



Living with Metastatic Breast Cancer

One simple, routine, minimally invasive blood test: For women with HER-2/neu positive metastatic breast cancer, a particularly aggressive cancer, this test could be the key that helps determine their fate. Siemens innovative Serum HER-2/neu test is the only FDA-cleared Serum HER-2/neu blood test that can indicate whether metastatic breast cancer is progressing or responding to treatment.

By Diana Smith

HER-2 positive breast cancer is a virulent cancer identified every year in 25 percent of the nearly 1.3 million women diagnosed with breast cancer worldwide annually. HER-2/neu positive patients are often given devastating prognoses – shorter survival rates and higher recurrence. That’s why identifying changes in health are critical. For women with HER-2/neu positive metastatic breast cancer, the Siemens Serum HER-2/neu test supplies accurate information which helps determine whether the disease is advancing, so that patients and clinicians can face the disease head-on.

One Woman’s Story

As a career health educator, New Jersey-native Christine Druther, MSPH (Master of Science in Public Health), practiced what she preached – following a healthy lifestyle, eating right, and performing regular breast self-exams. In 1990, she found a small lump in her left breast. “It was hard, like a marble, and I definitely knew something was wrong,” she says.

At age 40, Druther was married with two small daughters, ages six and four. Only ten months earlier, she had watched her mother battle and die from breast cancer. Now, she was facing her own struggle with the same disease. Druther had a lumpectomy and underwent a grueling regimen of chemotherapy and radiation. For the next nine years, she was cancer-free and thought she had beaten the disease. But in 1999, the cancer came back. This time, the diagnosis was dire: Stage IV breast cancer, which had spread to her brain. And the cancer was HER-2/neu positive.

What is HER-2/neu Cancer?

“HER-2 positive breast cancer is a breast cancer that tests positive for a protein called Human Epidermal growth factor Receptor 2 [HER-2],” explains Walter P. Carney, PhD, inventor and developer of the Siemens Serum HER-2/neu test. “A normal breast cell has two copies of the HER-2/neu gene, which makes proteins that help control how the body’s cells grow.”

Periodic Serum HER-2/neu blood tests help Dr. Vicario (right) monitor his patient's response to current therapies and plan new ones. Christine Druther's (left) HER-2/neu positive cancer responded well to Herceptin.



In HER-2 positive breast cancer, the cancer cells make an excess of HER-2. When there are too many copies of the HER-2/neu gene or too many of its proteins in a tumor, a particularly aggressive cancer can result. These cancers are less responsive to hormone therapy, but new treatments that specifically target the HER-2 protein, such as the drugs Herceptin® and Tykerb®, have proven to be effective in blocking tumor cell growth. Patients with a positive HER-2 tissue test qualify for targeted HER-2/neu therapy. Carney adds, "It is very important to determine HER-2/neu status because that information is needed to guide therapy in these patients. The HER-2/neu blood test shows how well women are responding to targeted therapy."

Winning the War in the Laboratory

"Life has changed a lot," says Carney. "It used to be that if a woman was diagnosed with metastatic breast cancer, it was pretty much a death sentence. Now it is still serious, but there are many more therapies available so that people can live longer – and not only live longer,

but with a better quality of life." That is the primary reason why he developed the Serum HER-2/neu test. A cancer researcher for two decades, Carney theorized that materials lurking in the blood might play a key role in cancer diagnosis. "Scientists had this concept for a long time that things on the outer surface of cells probably break off and get into the blood," he says. The serum test monitors HER-2/neu, an oncoprotein found elevated in the blood of some breast cancer patients. Generally, a normal Serum HER-2/neu level is below 15 nanograms per milliliter (ng/mL), while an elevated level is 15 ng/mL or greater. Increasing levels reflect cancer progression. Falling levels signify treatment response or stable disease. Studies have shown that up to 90 percent of metastatic breast cancer patients can have an elevated Serum HER-2/neu level. Serum HER-2/neu positive metastatic breast cancer patients whose primary tissue HER-2/neu was negative may benefit from additional testing of tissue from the primary site or sites of metastasis to determine if their HER-2/neu status has changed. "For patients with HER-2/neu positive cancer, changes in Serum

HER-2/neu levels can help tell if treatment is effective or not," says Carney. "It's really an example of how therapies can be personalized."

