

## Facts About the Serum HER-2/neu Test

- The Serum HER-2/neu Test is a simple blood test.
- It is the only FDA-cleared blood test to check serum HER-2/neu levels in women with metastatic breast cancer and can be used to monitor changes in HER-2/neu status and to manage therapy.
- Tissue tests (IHC/FISH) guide therapy selection while serum HER-2/neu testing allows your doctor to routinely monitor change in your HER-2/neu status. Routine testing of serum HER-2/neu levels will help your doctor in managing and optimizing your therapy.
- Serum HER-2/neu Test results will determine how often you need the test.

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. Repeat testing will allow you and your doctor to know if your HER-2/neu status has changed.

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 metastatic breast cancer, ask your doctor about the Serum HER-2/neu Test.

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- \* 15 ng/mL means 15 nanograms of the HER-2/neu protein per one milliliter of blood. A nanogram is one billionth of a gram.
- \*\* IHC stands for ImmunoHistoChemistry. FISH stands for Fluorescence In Situ Hybridization. The results of these tests determine if your HER-2/neu status is positive or negative, and they are the only tests used to determine if you are eligible for Herceptin therapy.

### References:

1. Carney WP. Personalized Medicine 2005;2(4):317-324.

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## Monitoring and Managing Metastatic Breast Cancer

### Serum HER-2/neu Test

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# Knowing Your Serum HER-2/neu Level Helps You and Your Doctor Optimize Your Treatment



## **New hope for HER-2/neu-positive women with metastatic breast cancer.**

A normal breast cell has two copies of a gene called HER-2/neu. This gene makes proteins that help control how the body's cells grow. If you have too many copies of the HER-2/neu gene and/or too many HER-2/neu proteins in your tumor, you are considered HER-2/neu positive. Breast cancer tumors that are HER-2/neu positive grow more quickly and are more aggressive than HER-2/neu-negative tumors. If your HER-2/neu status is positive, HER-2/neu-targeted therapies such as Herceptin® (trastuzumab) may help you.

## **A simple blood test may help to determine if your treatment is effective.**

The Serum HER-2/neu Test is the only blood test cleared by the U.S. Food and Drug Administration to help doctors monitor the serum HER-2/neu levels. Doctors can use this information in conjunction with other diagnostic tools to manage and monitor the therapy of women with metastatic breast cancer. "Metastatic" means a cancer that has spread from the breast to another part of the body.

Changes in your serum HER-2/neu level can help tell you and your doctor if your treatment is effective or may need to be altered. A normal serum HER-2/neu level is below 15 ng/mL, while an elevated level is 15 ng/mL or greater. Increasing levels reflect cancer progression.\* If your serum HER-2/neu level decreases, it may mean that your cancer is responding to treatment.

## **The Serum HER-2/neu Test complements tissue tests.**

Did you know your HER-2/neu status can change? In recent clinical studies, 10% to 40% of women with metastatic breast cancer who were HER-2/neu negative at first diagnosis later became

HER-2/neu positive.<sup>1</sup> The change in HER-2/neu status can be determined using the Serum HER-2/neu Test.

When used together with tissue test results (IHC and/or FISH\*\*) in your pathology report, the Serum HER-2/neu Test may help determine your HER-2/neu status.

## **Monitor your HER-2/neu level for life.**

The Serum HER-2/neu Test can be performed periodically to update you and your doctor about your HER-2/neu level and keep you informed about any changes in your HER-2/neu status. You should receive your test results within a few weeks. If you have a normal serum

HER-2/neu level (less than 15 ng/mL), discuss how often you should repeat testing with your doctor.

Monitoring your levels will allow you and your doctor to know if your HER-2/neu status has changed. If you have an elevated serum HER-2/neu level (15 ng/mL or greater), you can be tested routinely to manage and monitor your therapy.

## **Ask your doctor if the Serum HER-2/neu Test is right for you.**

If you have metastatic breast cancer and you don't know your serum HER-2/neu level, ask your doctor about the Serum HER-2/neu Test. Below are some questions that may help you talk to your doctor.

- Has my serum HER-2/neu level ever been tested?
- Should I have my serum HER-2/neu level tested now?
- How does my serum HER-2/neu level affect my treatment?
- How often will I need the test?