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Current Advances in HER-2/neu Biomarker Testing

About the Serum HER-2/neu Test

The Serum HER-2/neu test is a simple biomarker for metastatic breast cancer (MBC). The test measures the portion of the HER-2/neu protein present on the outside surface of cells and shed into the serum of MBC patients. It provides information to help monitor a patient's therapy over the course of disease. Patients who have elevated HER-2/neu levels tend to have tumors that grow more aggressively and resist hormonal therapy and some chemotherapies, and patients generally have a poorer prognosis.¹ Serum levels of HER-2/neu parallel the clinical course of disease regardless of the treatment regimen.^{2,3} Increases reflect progression; decreases

reflect treatment response or stable disease. This allows Serum HER-2/neu to help manage therapy.⁴ Knowing real-time HER-2/neu status may be important in creating a more efficient treatment regimen in patients with metastatic breast cancer.

Clinical Utility of the Serum HER-2/neu Test

Allows more precise monitoring regardless of therapy.

Many studies of patients with MBC receiving hormone or chemotherapy have shown that longitudinal changes in Serum HER-2/neu levels reflect the clinical course of a patient's disease.⁵

Data reported by Schippinger et al.³ and Lipton et al.⁴ indicated that patients with MBC who had a Serum HER-2/neu level <15 ng/mL had improved overall survival. Results of the studies indicated that when therapy successfully keeps the Serum HER-2/neu levels less than 15 ng/mL, the patients generally have improved clinical outcomes.

Numerous reports of patients with MBC, including those by Esteva et al.⁶ and Schondorf et al.,⁷ have indicated that serial changes in Serum HER-2/neu parallels the clinical course of disease in patients treated with various therapies in the majority of cases. These studies evaluated the clinical utility of monitoring Serum HER-2/neu levels in patients treated with trastuzumab plus various combinations of chemotherapy.

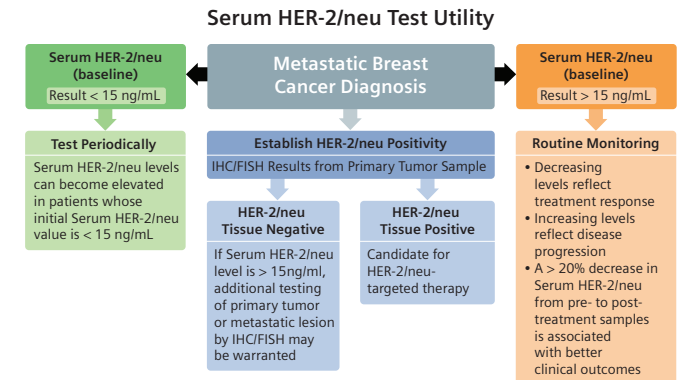
May add greater insight in combination with tumor markers such as CEA and CA 15-3.

A number of studies have investigated the clinical utility of monitoring Serum HER-2/neu in combination with carcinoembryonic antigen (CEA) and CA 15-3. In general, these studies have reported that monitoring Serum HER-2/neu in combination with either CEA or CA 15-3 may improve sensitivity for early detection of breast cancer recurrence.⁸⁻¹³

When to Perform the Serum HER-2/neu Test

Upon a diagnosis of MBC, a baseline Serum HER-2/neu should be established. Patients with Serum HER-2/neu levels greater than 15 ng/mL should have subsequent monitoring.

Regardless of whether the tissue test is negative or positive for HER-2/neu, it is important to establish a Serum HER-2/neu baseline using the Serum HER-2/neu test. 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 as a result of disease progression.



Serum HER-2/neu Test Utility at a Glance¹⁴⁻¹⁸

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.

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