Serum HER-2 ELISA Kit
Item - 06489876
Serum HER-2 Controls
Item - 06489884

Intended Use
For in vitro diagnostic use

The HER-2/neu ELISA is an in vitro, diagnostic device intended for use in the quantitative determination of serum HER-2/neu in women with metastatic breast cancer who have an initial value of 15 ng/mL or greater. HER-2/neu values obtained may be used in the follow-up and monitoring of patients with metastatic breast cancer. HER-2/neu values should be used in conjunction with information available from clinical and other diagnostic procedures in the management of breast cancer. The clinical utility of the serum measurement of HER-2/neu as a prognostic indicator for early recurrence and in the management of patients on immunotherapy regimens has not been fully established.

Monitoring Serum HER-2/neu to Help Manage Metastatic Breast Cancer Patients

Metastatic breast cancer (MBC) patients who overexpress the HER-2/neu protein tend to have a worse prognosis and a more aggressive disease that can be resistant to certain types of chemotherapy [1]. HER-2/neu protein overexpression is determined by running a tissue test like immunohistochemistry. If a patient overexpresses the HER-2/neu protein, they are considered HER-2/neu-positive and a candidate for HER-2/neu-targeted therapy such as trastuzumab. HER-2/neu-targeted therapy is helping to improve survival rates for HER-2/neu-positive, MBC patients everywhere [2].

Serum HER-2/neu testing does not determine HER-2/neu overexpression but is complementary to tissue testing because it can be used to help monitor certain patients on HER-2/neu-targeted therapies once tissue testing already has established that the patient overexpresses HER-2/neu. The serum HER-2/neu ELISA measures a portion of the protein present on the outside surface of cells. This portion, often referred to as the extracellular domain (ECD), can cleave off into the blood of MBC patients. Serum HER-2/neu testing can measure the amount of HER-2/neu ECD shed into the blood.

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The HER-2/neu ELISA is a simple, non-invasive serum test that can be used as a clinical tool for monitoring and managing certain patients with MBC when used in conjunction with clinical and other diagnostic procedures. When serum values are equal to or greater than 15 ng/mL, the test can be used to monitor a patient's HER-2/neu status and has been shown to parallel the clinical course of disease regardless of a patient's treatment regimen [3-8]. Increasing levels in serum can reflect disease progression while decreasing levels can reflect treatment response or stable disease [8-13]. Monitoring the changes of serum HER-2/neu levels can help manage these metastatic breast cancer patients. The clinical utility of serum measurement of HER-2/neu as a prognostic indicator for early detection of recurrence and in the management of patients on immunotherapy regimens has not been fully established.

Establish a Baseline Serum HER-2/neu

Upon a diagnosis of MBC, a baseline serum HER-2/neu level should be established. Patients with an initial serum HER-2/neu level equal to or greater than 15 ng/mL should have subsequent monitoring. Regardless of whether a HER-2/neu tissue test is negative or positive for overexpression of HER-2/neu, it is important to establish a serum HER-2/neu baseline. Some studies have noted a possible discordance between HER-2/neu expression in primary versus metastatic breast cancer tumors [14,15]. However, serum HER-2/neu levels can become elevated in patients whose initial serum HER-2/neu value was less than 15 ng/mL [16]. This may indicate a change in HER-2/neu status as a result of disease progression.

Use In Conjunction with Other Diagnostic Procedures such as Traditional Tumor Marker Tests

Unlike traditional tumor markers, the HER-2/neu oncoprotein, which is quantitatively measured by the serum

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HER-2/neu ELISA, is derived from a known oncogene which is biologically involved in converting normal cells to cancer cells. Serum HER-2/neu testing can offer a real-time assessment of a patient's HER-2/neu status. A number of studies have investigated the clinical utility of monitoring serum HER-2/neu in conjunction with other diagnostic procedures such as tumor marker tests [8,17,18]. In particular, Dnistrian AM et al. found that measuring serum HER-2/neu levels in conjunction with certain tumor markers helped monitor patient response to targeted therapy [18].

Monitor the Course of Disease Regardless of Therapy

As previously mentioned, 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 [9]. Other reports indicate that patients with MBC whose serum HER-2/neu level remained below 15 ng/mL when monitored over a period of time were responding to certain therapies [5,11,13]. Numerous studies have evaluated the clinical utility of monitoring serum HER-2/neu levels in MBC patients treated with several types of therapies, including trastuzumab plus various combinations of chemotherapy.

![Graph showing changes in serum HER-2/neu levels over time.

Monitoring of a 74-year-old Stage Iv breast cancer patient with the serum HER-2/neu ELISA. Longitudinal changes in serum HER-2/neu levels correlate with changes in disease status.

Principle of the Assay

The Serum HER-2/neu ELISA test is a sandwich enzyme immunoassay that utilizes a mouse monoclonal antibody for capture and a different biotinylated mouse monoclonal antibody for the detection of human HER-2/neu protein. Both capture and detector reagents specifically bind to the extracellular domain of HER-2/neu protein. The Capture Antibody has been immobilized on the interior surface of microtiter plate wells. To perform the test, an appropriate volume of specimen is incubated in the coated well to allow binding of the antigen by the Capture Antibody. The immobilized antigen is then reacted with the detector antiserum. The amount of Detector Antibody bound to antigen is measured by binding it with a streptavidin/horseradish...
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peroxidase Conjugate, which then catalyzes the conversion of the chromogenic Substrate o-phenylenediamine (OPD) into a colored product. The colored reaction product is quantitated by spectrophotometry and is related to the amount of HER-2/neu protein in the sample. For instructions, see the Detailed Protocol and Evaluation of Results sections of the assay protocol. Results are available in one day for customers who require a standardized, reliable result for comparing values within the laboratory or between laboratories.

**Patents**

Purchase of this kit licenses its use under the following U.S. patents 5,401,638 and 6,861,511.

**References**

*A study funded with Nuclea Biotechnologies Oncogene Science ELISA kits.


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