

## 2007 ASCO Breast Cancer Symposium – Abstract #87

### ER and PR assessment in ECOG 2197: Comparison of locally determined IHC with centrally determined IHC and quantitative RT-PCR

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**Introduction:** Accurate laboratory assessment of hormone receptors (HR) is therapeutically important. This study compares ER and PR measured by local laboratories using IHC and by central laboratories using IHC and quantitative RT-PCR by *Oncotype DX*<sup>TM</sup>.

**Methods:** Tumors from 776 pts (179 of whom relapsed) enrolled on E2197 were examined; pts had 0-3 positive nodes and received doxorubicin and cyclophosphamide or docetaxel plus hormonal therapy (if HR+). Central IHC for ER (1D5) and PR (636) used two 1.0 mm tissue microarrays. The Allred score (AS) was used for ER/PR semiquantitation (AS>2 = pos). Quantitative RT-PCR analysis used *Oncotype DX* and pre-defined cutoffs of 6.5 and 5.5 units. Hormone receptor (HR) positive was defined as ER and/or PR positive.

**Results:** Results from local IHC (776 pts) were compared with central IHC (769 pts) and RT-PCR (776 pts). The concordance between local or central IHC and central RT-PCR was high, and similar to the high concordance between local and central lab IHC (table). 6% of HR+ pts by central IHC (27/459) and 7% of local IHC (32/455) were HR- by RT-PCR. 8% of HR- pts by central IHC (24/302) and 12% of local IHC (38/321) were HR+ by RT-PCR. The likelihood of recurrence was significantly lower in HR+ than HR- pts by all three assays ( $p < 0.01$ ). 1% of ER+ pts by central (5/409) and 5% of local (21/435) IHC were ER- by RT-PCR. 14% of ER- pts by central (50/360) and 13% of local (45/341) IHC were ER+ by RT-PCR. Among ER+ pts receiving hormone therapy, RS was a highly significant predictor of recurrence ( $p < 0.001$ ), whereas ER by central RT-PCR ( $p = 0.05$ ) and ER by central IHC Allred score ( $p = 0.12$ ) were not.

**Conclusions:** There is a high degree of overall concordance among local IHC, central IHC and central RT-PCR for ER, PR, and HR status.

% Concordance (95% CI)			
Comparison	ER	PR	HR
Local IHC vs Central IHC	90 (88, 92)	84 (82, 87)	90 (88, 92)
Local IHC vs RT-PCR	91 (89, 93)	88 (85, 90)	91 (89, 93)
Central IHC vs RT-PCR	93 (91, 94)	90 (88, 92)	93 (91, 95)