

# Serum HER-2/neu and Breast Cancer: Recent Peer-Reviewed Clinical Studies

## Advanced Breast Cancer

Changes over time of extracellular domain of HER2 (ECD/HER2) serum levels have prognostic value in metastatic breast cancer.

Bramwell V, et al. Breast Can Res Treat. 2009 Apr;114(3):503-11.

**Design:** A study of 158 women with metastatic breast cancer (median age: 61; range: 20 to 84; 87% postmenopausal) were tested for Serum HER-2/neu. Samples were collected within 8 weeks of definitive diagnosis and before initiation of systemic therapy and every 6 to 12 weeks until death.

**Results:** Patients with elevated baseline Serum HER-2/neu had poorer survival and in univariate analysis had an elevated relative risk (RR) of 1.029. In multivariate analysis, Serum HER-2/neu levels greater than 12 ng/mL were the most prognostic for poor survival, with a relative risk of 6.097.

**Conclusions:** This paper provides additional data supporting the usefulness of Serum HER-2/neu in metastatic breast cancer. The authors stated that "increases over time of ECD/HER2 levels were strongly associated with poor survival."

Serum HER-2/neu and relative resistance to trastuzumab-based therapy in patients with metastatic breast cancer.

Ali SM, et al. Cancer. 2008;113(6):1294-301.

**Design:** This study evaluated the utility of the Serum HER-2/neu profile to predict patient resistance to trastuzumab and to establish a clinically relevant cutoff. It included 307 patients with metastatic breast cancer from seven medical institutions.

**Results:** The study found that 191 patients (62%) had a significant decline (>20%) in Serum HER-2/neu whereas 116 patients (38%) did not. The objective response rate was 57% for patients who achieved this decline in Serum HER-2/neu (>20%), compared with 28% for patients who did not. Patients who achieved this decline also had a significantly longer time to disease progression (320 days vs. 180 days;  $P < 0.0001$ ), longer duration of response (369 days vs. 230 days;  $P < 0.008$ ), and longer overall survival (898 days vs. 593 days;  $P < 0.018$ ).

**Conclusions:** The authors suggest that "individuals who did not achieve a significant decline ( $\geq 20\%$ ) in Serum HER-2/neu levels had decreased benefit from trastuzumab-based therapy, and these patients should be considered for clinical trials evaluating additional HER-2/neu-targeted interventions."

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## Advanced and Early-Stage Breast Cancer

### HER-2/neu expression in primary and metastatic breast cancer.

Lower EE, et al. Breast Can Res Treat.  
2009 Jan;113(2):301-6.

**Design:** This study compared HER-2/neu expression in primary and metastatic tumors in 382 breast cancer patients.

**Results:** Initially, 128 cases (34%) were discordant (positive at one site and negative at the other site). Median survival from the time of original diagnosis was significantly different between groups: for group 1 (negative primary / negative metastasis), 2105 days; for group 2 (positive primary / negative metastasis), 1787 days; for group 3 (negative primary / positive

metastasis), 3368 days; and for group 4 (positive primary / positive metastasis), 2290 days. Patients from group 3 (negative primary / positive metastasis) experienced the longest survival. When 2+ staining patterns were removed from the analysis, over 20% of specimens were still discordant, while the difference in survival was no longer significant.

**Conclusions:** Current trastuzumab treatment recommendations are based on analysis of the primary tumor only. This paper showed that discordant results ranged from 20% to 34%. The authors concluded that "the significant discordance between HER-2/neu expression in primary and metastatic tumors suggests that determination of HER-2/neu status in metastatic disease should be attempted."

Serum HER-2/neu values may be used in the follow up and monitoring of patients with metastatic breast cancer whose initial Serum HER-2/neu is greater than 15 ng/mL. Serum HER-2/neu values should be used in conjunction with information available from other clinical and diagnostic procedures in the management of breast cancer.

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