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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.

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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?

To determine if you are HER-2/neu positive, a small piece of tissue will be removed and sent to a pathologist 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.

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 used for the follow-up and monitoring of metastatic breast cancer patients whose initial Serum HER-2/neu level is greater than 15 ng/mL. 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 not. 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?

Your doctor will arrange to have your blood sample sent to the laboratory to be tested.

Your first Serum HER-2/neu test is called a baseline test. By comparing the results of the subsequent tests 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. Serum HER-2/neu levels can become elevated in patients whose initial Serum HER-2/neu value is <15 ng/mL. This may indicate a change in HER-2/neu status.

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 periodically to help determine if your treatment is effective or not.

If I was 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. Serum HER-2/neu levels can become elevated in patients whose initial Serum HER-2/neu value is <15 ng/mL. This may indicate a change in HER-2/neu status.

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

Ask your doctor about the Serum HER-2/neu 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 whose initial Serum HER-2/neu value is >15 ng/mL 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 metastatic breast cancer 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. Additional research is being evaluated to determine if Serum HER-2/neu would be beneficial to other patient populations.

What does FDA-cleared mean?

Most in vitro diagnostic devices require premarket notification (also called 510(k) notification) to the FDA and subsequent clearance by the FDA prior to being used as part of the management of patients in the United States. The Serum HER-2/neu test received clearance for use in the follow-up and monitoring of patients with metastatic breast cancer.

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.

For more information on

Serum HER-2/neu
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Reference:

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