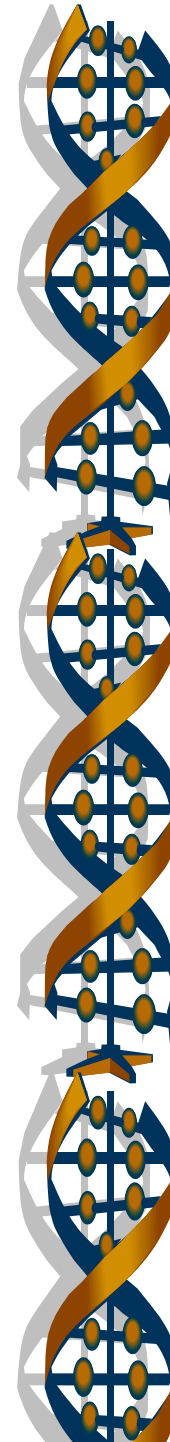


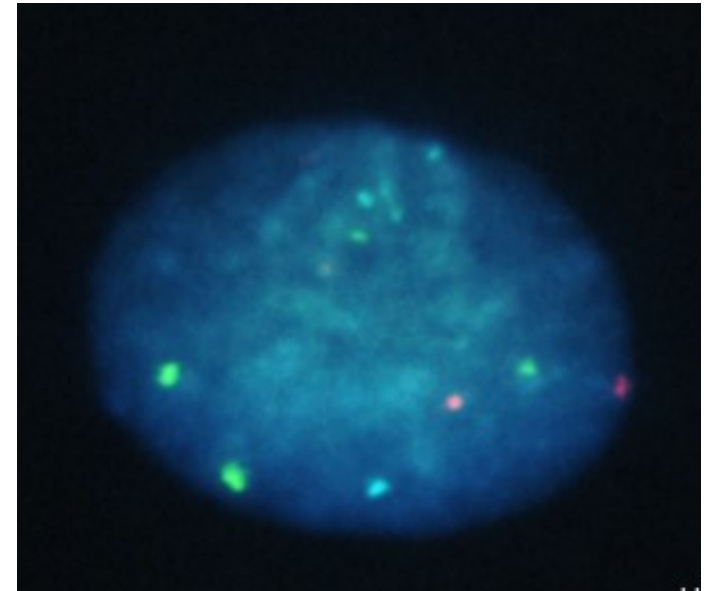
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Disclaimer: This laboratory test was developed and its performance determined by multiple laboratories among them National Cancer Institute and SunCoast Pathology Associates. This test has not been cleared or approved by the US FDA, although such approval is not required for clinical implementation. SunCoast Pathology Associates is CLIA certified to perform high complexity testing.



CERVI-GEN-DTEST™
Personalized genomic testing for cervical cancer



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Patients with ASCUS/HPV+ on LSIL (low grade squamous intraepithelial lesions) PAP results present challenges for appropriate case management. Approximately 30% of patients with a PAP diagnosis of ASCUS/HPV+ or LSIL may actually progress toward cervical cancer, additional diagnostic information is needed. Which patients with LSIL will progress clinically to a higher grade? Which will regress to normal? A more predictive tool to assist the clinician in managing these patients has not been available until now.

SunCoast Pathology Associates offers the CERVI-GEN-DTEST™ in conjunction with other clinical findings, to better manage these patients. Among the chromosomal changes associated with cervical cancer, the most consistent abnormalities detected involve 3q26, 5p15 and chromosome 7. Studies have shown that at least 90% of invasive cervical 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 cervical 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 of ASCUS/LSIL patients prior to colposcopy.

CERVI-GEN-DTEST™ is a fluorescent-in-situ hybridization (FISH) test for determining the acquisition of specific chromosomal aneuploids (within the 3q26 and 5p15 regions). The test is performed on cervical biopsies or cervicovaginal cytology specimens. It assesses amplification of the 3q3+ 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 cervical dysplasia in women with LSIL.

CERVI-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. CERVI-GEN-DTEST™ generates a personalized, clinically proven, genetic prediction of risk of disease progression or favorable genetic prognosis.

