

To learn more about the Serum HER-2/neu Test, ask your doctor.

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*IHC and FISH are tissue tests whose results determine HER-2/neu status (positive or negative). These test results are a standard part of a breast cancer pathology report.

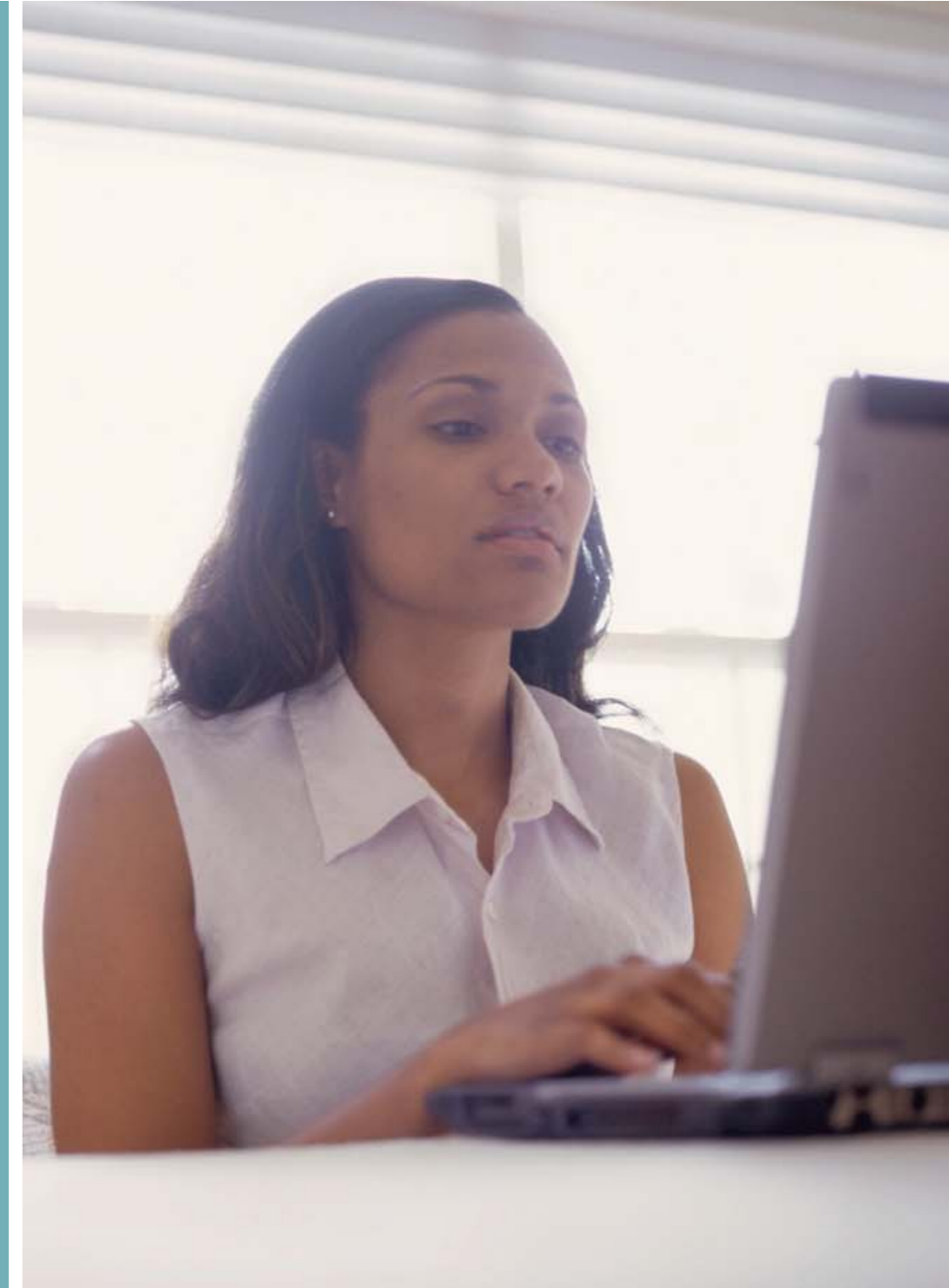
**"ng" means nanogram; "mL" means milliliter. A nanogram is one billionth of a gram; a milliliter is one thousandth of a liter. 15 ng/mL means 15 nanograms of the HER-2/neu protein in each milliliter of blood.

Reference:

1. Carney WP, et al. Clinical Breast Cancer 2004; 5(2):105-116, and Carney WP. Personalized Medicine 2005;2(4):317-324.

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Neu Answers: Frequently Asked Questions About the Serum HER-2/neu Test

Serum HER-2/neu Test

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Neu Answers to Frequently Asked Questions About the Serum HER-2/neu Test



What is HER-2/neu?

HER-2/neu stands for Human Epidermal Growth Factor Receptor 2. The HER-2/neu gene makes proteins that help control how a body's cells grow. Normal cells have two copies of the HER-2/neu gene. Cancer cells have an abnormal number of HER-2/neu genes which leads to abnormally high levels of HER-2/neu cancer-causing proteins referred to as oncoproteins.

How do I find out if I am HER-2/neu positive?

