

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.

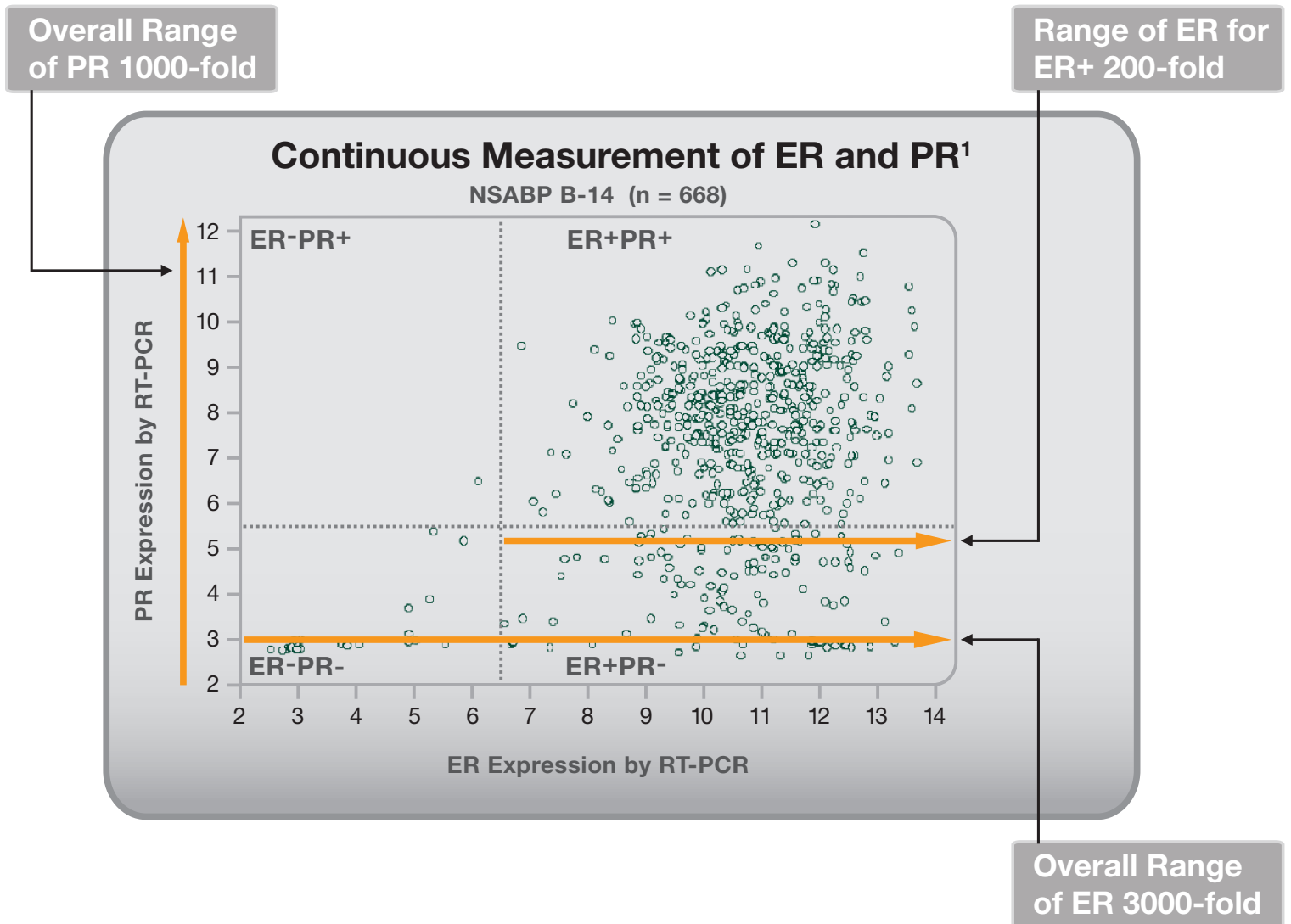
The patient's insurance company will be billed in this case.

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.

