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An Evolution in Serum HER-2/neu Monitoring

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Current Advances in HER-2/neu Biomarker Testing

Serum HER-2/neu Testing for Effective Disease Management

The Serum HER-2/neu test is a biomarker for metastatic breast cancer (MBC) patients whose initial serum level is >15 ng/mL. Increasing levels of Serum HER-2/neu reflect disease progression while decreasing levels reflect therapy response or stable disease.^{1,2,3}

This serum test monitors HER-2/neu, an oncoprotein found elevated in the blood of some breast cancer patients. Serum HER-2/neu testing may help identify MBC patients whose HER-2/neu status has changed.

The Serum HER-2/neu test does not replace tissue tests but is a complementary monitoring tool. The additional insight that a Serum HER-2/neu test offers can make an important difference in getting the right treatment to the right patient at the right time.

Serum HER-2/neu and Tissue Tests

Immunohistochemistry (IHC) or fluorescence in situ hybridization (FISH) provides a measurement of a patient's HER-2/neu status at initial diagnosis of breast cancer. The Serum HER-2/neu test complements tissue tests when a tumor spreads by monitoring response to therapy or disease progression. Serum HER-2/neu offers the following advantages:

- It is minimally invasive—requiring only a simple blood test
- Serum HER-2/neu can be used to monitor MBC patients on any therapy including hormone therapy, chemotherapy, HER-2/neu-targeted therapy and combination therapy
- It is the only test that can follow a patient's Serum HER-2/neu level once she is diagnosed with MBC and be used to help determine if the HER-2/neu status has changed
- Serum HER-2/neu should be monitored routinely in patients with an elevated Serum HER-2/neu level (15 ng/mL or greater)

Regardless of the HER-2/neu tumor result, it is important to establish a serum baseline using the Serum HER-2/neu test at the time that MBC is diagnosed. Serum testing can help identify women whose metastasis may be HER-2/neu positive, but who tested negative by IHC or FISH in the primary tumor. Studies have shown that up to 90% of MBC patients can have an elevated Serum HER-2/neu level.⁴ This has important clinical implications for determining whether a patient with MBC should receive HER-2/neu targeted treatment. Patients whose initial breast tumor tissue was HER-2/neu negative but who have elevated levels of Serum HER-2/neu and metastatic disease may benefit from additional testing of tissue from the primary site or sites of metastasis to determine if HER-2/neu status has changed.



Serum HER-2/neu and Commonly Used Tumor Markers

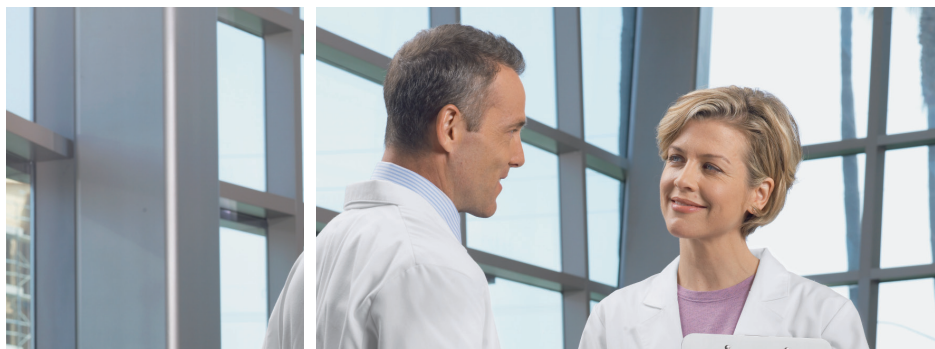
Because the Serum HER-2/neu test monitors an oncoprotein, it can provide insight into tracking patients with MBC who are receiving HER-2/neu-directed therapy.

For example, there are now specific HER-2/neu-targeted therapies, but no therapies targeted at other tumor markers such as CEA and CA 15-3. CEA and CA 15-3 are tumor markers associated with tumor bulk, while HER-2/neu has been shown to be an independent factor with respect to tumor bulk (Ali et al.).¹³

Patients who have an elevated Serum HER-2/neu level (15 ng/mL or greater) can be routinely monitored to help manage their 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. Serum HER-2/neu testing provides clear information: Rising levels reflect disease progression; falling levels reflect treatment response or stable disease. The Serum HER-2/neu test is simple, quantitative, and informative.

The Serum HER-2/neu Advantage

The Serum HER-2/neu test differs from other tumor marker tests in that it is a biomarker for MBC patients with breast cancer and is an important cellular target for a variety of new cancer therapies. In contrast to traditional tumor markers such as CA 15-3 and CEA which track tumor burden, Serum HER-2/neu monitors changes in the HER-2/neu oncoproteins which are independent of tumor burden. In addition, tumor markers such as CEA and CA 15-3 are not specifically associated with targeted therapies, unlike HER-2/neu.



Monitoring the rise and fall of Serum HER-2/neu levels can help guide therapy and manage the disease of MBC patients.

The Serum HER-2/neu test may be used in conjunction with tumor marker tests; in fact, studies show that serum testing for HER-2/neu may provide additional insight to monitoring with tumor markers CEA and CA 15-3.⁶⁻¹³

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

The Advantages of Serum HER-2/neu Over Other Commonly Used Tumor Markers

Serum HER-2/neu and Traditional Tumor Markers: A Comparison				
	HER-2/neu	CEA	CA 15-3	BR 27.29
Converts normal cells to cancer cells	✓			
Is the target of specific therapies	✓			
Provides specific information about status of HER-2/neu-positive tumors	✓			
Guides the use of HER-2/neu targeted therapies	✓			
Is independent of tumor bulk	✓			

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