

## P145 A COMPARISON OF RISK CLASSIFICATION AS ASSESSED BY THE MAMMAPRINT® AND ONCOTYPE DX® ASSAYS

### Poster Abstracts I

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**Goals:** The 21-gene Oncotype DX® Recurrence Score® assay has been validated for prediction of 10-year risk of distant recurrence and likelihood of benefit from chemotherapy (CT) in patients (Pts) with ER+ early stage breast cancer. MammaPrint® is a multi-gene assay that has been validated as a prognosticator in a heterogeneous Pt population that includes ER+, ER-, triple negative and HER2+ Pts. While the development and validation cohorts for these genomic assays are significantly different, the tests are frequently believed to provide equivalent information. The aim of the present study was to assess how these tests classify patients when compared side by side in the same Pt specimen.

**Methods:** Pts with ER+, HER2?, ESBC in which the MammaPrint® assay had been sent were identified at the Institut du Sein, Paris, France. Clinical and pathological characteristics and the MammaPrint® results (failure, low or high risk) were collected. Oncotype DX® quantitative RT-PCR analysis was performed at Genomic Health and was blinded to the clinical and MammaPrint® data. Descriptive statistics were calculated for failure rates, cross classification, and tumor characteristics.

**Results:** Informed consent and sufficient tumor material for analysis was available from 67 Pts who were predominantly low and intermediate risk by clinicopathologic features: Tumor grade – 24 low, 36 intermediate and 7 high; Histology – 49 ductal, 14 lobular and 4 other. 29% of patients had received chemoendocrine and 71% endocrine treatment alone. MammaPrint® analysis had failed to deliver result for 10 of the 67 Pts. Recurrence Score results were generated in all 67 Pts. 22 pts were classified as high and 35 as low risk by MammaPrint®. 2 patients had high, 22 intermediate and 33 low Recurrence Scores. 45% of the Pts with high risk MammaPrint® result had a low Recurrence Score result; they also had high ER expression determined either by immunohistochemistry or RT-PCR, which is associated with likely hormonal therapy benefit. There was no clear association between tumor characteristics and MammaPrint® failure or differences in risk classification.

**Conclusion:** This direct comparison demonstrates that the MammaPrint® and Oncotype DX® tests classify a large proportion of Pts differently. Of note, nearly half of the Pts with high risk MammaPrint® result had a low Recurrence Score indicating minimal, if any, benefit from chemotherapy. 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.

