

## P147 THE ONCOTYPE DX<sup>®</sup> DCIS SCORE AND QUANTITATIVE GENE EXPRESSION FOR ER, PR, AND HER2: 1,071 PATIENTS

### Poster Abstracts I

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**Goals:** The DCIS Score<sup>™</sup> has been validated as a predictor of the 10 year risk of any local recurrence (DCIS or invasive) (Solin et al, SABCS 2011). Here we report the Genomic Health Clinical Laboratory experience with DCIS patient samples.

**Methods:** 1,071 patient samples from 12/28/11 through 9/28/2012 that passed pathology review and RT-PCR quality measures were included. The 21-gene assay was performed, and the DCIS Score was calculated based on the validated algorithm using 7 of the 16 cancer-related genes, measured from 0 to 15 (relative to reference genes, one unit increment associated with a 2-fold change in expression). Low, intermediate, and high risk categories are defined as DCIS Scores of <39, 39–54, and >54, respectively. Descriptive statistics for the DCIS Score, ER, PR, and HER2 were obtained. ?6.5 is the ER cut-off; ?5.5 is the cut-off for PR and for HER2, ?11.5 is positive, 10.7 to 11.4 is equivocal, <10.7 is negative.

**Results:** Of 1,071 samples, 785 (73%) were excisions and 286 (27%) were core biopsies, median age was 59.0 (range 23.0–91.0), 1,069 females and 2 males. The histologic subtype distribution was: cribriform 38%, solid 37%, DCIS with ?50% comedonecrosis 10%, papillary 9%, micropapillary 5%, apocrine 0.4%, and other 0.5%. The mean DCIS Score was 30.8 (range 0–96.7) with a mean score result of 30.9 for excisions and 30.4 for cores. 687 (64%) were low risk, 190 (18%) were intermediate risk, and 194 (18%) were high risk. The mean DCIS Score per histologic subtype was: apocrine 23.1, cribriform 26.0, DCIS with ?50% comedonecrosis 48.5, micropapillary 23.5, papillary 19.1, and solid 35.1. The mean ER, PR, and HER2 expression levels were 9.5, 7.4, and 9.9, respectively, and were similar between excisions and cores. The mean ER and PR for each histologic subtype were: apocrine (6.9, 5.1), cribriform (9.7, 7.6), DCIS with ?50% comedonecrosis (8.4, 6.3), micropapillary (9.4, 7.5), papillary (10.9, 8.6), and solid (9.4, 7.2) and for HER2: apocrine (9.2), cribriform (9.8), DCIS with ?50% comedonecrosis (10.0), micropapillary (9.9), papillary (9.7), solid DCIS (9.9).

**Conclusion:** A wide DCIS Score distribution was observed for each histologic subtype. Similar results were observed in DCIS Score value, ER, PR, and HER2 gene expression between excisions and cores. The majority of samples submitted were ER/PR+ and HER2-negative. As an employee at Genomic Health, Inc., I am compensated with salary, benefits, and stock. I also have stock options as an employee of Genomic Health, Inc.