

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.

All associated marks are trademarks of Siemens Healthcare Diagnostics Inc. All other trademarks and brands are the property of their respective owners.

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

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

Global Division

Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
www.siemens.com/diagnostics

www.siemens.com/diagnostics

Order No. A91DX-0700066-C3-4A00 | Printed in USA | © 2009 Siemens Healthcare Diagnostics Inc.



Serum HER-2/neu Test: A New Way to Manage Breast Cancer Patient Care

Answers for life.

SIEMENS

Testing that could make a difference in the lives of your patients.



A commitment to better patient treatment and care

Siemens Healthcare Diagnostics is committed to evolving our oncology portfolio with diagnostic products that will improve the care and treatment of cancer patients around the world.

The Serum HER-2/neu test from Siemens Healthcare Diagnostics helps positively impact the management and care of breast cancer patients.

The lifetime risk of developing breast cancer for women is on the rise. Fortunately, so is patient survivability — thanks in large part to improved oncology diagnostics.

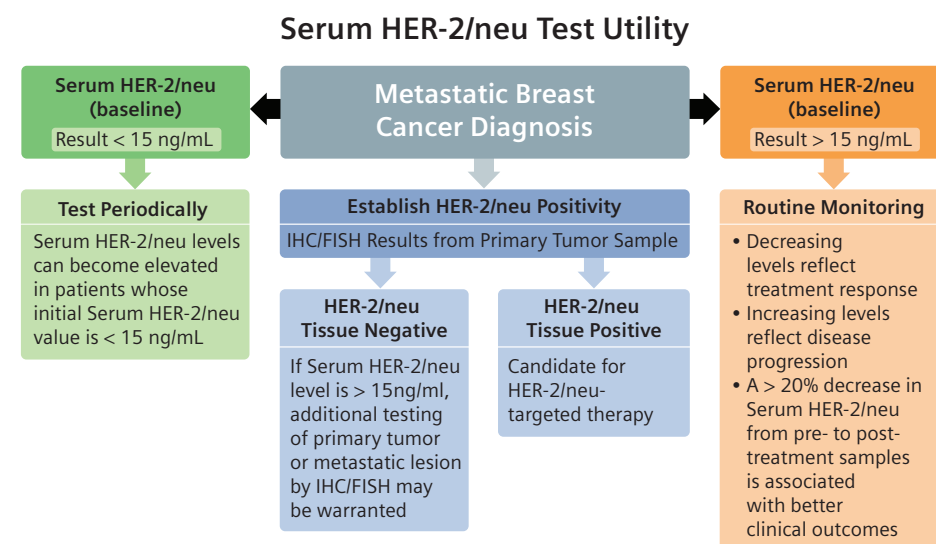
Leading the way on this front is the Serum HER-2/neu test from Siemens, the first FDA-cleared blood test for measuring circulating levels of the HER-2/neu oncoprotein in the follow-up and monitoring of patients with metastatic breast cancer. **It is the only serum test available to monitor HER-2/neu level changes over the course of disease.**

The availability of this innovative new test is an essential part of Siemens' ongoing mission: To identify key oncoproteins from which to develop new tests, and to link these tests with the appropriate treatment options for potentially life-saving results.

Why Serum HER-2/neu Testing?

Extensive studies have concluded that the HER-2/neu oncoprotein plays a pivotal role in the development and progression of breast cancer. Overexpression of HER-2/neu has been shown to be an indicator of poor prognosis in patients exhibiting aggressive disease, decreased overall survival, and a higher probability of recurrence.^{1,2}

Over the course of disease, monitoring HER-2/neu levels yields important information about response to therapy, and may help physicians make more informed decisions when developing and modifying patient treatment regimens.³⁻⁵



Serum HER-2/neu Test Utility at a Glance¹⁰⁻¹³

The Serum HER-2/neu test is used to monitor a patient's HER-2/neu status once a diagnosis of metastatic breast cancer has been established. The chart above shows how the Serum HER-2/neu test is typically used as a monitoring tool complementary to tissue testing.

Unprecedented Benefits

- **High degree of confidence in results:** The Serum HER-2/neu test offers excellent precision and resistance to interference from HER-2/neu-based therapy.⁶
- **Well-suited to long-term patient monitoring:** The Serum HER-2/neu test has low reagent lot-to-lot variability.⁶
- **Effective for the management and follow-up of patients with metastatic breast cancer:** Increasing levels of Serum HER-2/neu reflect disease progression while decreasing levels reflect response or stable disease.^{7,8}

Tissue and Serum HER-2/neu Testing

Traditional HER-2/neu testing has been generally limited to tissue from primary breast cancer and does not provide information regarding the HER-2/neu status at the time of recurrent, metastatic breast cancer.

The Serum HER-2/neu test picks up where tissue testing leaves off. It allows you to monitor changes in HER-2/neu levels over the course of metastatic disease with a simple blood draw, enabling you to assess response to treatment.

For more information on Serum HER-2/neu visit www.siemens.com/herstory or email herstory.healthcare@siemens.com.

References:

1. Slamon DJ, et al. *Science* 1987;235:177.
2. Sahin AA, et al. *Adv. in Anatomic Path.* 2000;7(3):158.
3. Schwartz MK, et al. *International Journal of Biological Markers* 2000;15(4):324.
4. Lipton A, et al. *Journal of Clinical Oncology* 2002;20(6):1467.
5. Esteva FJ, et al. *Journal of Clinical Oncology* 2002;20(7):1800.
6. Payne RC, et al. *Clinical Chemistry* 2000;46(2):175.
7. Cook GB, et al. *Anticancer Research* 2001;21:1465.
8. Siemens Healthcare Diagnostics FDA submission/HER-2/neu method sheet.
9. Ali SM, Carney WP, 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.
10. Lipton A, Leitzel K, Chaudri-Ross HA, et al. Decrease in serum extracellular domain of HER2 at 4 and 8 weeks is associated with prolonged progression-free survival on lapatinib monotherapy. Proceedings of the 31st Annual CTRC-AACR San Antonio Breast Cancer Symposium, 2008. December: Abstract No. 3140.
11. Zidan J, Dashkovsky I, Stayerman C, et al. Comparison of HER-2 overexpression in primary breast cancer and metastatic sites and its effect on biological targeting therapy of metastatic disease. *Br J Cancer*. 2005 Sep 5;93(5):552-6.
12. Lower EE, Glass E, Blau R, Harman S. HER-2/neu expression in primary and metastatic breast cancer. 1: *Breast Cancer Res Treat*. 2009 Jan;113(2):301-6. *Epub* 2008, Feb 14.
13. 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.