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DIAGNOSTIC TESTING FOR EARLY-STAGE BREAST CANCER

Each year, approximately 230,000 women in the U.S. and about 2,300 men are diagnosed with breast cancer. If you are diagnosed with breast cancer, it's important that doctors get as much information as they can about your tumor so they can make the best recommendations to treat

the cancer. This fact sheet provides an overview of the general diagnostic tests that help doctors understand tumor types. It also describes newer tests that offer additional information for women with certain types of earlystage (stage I or II) breast cancer.

UNDERSTANDING YOUR TUMOR TYPE

Tests performed on tumor samples give valuable information that helps guide treatment decisions for breast cancer. By examining tumor samples under a microscope, doctors can determine if the tumor is invasive or noninvasive (in situ). The tumor sample will also help identify your tumor's grade—whether it is a fast-growing or slow-growing form of breast cancer—as well as the tumor's hormone receptor status and HER2 status. All of these tests will inform your oncologist about your recommended treatment plan.

Sentinel node mapping also helps doctors determine if breast cancer cells have spread to other parts of the body. If the sentinel (first) lymph node is cancer free, the nearby lymph nodes may also be unaffected and left intact. Removing a patient's lymph nodes can increase the risk of lymphedema, a painful swelling of the arm.

DETERMINING HORMONE STATUS

Estrogen and progesterone

receptors are structures present on the surface of some cancer cells. These structures allow estrogen and progesterone to enter the cells and encourage them to grow. Tumors that test positive for these



structures are called hormone receptor-positive and may be treated with hormonal therapy (e.g., tamoxifen). This treatment prevents estrogen from attaching to receptors on breast cancer cells. As a result, estrogen cannot get in the cells, and tumor growth is slowed. The treatments also reduce the amount of hormones circulating in the body that attach to estrogen or progesterone receptors. By blocking hormones, the treatments deprive tumor cells of the substances they need to grow.

HER2-positive breast cancers are

breast tumors that make too much of a protein called HER2/neu, which speeds the growth of cancer cells. About 15 to 20 percent of breast cancers are HER2-positive. Drugs that target HER2/neu slow the growth of the tumor. Some of these drugs include trastuzumab (Herceptin), lapatinib (Tykerb), pertuzumab (Perjeta), and adotrastuzumabemtansine (T-DM1; Kadcyla). Your breast cancer will be tested to identify if it is HER2positive to determine the best treatment options. **Triple-negative breast tumors** do not depend on estrogen, progesterone, or HER2 for their growth, and account for about 15 percent of all breast cancers. The standard treatments include surgery, radiation and chemotherapy. Researchers are looking for new ways to combine chemotherapy and targeted drugs to offer the most benefit to those living with triple-negative breast cancer.

PERSONALIZING BREAST CANCER TREATMENT

Some of the newest tools for women with breast cancer are tests that estimate the likelihood of the patient benefiting from chemotherapy. Four tests are available that analyze breast cancer genes to predict recurrence: the Oncotype DX test, the Mammostrat test, the MammaPrint test, and the Prosigna assay. Currently, the only diagnostic test for early-stage breast cancer included in the NCCN (National Comprehensive Cancer Network) and ASCO (American Society of Clinical Oncology) guidelines is the Oncotype DX test.

Oncotype DX is appropriate for women with stage I or II breast cancer that is hormone receptor-positive and will be receiving hormonal therapy. The test analyzes the genes in tumor tissue removed during surgery, looking for patterns of abnormal genetic activity to predict how the tumor will behave. The test produces a Recurrence Score result; patients with lower score results have a lower risk of their cancer returning.

Currently, the RxPONDER clinical trial is studying whether chemotherapy benefits patients with node-positive breast cancer who have a low to intermediate score. This trial illustrates how research is transforming the way that doctors treat breast cancer—that is, basing treatment approach on the patient's tumor. If doctors know in advance that a treatment won't be of benefit, the patient could be spared unnecessary side effects from treatment. And for people who are undecided about embarking on a course of chemotherapy, diagnostic testing may provide information to make the decision clearer and easier.



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