

Factsheet HER-2/neu

What is HER-2/neu?

- HER-2/neu is an Acronym for „Human Epidermal Growth Factor Receptor-2“
- It is an Oncogene; a gene, which plays an important part in uncontrolled cell growth
- HER-2 genes lead to the creation of HER-2-Proteins, which are located on the surface of breast cancer cells
- While normal cells only possess two copies of the HER-2 gene, cancer cells have a much larger number, which is called gene amplification. This leads to an overproduction of HER-2/neu proteins on the cell surface
- HER-2/neu protein overproduction is found in an estimated 20-30 % of all breast cancer cases. This type of cancer is more aggressive and reacts differently to standard therapy for women who are estrogen/progesterone receptor positive

Which tests identify a HER-2/neu overproduction?

- **Tissue Testing:** During an operation, tumor tissue is removed to examine the tumor's characteristic biological attributes. The resulting data are the basis for a detailed pathological report.
 - HER-2/neu tissue tests require a biopsy sample from the original tumor and are used to diagnose HER-2/neu positive breast cancers
 - A HER-2/neu tissue test is required to predict a patient's response to HER-2 targeted therapies, such as Herceptin[®] and Tykerb[®]
 - A positive tissue test result is required for a patient to qualify for HER-2 targeted therapies
 - The positive tissue tests can either be (1) an IHC test that confirms overexpression of HER-2/neu oncoproteins or (2) a FISH test that confirms amplification of HER-2/neu oncogenes.

Serum (blood) HER-2/neu Testing: Serum HER-2/neu is a simple blood test for monitoring real-time HER-2/neu status after initial tissue diagnosis. The Serum HER-2/neu test is FDA-cleared for all patients with metastatic breast cancer, regardless of HER-2 positivity determined by tissue. Serum testing is recommended since its variations results over the course of the disease give important indications for therapy response or disease progression.

- **Decreasing Serum HER-2/neu** levels may indicate a positive response to treatment
- **Increasing Serum HER-2/neu** levels may indicate a weak response to response or disease progression

What are the advantages of HER-2/neu?

- Treatment decisions can be adjusted earlier
- It is a simple blood test that is non-invasive than can be performed with normal blood work
- Serum HER-2/neu may be elevated and/or increasing when there is no clinical evidence of disease. An elevated level may prompt a clinician to order imaging for confirmation.
 - The Serum HER-2/neu test monitors real-time HER-2/neu status after initial tissue diagnosis.
 - The Serum HER-2/neu test is used to monitor changes in HER-2/neu levels which may indicate response to treatment or disease progression.