

Reporter Backgrounder: Oncotype DX Genomic Prostate Score[®] (GPS[™])

Optimizing Prostate Cancer Treatment

In the U.S. alone, more than 160,000 men are diagnosed each year with clinically low-risk disease that is unlikely to progress or spread. Yet, the majority of these patients receive immediate aggressive treatment such as surgery or radiation, which may result in significant complications, including impotence and incontinence.

The Oncotype DX[®] GPS test can help optimize treatment selection, allowing men with low-risk disease to more confidently choose active surveillance, while also identifying those with more aggressive tumor biology who should be more aggressively treated at diagnosis.

What is the Oncotype DX GPS Test?

The GPS test is the only genomic assay designed and validated for men with clinically low-risk or favorable intermediate-risk cancer to help make treatment decisions at diagnosis.

Developed by Genomic Health, based on results from multiple studies led by Cleveland Clinic and the University of California, San Francisco, the GPS test optimizes treatment by providing physicians with an assessment of both the current status and future risk of a patient's cancer to help them make a confident treatment decision.

Additionally, the GPS test is included within National Comprehensive Cancer Network (NCCN) Guidelines[®] as a Category 2A molecular testing option for consideration in prostate cancer patients with clinically low-risk and favorable intermediate-risk disease.

How Does the Test Work?

The Oncotype DX GPS test analyzes prostate cancer gene activity in the patient's individual tumor using tissue removed during biopsy to better understand the unique biology of his cancer – a science known as genomics. The test provides a GPS result with a number ranging from 0-100 that corresponds to the biologic aggressiveness of the tumor in the prostate and the patient's likelihood of prostate cancer metastasis and death at 10 years.



Jim, Oncotype DX GPS-tested patient

**ACTIVE
SURVEILLANCE**

This is the program of regular monitoring of the cancer that helps some patients avoid side effects of unnecessary immediate invasive treatment.

OVER 50% OF NEWLY-DIAGNOSED MEN HAVE **LOW-RISK PROSTATE CANCER** THAT IS UNLIKELY TO SPREAD.



YET A MAJORITY OF THEM RECEIVE IMMEDIATE AGGRESSIVE TREATMENT which may lead to impotence and incontinence.

What Does Research Say?

The collective published clinical utility evidence for the Oncotype DX GPS test includes four studies in over 5,000 men, demonstrating the actionable impact of the test in treatment planning. The GPS test was specifically developed and validated to assess the aggressiveness of prostate cancer prior to treatment intervention. A positive clinical validation study led by UCSF showed that the GPS test strongly predicted the likelihood of aggressive disease at the time of biopsy, offering information beyond currently available clinical factors and potentially tripling the number of patients who can confidently choose active surveillance and avoid side effects of invasive treatments. This study was published in *European Urology*.

A second clinical validation study conducted in collaboration with the Center for Prostate Disease Research and published in *European Urology*, reconfirmed the biopsy-based GPS test as a predictor of adverse pathology at biopsy, and validated the test as a strong independent predictor of PSA following surgery. This study also demonstrated that the Oncotype DX GPS test was similarly predictive of outcomes in Caucasian and African-American men.

A third multi-center clinical validation study, conducted at Kaiser Permanente, confirmed that the GPS test is a strong independent predictor of prostate cancer-specific death and disease progression (metastases) at 10 years in treated men with localized prostate cancer across all NCCN clinical risk groups.

Multiple independent studies have also demonstrated that the GPS test helps identify men with higher-risk disease who may need to be treated more aggressively at the time of diagnosis.

“No other test has this type of impact on driving guideline-based recommendations for qualified patients,”

- Steven Canfield, M.D., chief of urology at UT Health McGovern Medical School

Is It Covered by Insurance?

The GPS test is covered by Medicare and multiple private insurance companies in the United States.