

The 17-Gene Genomic Prostate Score Assay: Initial Commercial Experience of 2,500 Patients

Bela Denes*, Emily Burke, Megan Rothney, Athanasios C. Tsiatis, Michael Bonham, H. Jeffrey Lawrence, Phillip G. Febbo

*Genomic Health Inc., Redwood City, CA

Background: The Oncotype DX[®] Prostate Cancer Assay (Genomic Health Inc. Redwood City, CA) is a biopsy-based predictor of prostate cancer (PCa) aggressiveness and has been clinically validated to predict the likelihood of adverse pathology at time of diagnosis and biochemical recurrence (Klein Eur Urol. 2014, Cullen Eur Urol 2014). Here we report the clinical laboratory experience from the first 2,500 patients tested.

Methods: 2,500 samples that passed pathology review and RT-PCR quality measures were included. The Genomic Prostate Score (GPS, scale 0-100) was calculated based on the validated algorithm of 12 cancer-related and 5 reference genes. NCCN[®] clinical risk group classification was provided by submitting physicians. All submitted biopsy samples were centrally reviewed at GHI for Gleason score (GS). Descriptive statistics for the GPS were obtained.

Results: The mean GPS for the cohort was 24.5 (median 23, range 0-97). 1,966 submitted samples (78.6%) were GS 3+3 (mean GPS 22.6, range 0-97) and 534 samples were GS 3+4 (mean 31.2, range 0-80). By age, 77 patients (3.1%) were ≤50y, 650 (26.0%) 51-60y, 1,176 (47.0%) 61-70y, and 597 (23.9%) >70y, with a mean GPS result of 20.8 (range 0-64), 21.7 (range 0-79), 24.8 (range 0-97), and 27.3 (range 0-77), respectively. Of patients with NCCN risk classification provided (n=2,356), 28.9% (n=680) patients were classified as very low, 39.9% (n=940) low, and 31.2% (n=736) low-intermediate risk, and had a mean GPS of 22.3 (range 0-67), 22.8 (range 0-97), and 28.7 (range 0-85), respectively. Overall, use of the GPS changed the risk group in 26.0% (613/2,356) of patients with pre-assigned NCCN risk assessment. Amongst NCCN low risk patients, GPS changed risk estimation in 48.2% of patients; decreasing risk estimation from low to very low in 38.3% and increasing risk estimation from low to intermediate in 9.9% of cases.

Conclusion: The GPS results generated by our clinical laboratory from the first 2,500 biopsy samples displayed a wide range within each GS, age, and NCCN risk group, demonstrating a wide spectrum of underlying tumor biology within currently used clinical risk assessment categories. The risk group reclassification by the GPS is consistent with the results from the UCSF validation cohort. Use of the GPS provided improved risk stratification for men with newly diagnosed PCa, allowing physicians and their patients to make informed treatment decisions with more confidence regarding the initial management of their disease.