

[576] The 12-Gene Colon Cancer Assay: Experience With 12,776 Stage 2 Patients

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Background: Genomic assays have the potential to provide information beyond the traditional methods used for assessing risk of recurrence. The 12-gene Colon Cancer Assay (Oncotype DX) is clinically validated and predicts recurrence risk after surgical resection in patients (pts) with stage 2 colon cancer (CC).¹⁻³ We report the Genomic Health Clinical Laboratory experience with stage 2 CC since the product became commercially available. The assay incorporates the expression of 12 genes (7 cancer related [3 cell-cycle genes, 3 stromal genes, and the early response gene, *GADD45B*] and 5 reference genes) and gives a Recurrence Score result (a numeric score between 0 and 100) that is a quantitative estimate of the risk of recurrence based on individual tumor biology in MMR-proficient tumors.

Design: 12,776 samples from stage 2 CC pts submitted 4/2010 to 8/2014 passed pathology review and RT-PCR quality measures. Descriptive statistics for the clinical characteristics of pts, Recurrence Score results and distributions were calculated. Low, intermediate, and high risk groups are defined as: <30, 30-40, and ≥41, respectively.

Results: Of 12,776 samples, 11,696 (91.6%) were adenocarcinoma and 1,062 (8.3%) were mucinous. Median age was 64; with equal numbers of men (6,401, 50%) and women (6,375, 50%). Samples were received from 36 countries. The median Recurrence Score result was 25 (range 0-75); 8,684 (68%) low, 2,926 (23%) intermediate, and 1,166 (9%) high. Mucinous carcinoma had a significantly higher median Recurrence Score result (34) than adenocarcinoma (24; Wilcoxon test $p < 0.001$). Of adenocarcinoma pts, 8,330 (71%) had low scores; 2,547 (22%) intermediate, and 819 (7%) had high. Mucinous pts were evenly distributed in the three risk groups with 32% low, 35% intermediate and 32% high.

Conclusions: In the first 4 years of experience, there were more than 12,000 samples submitted from stage 2 CC pts for the 12-gene colon assay. While the vast majority of samples were adenocarcinoma, mucinous subtype was found to have a higher median score (34 vs 24) and more high scores (32% vs. 7%). Overall there was a wide range of Recurrence Score results (0-75) indicating that risk of recurrence is continuous and not simply high or low. Traditional methods for assessing risk do not reveal the full picture and the 12-gene colon cancer Recurrence Score result provides a quantitative and more individualized risk assessment for stage 2 CC pts beyond T-stage and MMR status. This will greatly improve the ability to personalize care and treatment decisions in pts with stage 2 CC.

¹Gray, et al, 2011; ²Venook, et al, 2013, ³Yothers, et al, 2013.

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