

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

Addressing the Overtreatment of Prostate Cancer

More than 240,000 men are diagnosed with prostate cancer each year in the United States, and more than half are estimated to have clinically low- and intermediate-risk disease. Most of these men receive immediate aggressive treatment such as radiation or surgery to remove the prostate, despite the cost, minimal benefit and risk of serious side effects such as incontinence and impotence. There is growing evidence that many prostate cancers can be safely managed with active surveillance, a program of regular monitoring of the cancer that helps some patients avoid 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 is the Oncotype DX Genomic Prostate Score test?

The Oncotype DX Genomic Prostate Score test is the only prostate cancer genomic test validated to predict both near-term adverse pathology and long-term outcomes such as prostate cancer-specific death and development of metastases. It was developed in collaboration with the University of California, San Francisco (UCSF) and Cleveland Clinic to specifically address the challenges inherent in prostate cancer risk assessment. Results are reported as a Genomic Prostate Score (GPS[™]), which can help patients and their doctors confidently make decisions about a management plan that's best for them.

THE ONLY GENOMIC TEST DESIGNED TO HELP MAKE TREATMENT DECISIONS AT THE TIME OF DIAGNOSIS

How Does the Test Work?

Performed on a small sample of tumor tissue removed during the biopsy, the Oncotype DX GPS test measures tumor biology through the expression of 17 genes across four important genetic pathways. In conjunction with other clinical factors, the test result – a GPS ranging from 0 to 100 – predicts an individualized risk of having adverse pathology, developing metastases and dying of prostate cancer. The GPS test enables confident treatment decision making by clarifying the current and future risk of a man's cancer prior to treatment intervention.



What Does Research Show?

- More than 22 studies including more than 4,200 patients have evaluated the Oncotype DX® Genomic Prostate Score™ (GPS™) test. The test has been validated in two large, contemporary studies as a strong, independent predictor of adverse pathology at the time of radical prostatectomy. The first-ever prospective validation study of a tissue-based molecular marker in prostate cancer reconfirmed that the GPS test is an accurate predictor of adverse pathology.
- A positive clinical validation study led by UCSF and published in European Urology showed that the GPS test strongly predicted the likelihood of aggressive disease at the time of the biopsy, offering information beyond currently available clinical factors and potentially tripling the number of patients who can confidently choose active surveillance.
- A second clinical validation study conducted in collaboration with the Center for Prostate Disease Research and published in European Urology reconfirmed the GPS test as a predictor of adverse pathology at surgery, 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 study in collaboration with Kaiser Permanente demonstrated that the GPS test is the only genomic prostate test validated in all major short- and long-term endpoints, including adverse pathology, biochemical recurrence, the development of metastases and prostate cancer-specific death. The study confirmed that the GPS test is a strong independent predictor of prostate cancer-specific death and disease progression (metastases) at 10 years in men with localized prostate cancer across all National Comprehensive Cancer Network clinical risk groups.
- Two clinical utility studies demonstrated how the Oncotype DX GPS test helps with treatment planning:
 - A prospective study assessed changes in urologists' treatment recommendations pre- and post-Oncotype DX GPS results. This decision-impact study demonstrated a 26% absolute change in management recommendations. Physician confidence improved in 85% of cases.
 - A retrospective study compared 6-month management received in clinically low-risk patients with and without the Oncotype DX GPS results. This chart-review analysis revealed a 56% relative increase in the number of patients on active surveillance at 6 months post-diagnosis when GPS testing was added to standard decision making tools.
- An analysis published in Urology demonstrated that the GPS test greatly increases use of and persistence on active surveillance.
- A comprehensive economic analysis published in Reviews in Urology demonstrated that use of the GPS test saves over \$2,000 per patient by optimizing care and healthcare spending.

“Data from actual patient charts add an important real-life perspective on the value of our test.”

- Phil Febbo, M.D., Chief Medical Officer, Genomic Health

“Genomic analysis provides information beyond traditional factors to enable us to more accurately distinguish aggressive or life-threatening disease from indolent disease. That's precision medicine in practice.”

- Eric A. Klein, M.D., Chairman, Glickman Urological and Kidney Institute, Cleveland Clinic

Is It Covered by Insurance?

Palmetto GBA, a Medicare Administrative Contractor that assesses molecular diagnostic technologies, has initiated reimbursement coverage of the Oncotype DX GPS test for qualified low- and very low-risk Medicare patients throughout the United States. Palmetto GBA has also issued a draft local coverage determination (LCD) for the GPS test recommending Medicare coverage for use of the test in qualified patients with favorable intermediate-risk prostate cancer. Once the new LCD has been finalized, the total number of Medicare patients eligible for GPS test coverage in the U.S. will be 80,000.