

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.
- The 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.

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.

Legal Manufacturer

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA

Global Division

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
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

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 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.¹ 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?

Reference:

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

* 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.