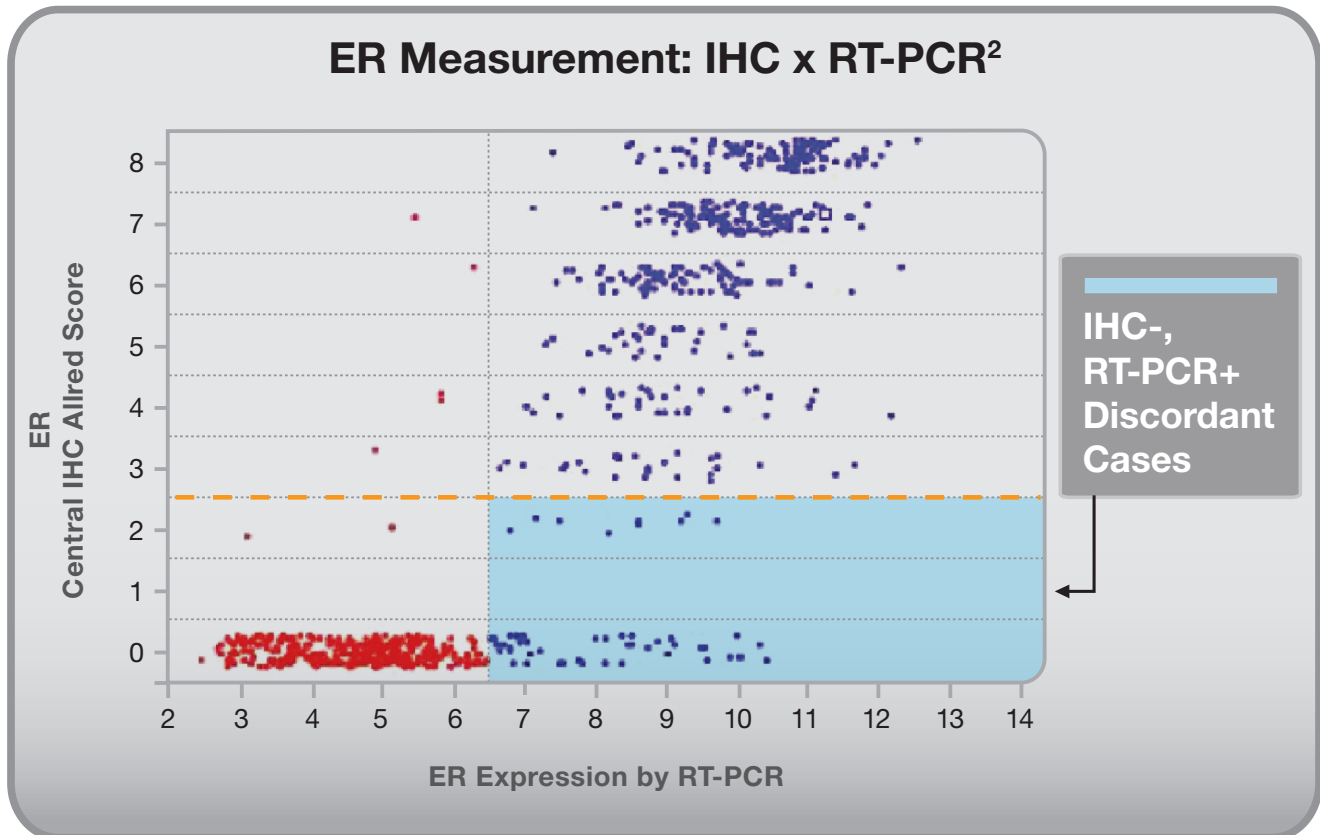


- Delay to fixation, duration of fixation and choice of fixative may affect accurate hormone receptor assessment.
- Our RT-PCR employs a wide range of controls and calibrators including reference gene normalization to reduce this impact and to enhance accuracy and reproducibility in quantitative single gene assessment.

