Quantitative Determination of ER: Adding Clarity to Your Patients’ ER Status

- Accurate and reproducible methods for evaluating Estrogen Receptor status are essential for making the appropriate hormonal treatment decisions for breast cancer patients.
- Our quantitative ER score determined by RT-PCR is another measure determining ER status, and provides further insight into an individual’s breast cancer biology and their magnitude of tamoxifen benefit.

Facilitating Identification of Patients Who Are ER-positive

An Oncotype DX® Recurrence Score® will automatically be generated if the ER status is:

1) positive by IHC or
2) positive by RT-PCR.

The patient’s insurance company will be billed in this case.

If the sample is ER-negative by both IHC and RT-PCR, Genomic Health will not provide the Oncotype DX Recurrence Score or quantitative single gene results, but will provide a qualitative report confirming the patient’s ER-negative status.

The patient’s insurance company will not be billed in this case.
Continuous Measurement & Wide Range of Expression

- Breast cancers show a broad range of hormone receptor expression, and RT-PCR is able to measure ER as a continuous variable and capture this wide range of gene expression.

- Delay to fixation, duration of fixation and choice of fixative may affect accurate hormone receptor assessment.

- Our RT-PCR employs a wide range of controls and calibrators including reference gene normalization to reduce this impact and to enhance accuracy and reproducibility in quantitative single gene assessment.

\[ \text{Data on file compiled from Paik, et al.} \]
Data from ECOG & Kaiser Studies

- Studies have demonstrated a high degree of concordance between ER status determined through our quantitative RT-PCR and IHC:
  - 93% concordance for ER status: E2197 (769 patient samples)\(^2\)
  - 96% concordance for ER status: Northern California Kaiser Permanente (607 patient samples)\(^3\)

- Although concordance was high, IHC ER-negative cases that were RT-PCR positive were more common than IHC ER-positive cases that were RT-PCR negative.
  - In one study, 14% (central IHC) and 13% (local IHC) of samples classified as ER-negative by IHC are ER-positive by central RT-PCR.\(^2\)

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Accurate, Precise and Reproducible

Now Accepting All Appropriate* Early Stage Breast Cancer Samples

Please designate your patient's ER-negative status on the Requisition Form in the Exception Criteria box in the Physician Signature area.

Analysis by IHC (or Unknown)

Quantitative Analysis by RT-PCR

Report Generation

*Decision to submit samples for testing based on medical necessity as determined by the referring physician.