False negative tests in breast cancer may lead to wrong drug choice

June 27 2011

A team of Yale Cancer Center researchers has confirmed that between 10-20% of breast cancers classified as Estrogen Receptor (ER) negative are really positive. Understanding when and why breast cancers may be misclassified has important implications for treatment and outcomes for women diagnosed with breast cancer. Its findings are published online in the June 28 *Journal of Clinical Oncology*.

A woman diagnosed with breast cancer can be tested by immunohistochemistry (IHC), a process that detects the presence of specific proteins in cancer tissue. Those who test positive for ER are prescribed an endocrine therapy, like Tamoxifen, Letrazol or a similar drug. The 10-20% of cancer patients who are incorrectly classified as ER negative may be treated with less effective therapies.

Led by David Rimm, M.D., professor of pathology at Yale School of Medicine, the research team highlighted the limitations of IHC in the assessment of Estrogen Receptor in breast cancer and defined a new method for standardizing ER measurement. It used a novel method to detect the estrogen receptor that uses fluorescent detection in conjunction with a series of standard controls. The team reported that this more sensitive and reproducible method finds cases initially called "negative" that behave as "positive."

"Our research shows that the conventional methods of measurement of Estrogen Receptor may result in a 10-20% false negative rate," said Rimm. "This may be leading to under-treatment of breast cancer patients

and we may be missing the opportunity to use one of our best drugs (Tamoxifen) due to inadequate testing."

The assay has been licensed to HistoRx Inc. of Branford, Conn. The test will soon be available to patients in Clinical Laboratory Improvement Amendments-certified labs. The first lab to release the test will be Genoptix Inc. based in Carlsbad, California.

Provided by Yale University