¹Data 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

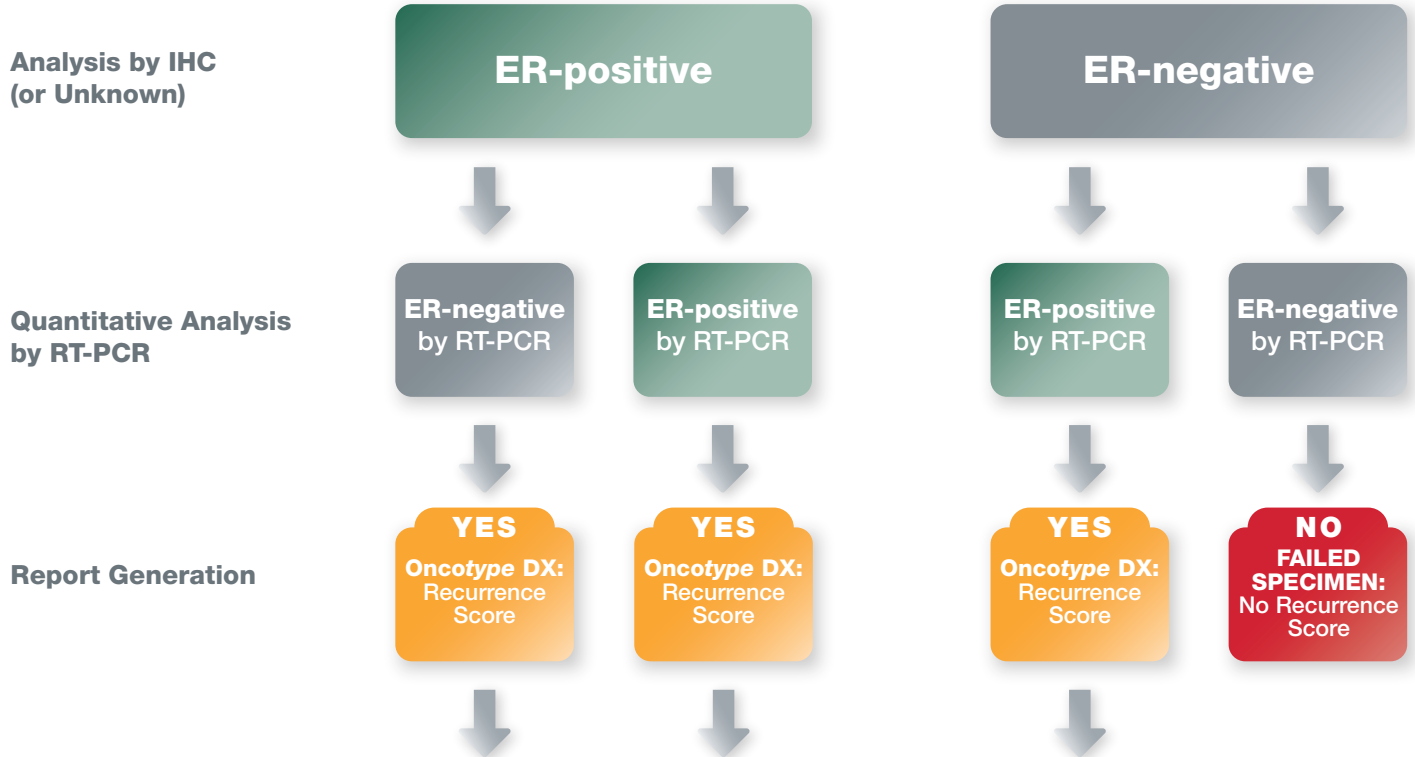
² *J Clin Oncol.* 2008;26(25). Badve SS, Baehner FL, Gray R, et al. Estrogen- and progesterone-receptor status in ECOG 2197: comparison of immunohistochemistry by local and central laboratories and quantitative reverse transcription polymerase chain reaction by central laboratory. *J Clin Oncol.* 2008;26(15):2473-2481.

³ Baehner FL, Maddala T, Alexander C, et al. A Kaiser Permanente population-based study of ER and PR expression by the standard method, immunohistochemistry (IHC), compared to a new method, quantitative reverse transcription polymerase chain reaction (RT-PCR). Presented at the ASCO Breast Cancer Symposium. September 7-8, 2007; San Francisco, CA. Abstract #88.

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.



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



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Breast Cancer Assay