Oncotype DX prostate cancer test, 9/13

Genomic Health made its Oncotype DX prostate cancer test available recently after a presentation of a positive clinical validation study by the University of California, San Francisco, at this year's American Urological Association annual meeting.

Results showed that the test, developed in collaboration with the UCSF and Cleveland Clinic, strongly predicted disease aggressiveness (P=0.002). The multi-gene test has been validated to guide treatment decisions using the prostate needle biopsy sample taken before the prostate is removed.

In the UCSF validation study of 395 patients, adding the biological information revealed by the test's Genomic Prostate Score significantly increased the number of patients identified as having very low-risk disease (from five to 10 percent to 26 percent), making them appropriate candidates for active surveillance. More than one-third of patients originally classified as low risk based on clinical measures were identified by the GPS as very low risk and could confidently choose active surveillance. About 10 percent of patients originally classified as very low or low risk by clinical factors were identified by the GPS as having more aggressive disease.
To develop the Oncotype DX prostate cancer test, Genomic Health conducted, in collaboration with the

Cleveland Clinic, six feasibility and development studies evaluating more than 700 patients. In the development studies, an optimized RT-PCR platform was used to measure and analyze gene expression in prostate cancer tissue samples from radical prostatectomy and very small needle biopsy specimens. Of more than 700 candidate genes, 81 genes were selected to be tested in biopsy samples. The final analysis yielded 17 genes across four biologic pathways and a GPS to predict disease aggressiveness of the entire prostate before intervention.

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