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#### For more information on HER-2/neu:

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## Including Serum HER-2/neu in Metastatic Breast Cancer Monitoring

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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 HER-2/neu-positive breast cancer. The test measures the portion of the HER-2/neu protein present on the outside surface of cells and shed into the serum of metastatic breast cancer (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.<sup>1</sup> Serum levels of HER-2/neu parallel the clinical course of disease regardless of the treatment regimen.<sup>2,3</sup> Increases reflect

progression; decreases reflect treatment response or stable disease. This allows serum HER-2/neu to help manage therapy.<sup>4</sup> Knowing real-time HER-2/neu status may be considered important to 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 of hormone or chemotherapy.

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

Data reported by Schippinger et al.<sup>3</sup> and Lipton et al.<sup>4</sup> 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 managing therapy to keep the serum HER-2/neu <15 ng/mL may improve the clinical outcome of patients with HER-2/neu-positive tumors.

### Allows more precise monitoring of trastuzumab-based therapy.

Numerous reports of patients with MBC, including those by Esteva et al.<sup>6</sup> and Schondorf et al.,<sup>7</sup> have indicated that serial changes in serum HER-2/neu parallels the clinical course of disease in patients treated with various therapies. 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 HER-2/neu in combination with carcinoembryonic antigen (CEA) and CA 15-3.<sup>8-14</sup> In general, these studies

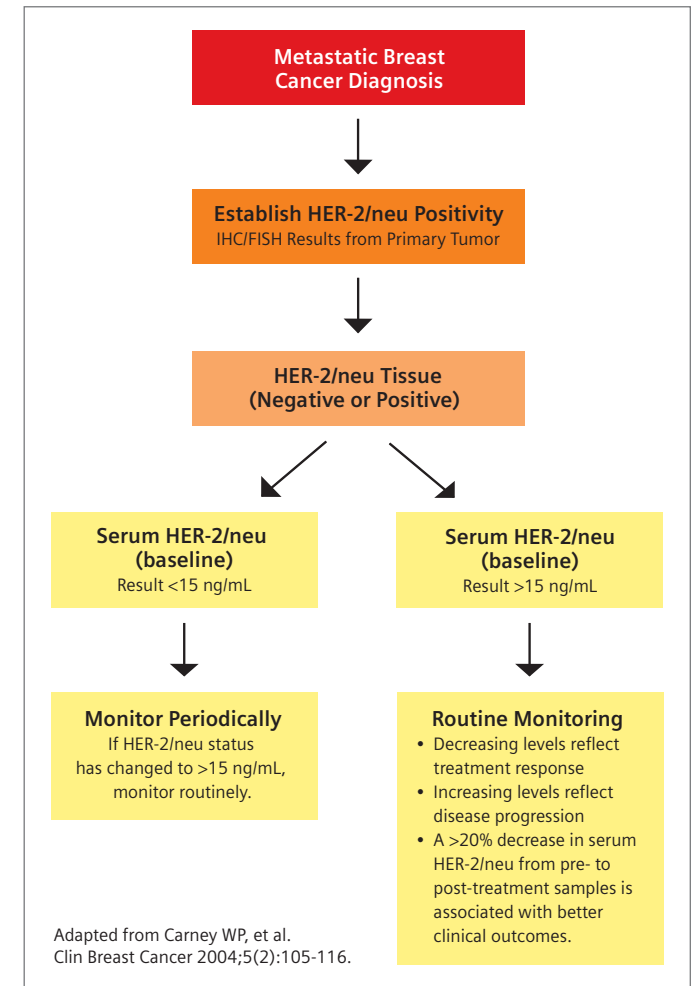
have reported that monitoring serum HER-2/neu in combination with either CEA or CA 15-3 may improve sensitivity for early detection of breast cancer recurrence.

## When to Perform the Serum HER-2/neu Test

Upon a diagnosis of MBC, an established baseline of serum HER-2/neu level should be obtained for 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. Studies have shown that serum testing could help identify HER-2/neu-positive tumors in a population of women with breast cancer (10-40%, approximately 20% on average) who tested negative by IHC or FISH in the primary tumor.<sup>5</sup>

Women who have an elevated serum HER-2/neu level (15 ng/mL or greater) can be routinely monitored to help manage their therapy options. Women who have a normal serum HER-2/neu level (less than 15 ng/mL) can be tested periodically to determine if the HER-2/neu status has changed.



Adapted from Carney WP, et al. Clin Breast Cancer 2004;5(2):105-116.

## Serum HER-2/neu Test Utility at a Glance

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 summarizes the clinical utility of the Serum HER-2/neu Test as a monitoring tool complementary to tissue testing.

For more information about the Serum HER-2/neu Test, visit [www.neunews.net](http://www.neunews.net).