

NEW NONINVASIVE PAP TEST FOR BREAST MAY IDENTIFY BREAST DISEASE UP TO EIGHT YEARS EARLIER

Five-Minute Automatic Test Now Available To Help Identify Women at Risk For Developing Breast Cancer

SAN DIEGO, Calif. – November 14, 2005 – Designed to detect abnormal cells in the breast, a new Pap Test for the breast may identify breast disease – often a precursor to cancer – up to eight years earlier than a lesion might be found on a mammogram or a self exam. The first automatic, noninvasive test of its kind, the Halo Breast Pap Test System from NeoMatrix is now available in clinical practice.

Virtually all breast cancer (95 percent) originates in the ductal system of the breasts and progresses through identifiable stages of development. According to a recent article in the *New England Journal of Medicine*, benign breast disease – which can present as abnormal cells – is an important risk factor of breast cancer. This study joins a growing body of research that demonstrates that the cytological assessment of breast duct fluid, or Nipple Aspirate Fluid (NAF), can identify a woman's specific risk of breast cancer. For example, a woman with a family history of breast cancer typically has a risk of developing breast cancer that is two to three times higher. However, when family history and abnormal breast cell cytology are combined, the risk of cancer has been shown to be increased 11 times.

“For years we have known that fluid from the breast ducts can be an excellent tool for evaluating the risk of breast disease in women of all ages,” said Dr. Rosalyn Baxter-Jones, Ob-Gyn and Medical Director of the Preventive Women's Health Care Medical Group in San Diego. “Until now however, there were only invasive surgical or manual methods to collect samples, which impacted acceptance by both physicians and patients. The new HALO system provides a simple, noninvasive tool to collect ductal fluid in minutes and can easily be incorporated into a well woman visit.”

Dr. Baxter-Jones, the first physician to use the system in clinical practice, recommends that all women between the ages of 25 and 55 have the HALO Breast Pap Test to evaluate their risk of breast disease. Whether the test is administered annually will be determined by the patient's history. Since the introduction of the cervical pap smear in the 1950s, the death rate from cervical cancer has declined over 70%. However, the mortality rates for breast cancer have declined only modestly during the same time period. Currently, some 3,700 women die of cervical cancer while more than 40,000 die of breast cancer annually.

Using gentle suction like a breast pump, the HALO Breast Pap Test uses adjustable breast cups to collect NAF. During the 5-minute cycle, the HALO system generates mild compression on both breasts while simultaneously applying heat. Toward the end of the cycle, the HALO system initiates gentle suction to retrieve any fluid from the ducts.

In the National Cancer Institute's report, "The Nation's Investment in Cancer Research 2006: Cancer Prevention, Early Detection and Prediction," the NCI expresses a need for more accurate methods of predicting who is at high risk for developing cancer. This is particularly important in breast cancer as the majority (more than 70%) of women who develop breast cancer have no known risk factors other than age.

Dr. George Papanicolaou, who developed the cervical Pap Test in the 1950s, first demonstrated that it is also possible to identify abnormal cells and potential precursors of cancer by analyzing cells collected from fluid from the breast ductal system. Specifically, examination of Nipple Aspirate Fluid (NAF) has been cited in several large cohort studies as a predictor of benign breast disease that may lead to increased risk of breast cancer. The common conclusion from these studies is that routine NAF assessment may be a useful objective tool to improve the prediction of breast cancer risk.

"We are excited about this noninvasive test to collect ductal fluid and the potential impact it can have to provide early warning signs of breast disease, particularly among younger women who have no other known risk factors and where cancers are typically very aggressive," said Dr. Baxter-Jones. "Once benign breast disease is detected and evaluation of other factors conducted, such as age and family history, a defined course of therapeutic intervention or increased monitoring can be determined."

Excluding skin cancer, the breast is the leading site of cancer among women. Breast cancer also ranks as women's number one health concern today. For example, in the United States, the average woman has a 12.5 percent lifetime risk of developing invasive breast cancer. According to the American Cancer Society (ACS), early detection is key to survival.

"With such overwhelming evidence of the value of NAF assessment in detecting breast disease, we were committed to developing an economical and noninvasive way to collect ductal fluid," said Kevin Morton, president and CEO of NeoMatrix. "We believe the HALO system provides the answer to this challenge. The ability for women to access this easy five-minute test during routine exams at their Ob-Gyn or primary care physician's office could have a profound impact on breast health."

About NeoMatrix, LLC

Based in Irvine, Calif., NeoMatrix© develops innovative devices that allow women and their Ob-Gyns to promote optimal breast health. The company's premier product, the HALO Breast Pap Test System, is the first fully automated, noninvasive breast disease screening device designed for use in the Ob-Gyn office. The System has been FDA cleared for the collection of nipple aspirate fluid for cytological evaluation for the determination and/or differentiation of normal versus pre-malignant versus malignant cells. For further information, visit www.neomatrix.com.

###

Media Contacts:

Chris K. Joseph
510.339.2293
chris@ckjcomm.com

Laurie Hallwyler
650.248.9081
laurie@ckjcomm.com