Striking a Balance between Science and Hope

"Even with more advanced stages, like Stage IV metastatic breast cancer, there are reasons to be very hopeful and optimistic because we have new therapies available," says Daniel Vicario, MD, Druther's oncologist and a partner at the San Diego Cancer Center in Encinitas, California, USA. "And we see, every day, women with metastatic breast cancer who live beyond limits, live beyond all of the statistics, even beyond what we could have imagined 15 years ago." The Siemens HER-2/neu test gives the physician one more tool to use while monitoring women diagnosed with metastatic breast cancer. "The Siemens Serum HER-2/neu test can help identify that cancer may be progressing before its progress is identified by imaging," says Vicario. Periodic HER-2/neu blood tests help doctors monitor the response to current therapies and plan new ones. By combining advanced drug therapies

with diagnostics, doctors have been able to fight metastatic cancers. With the unique Serum HER-2/neu test plus an advanced array of sophisticated diagnostic tools, including mammography, magnetic resonance imaging, breast ultrasound, and positron emission tomography-computed tomography solutions, Siemens is leading the way and providing maximum information to physicians and patients to monitor and manage metastatic breast cancer. The result? Doctors can monitor and treat their patients with more targeted, more effective therapies.

No Time to Waste

Druther's cancer was particularly aggressive and spread to her brain and chest. Yet, she says, "I took matters into my own hands. I knew education was my best tool for survival." Already a career health educator, she became a specialist in the complex world of HER-2/neu positive breast cancer. Druther was well-versed about chemotherapy drugs and the side effects of each, as well as clinical trials and new research. She could decode medical jargon and peppered her visits to the oncologist with questions about the latest treatments and most effective protocols.

"It is bad news to be diagnosed with HER-2/neu positive cancer, but the good news is that there are targeted drugs that can work for this kind of cancer," says Druther. "Because of my research, I knew I wanted Herceptin." Druther's cancer responded well to the Herceptin, and she also underwent gamma ray radiation for the cancer in her brain.

Future Applications

The Serum HER-2 test offers a two-pronged benefit for both physicians and patients. Medically, the test helps physicians optimize treatment for HER-2/neu positive breast cancer patients. On an emotional level, it can help keep patients informed about their health status. "My position is that anyone who gets diagnosed with metastatic breast cancer should have a baseline Serum HER-2 level and if it is elevated, be monitored for life, especially if they are

HER-2/neu positive by tissue tests," says Carney.

Additionally, the test is showing promise for use in other cancer diagnoses. "The Serum HER-2/neu test was first used as a breast cancer marker for HER-2 positive breast cancer," says Carney. "But as it turns out, there are HER-2 positive gastric cancers and HER-2 positive lung cancers, so now we're seeing it used in studies for these cancers as well." He continues, "We've focused efforts over the years on breast cancer, but what is really clear is that this can go beyond breast cancer, and it already has. The Serum HER-2 test may cross over a number of cancers and may cross over a variety of therapies. In a way, we've only scratched the surface of the value of this test. I see HER-2 as a model for how we should be building biomarkers for the future."

A New Role

Today, Christine Druther has been in remission for nine years from HER-2/neu positive metastatic breast cancer. "I am happy to say I survived it, and I have a great quality of life," she says. "I wish that for everyone."

Druther and her husband, Joe, have started a comprehensive Website, www.her2support.org, to provide help and valuable information to HER-2/neu positive patients. The Website was launched on December 24, 2001. "I had this vision that we had to create a Website to inspire women to take control of their health," she says. "The best patient is the one who is best informed about her own disease." In addition, every month, Druther gets the Siemens Serum HER-2/neu blood test to monitor her condition. "I trust my life to this test," she says. "Women who are not getting the Serum HER-2/neu test are being underserved."

Diana Smith is a freelance medical writer based in Liberty Hill, Texas, USA.

Further Information

www.siemens.com/herstory
www.her2support.org

Summary

Challenge:

- Identifying changes in health status for patients with HER-2/neu positive metastatic breast cancer, a particularly aggressive cancer
- Identifying patients whose tissue tests were initially negative for HER-2/neu who may benefit from additional tissue testing
- Improving management of HER-2/neu positive metastatic breast cancer patients, who are often given dire prognoses
- Reducing the amount of time to implement appropriate treatment and therapies to manage HER-2/neu positive metastatic breast cancer

Solution:

- Utilizing the Serum HER-2/neu test to monitor patient condition and determine if the disease is progressing or stable
- Establishing a protocol for use of the Serum HER-2/neu test that allows for ongoing management of the disease and best patient care
- Educating physicians, clinicians, and patients about the benefits of the serum test

Result:

- The Siemens Serum HER-2/neu test accurately monitors disease progression in metastatic breast cancer patients whose initial value is greater than 15 ng/mL, providing information about disease progression and effectiveness of treatment
- Optimizing treatment not only improves the speed of patient therapy, but also allows for targeted treatment for HER-2/neu positive metastatic breast cancer
- Ongoing monitoring helps keep patients informed of their health status, and in those responding to therapy, alleviates concern about the return of the disease
- Low-cost, noninvasive diagnostic tool