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For Immediate Release

BETTER BIOPSIES: BREAST CANCER TESTS GET SMARTER
New assays save time — and lives

Plainview, NY, February 2009 – Breast cancer is the second most common cancer among women in the U.S., and each year, more than 211,000 American receive a breast cancer diagnosis. New treatment options promise longer and healthier lives for breast cancer patients, and new testing methods are helping doctors decide which of these treatments will work best on an individual woman, says Olga Falkowski, MD, a board-certified pathologist and associate medical director of Acupath Laboratories, Inc., a specialty medical laboratory that conducts cutting-edge molecular and cytogenetic analyses.

Doctors now know that cancer cells can develop because of a problem in the genes that are involved in normal cell growth. In some cases, this process begins with an amplification of a particular gene, called HER-2/neu (shorthand for human epidermal growth factor receptor 2), which causes an overproduction of the HER-2 protein (a process called overexpression), explains Dr. Falkowski. This disrupts cellular function and leads to the development of cancer. Having too much HER2 (or too many copies of the HER2/neu gene) is associated with more aggressive cancer — and cancer that's more likely to come back after treatment. Overly high HER-2 levels have been implicated in about 20 percent of breast cancer patients.

HER-2-positive cancers can be treated successfully with the drug trastuzumab (Herceptin), which can dramatically slow the growth of cancer cells and help women live longer. However, the drug is expensive and it can cause potentially serious side effects. It's also ineffective on cancers that don't involve HER-2. Thus, determining a breast cancer's HER-2 status is critical.

"HER-2 status is an extremely important piece of information," says Dr. Falkowski, "so we routinely test breast cancers for it." Knowing a woman's HER-2 status also helps doctors predict the efficacy of certain types of chemotherapy and hormonal therapy. "Recent research has shown that adding Herceptin to chemotherapy increases its effects and helps prevent recurrence of the cancer," Dr. Falkowski adds.

"The good news is that we now have new types of assay to help us better identify the women who will benefit from these treatments," she says.

Up until now, doctors relied on tests called fluorescent in situ hybridization (or FISH) and immunohistochemistry (IHC). The FISH test uses small DNA probes to count copies of the HER-2 gene, and immunohistochemistry tests measure overexpressed protein in the cells. But these tests have drawbacks, says Dr. Falkowski. For example, the FISH test is pricey and requires specimens be shipped to a special lab that's equipped to view fluorescent probes; the IHC is less expensive but is generally thought to be less accurate than the FISH test.

The first of the new tests is chromogenic in situ hybridization (CISH), which works much the same way as FISH but looks for color changes (not fluorescence) in the cells and doesn't require special microscopes. And unlike other tests, it can be used on tissue samples that have been stored in the lab. The Food and Drug Administration approved the CISH test last year, and test kits are now available to US doctors.

The second new test, silver enhanced in situ hybridization (SISH), deposits tiny amounts of silver to help ID the HER-2 genes present in the cells. It's used in many other countries but is awaiting FDA approval in the US.

"We've got a few targeted therapies that can dramatically improve your prognosis if you've been diagnosed with breast cancer, but we know that they're not for everyone," says Dr. Falkowski. "These new tests will help doctors quickly and accurately identify women, whose cancer is HER's-2-positive, thus getting them the best possible treatment in the shortest possible time."

Bio: OLGA FALKOWSKI, M.D., UNIT CHIEF, BREAST PATHOLOGY AND ASSOCIATE MEDICAL DIRECTOR OF ACUPATH LABORATORIES, INC.

Board-certified in anatomic and clinical pathology by the American Board of Pathology, Dr. Olga Falkowski, M.D. serves as the Unit Chief of Breast Pathology and the Associate Medical Director of Acupath Laboratories, Inc. Before joining Acupath, Dr. Falkowski served as an attending pathologist at the Long Island Jewish Medical Center. She prior served as an attending pathologist at New York University School of Medicine where she also fulfilled a surgical fellowship. After receiving her medical degree from the First Moscow Medical School in Russia, Dr. Falkowski decided to complete her residency in general pathology there as well. Subsequently, she fulfilled her anatomic and clinical pathology residency at St. Luke's-Roosevelt Hospital Center, University Hospital of Columbia University.

As part of her pathology work, Dr. Falkowski has served as an assistant professor at New York University School of Medicine, Hofstra University, as well as Albert Einstein College of Medicine, respectively. She is currently a member of the College of American Pathologists and the United States and Canadian Academy of Pathology. In addition, Dr. Falkowski is a noted author and lecturer in breast pathology and is often quoted in the press relating to issues concerning breast cancer diagnostics. www.acupath.com