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.

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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.).

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.  

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

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