

## **Comparison of Oncotype DX® Recurrence Scores between surgical and core biopsy specimens in breast cancer patients.**

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**Introduction:** The Oncotype DX® 21 gene assay is usually performed on surgical resection specimens (SRx) for patients (pts) with early stage, estrogen receptor positive (ER+) breast cancer to predict the risk of recurrence and likelihood of benefit from adjuvant chemotherapy (CT) and hormonal therapy (HT). Using the Recurrence Score (RS) to aid in making a decision to administer preoperative CT requires assaying the core biopsy specimen (CBx). The objective of this study is to compare the RS obtained from paired CBx and SRx specimens.

**Methods:** 25 pts with invasive breast cancer diagnosed by CBx with a subsequent Oncotype DX® 21 gene assay performed on the SRx were identified. Fixed, paraffin embedded tissue from these paired CBx were sent to Genomic Health. The H&E slide from the paired SRx sample sent for the RS was used to compare the histology with the paired CBx. The RS from the CBx and SRx pairs were examined descriptively with scatterplots and Pearson correlation coefficients.

**Results:** Median age of diagnosis was 64 (range 39-78). Sufficient RNA was obtained from all but 1 of the CBx. H&E from CBx and SRx were histologically dissimilar for 3 of 24 pairs with RT-PCR data. The Pearson correlation for RS between CBx and SRx was 0.83 (95% CI 0.64, 0.92) for all 24 pairs. The distribution of RS groups from CBx was 19 low (RS<18), 3 intermediate (RS 18-30), 2 high (RS≥31). The RS group from SRx was unchanged for 22 (92%) pts. Two pts switched RS groups, CBx RS 5 to SRx RS 18 and CBx RS 8 to SRx RS 24; only the latter is clinically meaningful because the former straddles the low-intermediate cutpoint. Correlations between CBx and SRx for individual single gene scores were 0.84 (95% CI 0.65, 0.93) for ER, 0.83 (95% CI 0.64, 0.92) for PR, and 0.82 (95% CI 0.61, 0.92) for HER2. Similar results were obtained excluding the 3 histologically dissimilar pairs.

**Conclusion:** The RS's obtained from CBx's were consistently similar to the RS's obtained from the paired SRx. Using an RS obtained from a CBx in pts with ER+ disease to make a decision regarding neoadjuvant CT or HT is clinically acceptable, thus, giving physicians an additional tool to improve pt care and outcomes.