

## 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 help 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 manage and optimize your therapy.
- 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.

For more information on  
**Serum HER-2/neu**  
visit us at  
[www.siemens.com/herstory](http://www.siemens.com/herstory)  
or email us at  
[herstory.healthcare@siemens.com](mailto:herstory.healthcare@siemens.com).

Siemens Healthcare Diagnostics, the leading clinical diagnostics company, is committed to providing clinicians with the vital information they need for the accurate diagnosis, treatment and monitoring of patients. Our comprehensive portfolio of performance-driven systems, unmatched menu offering and IT solutions, in conjunction with highly responsive service, is designed to streamline workflow, enhance operational efficiency and support improved patient care.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

### Global Division

Siemens Healthcare  
Diagnostics Inc.  
1717 Deerfield Road  
Deerfield, IL 60015-0778  
USA  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

### Siemens Global Headquarters

Siemens AG  
Wittelsbacherplatz 2  
80333 Muenchen  
Germany

### Global Siemens Healthcare Headquarters

Siemens AG  
Healthcare Sector  
Henkestrasse 127  
91052 Erlangen  
Germany  
Telephone: +49 9131 84 - 0  
[www.siemens.com/healthcare](http://www.siemens.com/healthcare)

[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)



## Monitoring and Managing Metastatic Breast Cancer

### Serum HER-2/neu Test

Answers for life.

**SIEMENS**

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

## New hope for 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 tissue status is positive, HER-2/neu-targeted therapies 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 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 not. 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? Studies show that up to 90% of metastatic breast cancer patients have an elevated Serum HER-2/neu level.<sup>1</sup>

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.

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.

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



## 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?

\* 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 tissue status is positive or negative, and they are the only tests used to determine if you are eligible for Herceptin therapy.

## Reference:

1. Valero V, Roche H, Pienkowski T, et al. BCIRG 007: Serum HER-2/neu levels in women with metastatic HER-2/neu-amplified breast cancer. *J Clin Oncol*. ASCO Annual Meeting Proceedings 2007, Abstract No: 10201.
2. Ali SM, Carney W, Esteva FJ, et al. Serum HER-2/neu and relative resistance to trastuzumab-based therapy in patients with metastatic breast cancer. *Cancer*, 2008. Sep 15;113(6):1294-301.
3. Ardavanisa A, Kountourakisa P, Kyriakoub F, et al. Trastuzumab plus Paclitaxel or Docetaxel in HER-2-Negative/HER-2 ECD-Positive Anthracycline- and Taxane-Refractory Advanced Breast Cancer. *The Oncologist*, 2008. 13:361-369.
4. Carney WP, Brown-Shimer S, Hamer PJ. Serum HER-2/neu testing can identify HER-2/neu positive patients previously classified as negative by tissue testing. American Association for Clinical Chemistry Annual Meeting Proceedings, 2008. *Clin Chem* Vol 54(56) Suppl, pg A130: Abstract No. C-96.
5. Carney W, Leitzel K, Ali SM, et al. HER-2/neu Diagnostics in Breast Cancer. *Breast Cancer Res Treat*, 2007. 9(3):207.
6. Colomer R, Llombart-Cussac A, Lloveras B, et al. High circulating HER2 extracellular domain levels correlate with reduced efficacy of an aromatase inhibitor in hormone receptor-positive metastatic breast cancer: a confirmatory prospective study. *Cancer*, 2007. 110(10):2178-85.