When you are first told that you have breast cancer, a small piece of tumor tissue will be removed for examination. This is called a biopsy. Your doctor will have the tumor tissue checked with a test called IHC (ImmunohistoChemistry) and/or a test called FISH (Fluorescence In Situ Hybridization).^{*} The results of these tests will appear in your pathology report, and they will tell you if your tumor is HER-2/neu positive or HER-2/neu negative.

What does it mean to be HER-2/neu positive?

A woman is considered HER-2/neu positive if she has:

- Too many copies of the HER-2/neu gene in her cells (this is called "gene amplification")
- Too many HER-2/neu proteins in her tumor (this is called "protein overexpression")

Why is it important to know if your breast tumor is HER-2/neu positive?

If you are HER-2/neu positive, you may be a candidate for HER-2/neu-targeted treatments such as Herceptin[®] (Trastuzumab).

What is the Serum HER-2/neu Test?

The Serum HER-2/neu Test is a blood test that measures the level of HER-2/neu oncoproteins in your blood. This test is cleared by the U.S. Food and Drug Administration (FDA) to help doctors monitor changes in serum HER-2/neu levels and to manage the therapy of women with metastatic breast cancer. Metastatic breast cancer is cancer that has spread from the breast to other parts of the body.

Why is the Serum HER-2/neu Test important to me?

If you have metastatic breast cancer, the Serum HER-2/neu Test is the only blood test doctors can use to monitor changes in your HER-2/neu status. Changes in your serum HER-2/neu level can tell you and your doctor if your treatment is effective or needs to be altered. Increasing serum HER-2/neu levels may be a sign that you are not responding to your particular treatment. Decreasing levels may mean that you are responding to treatment or your disease has stabilized.

What is a "normal" serum HER-2/neu level?

A normal serum HER-2/neu level is below 15 ng/mL, and an elevated serum HER-2/neu level is 15 ng/mL or greater.^{**}

How does the Serum HER-2/neu Test work?

When you visit your doctor, he or she will draw a small amount of blood from you and send it to a laboratory to be tested using the Serum HER-2/neu Test.

Your first Serum HER-2/neu Test is called a baseline test. Normally, your doctor will order a second Serum HER-2/neu Test 30-60 days after you start your cancer treatment. By comparing the results of the second test to your baseline test, your doctor can tell if your serum HER-2/neu level is going up or down. If you have an elevated serum HER-2/neu level (15 ng/mL or greater), you can be routinely monitored to help your doctor manage your therapy options. If you have a normal serum HER-2/neu level (less than 15 ng/mL), discuss how often you should monitor your levels with your doctor to determine if it has increased above 15 ng/mL. Repeat testing will allow you and your doctor to know if your HER-2/neu status has changed.

I have already started treatment. Should I still have my serum HER-2/neu level tested?

Your doctor can use the test to monitor your disease even if you have started treatment.

I know I'm HER-2/neu positive. Do I still need the Serum HER-2/neu Test?

Whether you are HER-2/neu positive or negative, if you have metastatic breast cancer, you should ask your doctor for the Serum HER-2/neu Test. Your doctor can use the Serum HER-2/neu Test to monitor your disease and the results of the test can be used by your doctor periodically to help determine if your treatment is effective.

If I were once HER-2/neu negative, can I now be HER-2/neu positive?

Yes. Even if your first breast cancer tumor was HER-2/neu negative, you can become HER-2/neu positive if your cancer spreads. In fact, studies have shown that 10% to 40% of women with metastatic breast cancer had elevated serum HER-2/neu levels even though their original tumors were HER-2/neu negative by tissue tests.¹ If you fall into this category, your doctor should request a re-evaluation of your original tissue sample to determine if your tumor is HER-2/neu positive or negative. Knowing your HER-2/neu status is very important for managing your therapy.

Where do I get the Serum HER-2/neu Test?

Ask your doctor for the test.

When do I get the test results?

Your doctor should have results within a few weeks; time varies between laboratories.

How is the Serum HER-2/neu Test different from tissue tests?

The Serum HER-2/neu Test shows changes in your serum HER-2/neu level. The test can be used to routinely monitor women with metastatic breast cancer and should be used often throughout the course of your treatment to help manage your therapy. In contrast, tissue tests are generally performed only on the original tumor and are not practical for routine monitoring of MBC patients.

Why is the Serum HER-2/neu Test only used for women with metastatic breast cancer?

At this time, the Serum HER-2/neu Test is cleared for use by the FDA for women with metastatic breast cancer only. More clinical research is being done to find out if the Serum HER-2/neu Test can be used for women with earlier stages of breast cancer.

Is "FDA-cleared" the same as "FDA-approved"?

It is similar. Most diagnostic devices receive a "clearance" from the FDA. The Serum HER-2/neu Test has been FDA-cleared for monitoring and managing metastatic breast cancer, which means it is safe and effective for these uses.

I've heard about a test called "ELISA." What is this?

ELISA stands for Enzyme-Linked ImmunoSorbent Assay. It is one of the methods used to test blood for HER-2/neu proteins. Serum HER-2/neu ELISA is another name for the Serum HER-2/neu Test.