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PhenoPath Laboratories  
Seattle, WA

FOR IMMEDIATE RELEASE:

**New PhenoPath Laboratories testing protocol may help breast cancer patients receive life-saving therapy**

Current testing protocols for HER2 amplification may exclude thousands of patients who actually have HER2 gene amplification, delaying or preventing them from receiving potentially life-saving treatment.

A new laboratory testing protocol can more accurately identify an important group of breast cancer patients who are most likely to benefit from a “targeted therapy” shown to dramatically improve survival. This recent discovery by PhenoPath Laboratories could improve the clinical prospects for a subset of the nearly 230,000 women in the United States diagnosed with breast cancer every year.

The new test protocol detects an alteration in the cancer cell’s DNA: the amplification of a gene on chromosome 17 called HER2. Accurate detection of those patients with amplified HER2 genes is critical, because only they can be successfully treated with HER2-targeted therapy, such as the drug trastuzumab (Herceptin™), which has been shown to dramatically improve survival.

In a paper published by the Journal of Clinical Oncology, specimens from 171 patients, whose breast cancers were shown by FISH testing to have elevated copy numbers of both HER2 and CEP17 had several other ‘comparison genes’ on chromosome 17 studied. Of 132 cases classified as negative (non-amplified) based on the HER2 to CEP17 ratios using current testing protocols, PhenoPath’s protocol reclassified 58 (43.9%) of these negative cases as positive, or amplified, and also reclassified 13 (92.9%) of 14 “equivocal” cases as positive, or amplified.

**PhenoPath’s demonstration of what appears to be true amplification of the HER2 gene in a subset of patients previously thought to be negative might alter treatment for thousands of women with breast cancer in the United States. Many patients whose breast cancers are misinterpreted as negative for amplification under current testing protocols methods would no longer be excluded from receiving trastuzumab and other HER2-targeted drugs.**

Although the ultimate response rate of these patients to therapy cannot yet be known, access to targeted therapy **could have a profound impact upon their survival.**

## How the protocol works

Tumors that have amplified HER2 genes (i.e. an increased number of copies) are candidates for treatment with HER2-targeted therapies. Current FISH testing protocols use two markers: one to the HER2 gene itself and one to a “comparison gene” called CEP17. Both the HER2 and the CEP17 genes are located on chromosome 17, and the ratio of the counts of these two genes has generally been thought to determine whether HER2 gene amplification is actually present or not.

PhenoPath Laboratories’ pathologist-scientists tested the hypothesis that in some cases current testing protocols may miss a subset of patients in which HER2 amplification on chromosome 17 extends to the region of the chromosome where CEP17 is located. In these cases, current testing protocol methods would indicate the ratio of HER2 to CEP17 is not elevated, so the test would be called negative. However, by using other “comparison genes” on chromosome 17 located further away from the HER2 gene, and that are not involved with amplification, a positive HER2 amplification test might be found.

To learn more, refer to the JCO article:

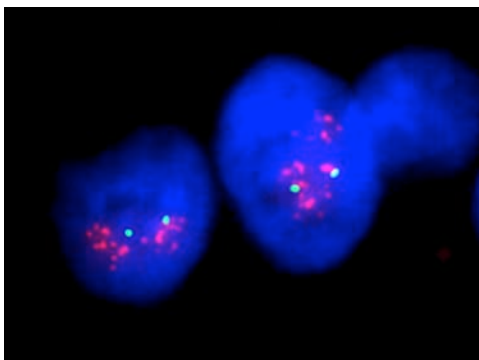
*Tse, CH et al. Determining True HER2 Gene Status in Breast Cancers With Polysomy by Using Alternative Chromosome 17 Reference Genes: Implications for Anti-HER2 Targeted Therapy. JCO: Published ahead of print on September 26, 2011.*

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### ***About PhenoPath Laboratories:***

***PhenoPath Laboratories is a physician-owned national pathology reference laboratory for diagnostic anatomic and molecular pathology services, committed to definitive diagnosis, rigorous testing and outstanding customer service.***



***Amplification (multiple copies) of the HER2 gene (red signals) in a breast cancer case***