References:

Disclaimer: This laboratory test was developed and its performance determined by multiple laboratories among them Predictive Biosciences 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.
SunCoast Pathology introduces personalized, breakthrough Genomic test panels for molecular analysis of prognostic indicators for prostate and bladder cancer.

SunCoast Pathology Associates introduces PROSTA-GEN-DX™ - a breakthrough genomic diagnostic and prognostic indicators for prostate cancers. This is a proprietary test in risk assessment for progression and prognosis of prostate cancers. This test uses fluorescent-in-situ hybridization (FISH) to examine specific genetic information in your chromosomes that has been correlated with increased progression of your disease.

This information obtained, in addition to your biopsy, would assist in treatment and management of your disease. This genomic information better differentiates increased risk for further tumor progression and behavior.

PROSTA-GEN-DX™ looks at genetic information located in chromosomes 10(q23.3) for PTEN and on chromosome 21(q22) for TMPRSS2:ERG. These results help guide treatment decisions.

PTEN (phosphatase and tension homolog) is a key tumor suppressor gene in various cancers. Deletion of PTEN occurs in 20-40% of localized prostate cancer and up to 60% of metastasis. Its deletion is associated with tumor recurrence. PTEN encodes a phosphatase that regulates a critical cell cycle involved in cell proliferation. When PTEN is deleted or otherwise inactivated, cell division continues unchecked, causing progression of cancer. PTEN deletions have been shown to correlate with poor outcome and varying stages of disease in prostate cancer.

TMPRSS2:ERG gene fusions are one of the most common genomic aberrations documented in prostate cancer. These are found in approximately 40% of primary prostate cancers. Studies have found that TMPRSS2:ERG gene fusions and translocations are associated with a more aggressive phenotype that correlates with cancer stage, Gleason score, tumor grade, and cancer specific survival rate.

PROSTA-GEN-DX™ analyzes these markers because each examines a major mechanism of prostate carcinogenesis: fusion/translocation and the loss of a tumor suppression gene. By examining these markers at the chromosomal level, PROSTA-GEN-DX™ is able to provide a molecular analysis of the aggressiveness of the patient’s prostate cancer and their long-term prognosis. It provides a useful, cost effective, and actionable prognosis information.

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