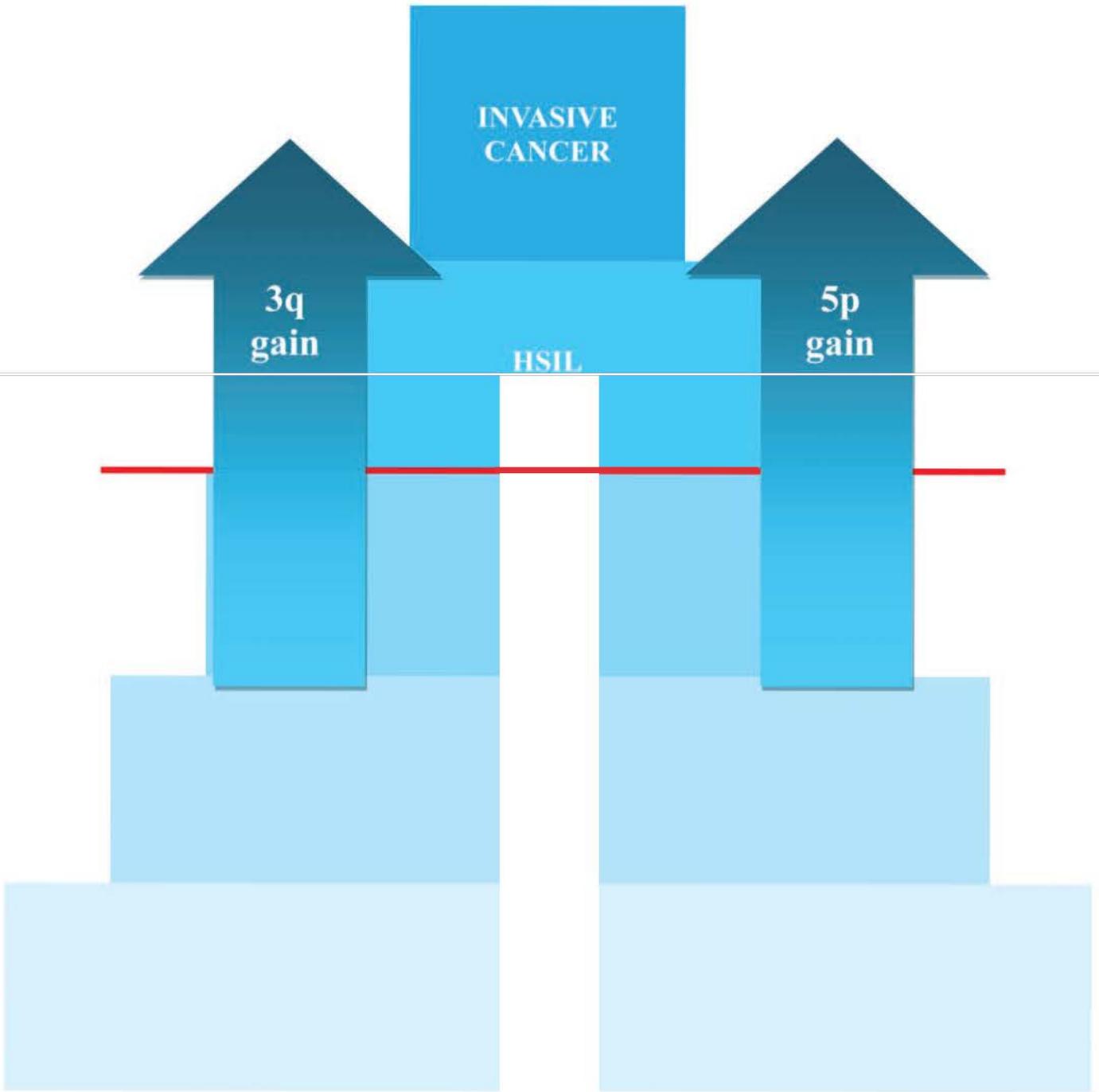
- Conclusion from numerous Squamous Cancer Studies
- Highly Sensitive and Specific test
- Prediction of progression risk of low-grade lesions
- Excellent correlation with histology
- Sample Flexibility (Liquid cytology, Biopsy)

INVASIVE
CANCER

3q
gain

HSIL

5p
gain



ORA-GEN DTEST™

SunCoast Pathology Associates offers the ORA-GEN-DTEST™ in conjunction with other clinical findings, to better manage these patients. Among the chromosomal changes associated with squamous cancer, the most consistent abnormalities detected involve 3q26, 5p15 and chromosome 7. Studies have shown that at least 90% of invasive squamous cancer cases have gains in these chromosomal markers. Additional research has demonstrated a correlation between the gain in the 3q26 as the severity and stage of squamous neoplastic disease prognosis. Using the fluorescent-in-situ hybridization (FISH) probes to look at the progression of individual patients; it has been that the sensitivity of these loci (3q26 and 5p15) for predicting progression from CIN1/CIN2 to CIN3 was 91% specificity, i.e. the prediction of regression was 70%. This genomic FISH probe for 3q26 and 5p13 is a test that the medical profession can use, in conjunction with other clinical data, to aid in management.

ORA-GEN-DTEST™ combines histologic, molecular and clinical parameters to predict disease progression. This test delivers clinically proven, reliable results providing physicians and patients with enhances insight for treatment decisions. ORA-GEN-DTEST™ generates a personalized, clinically proven, genetic prediction of risk of disease progression or favorable genetic prognosis.

REFERENCES

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