



Oncogene Science HER-2/neu ELISA

Human Epidermal growth factor Receptor-2
For In Vitro Diagnostic Use.

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→ Intended Use

The Oncogene Science® 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.

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 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].



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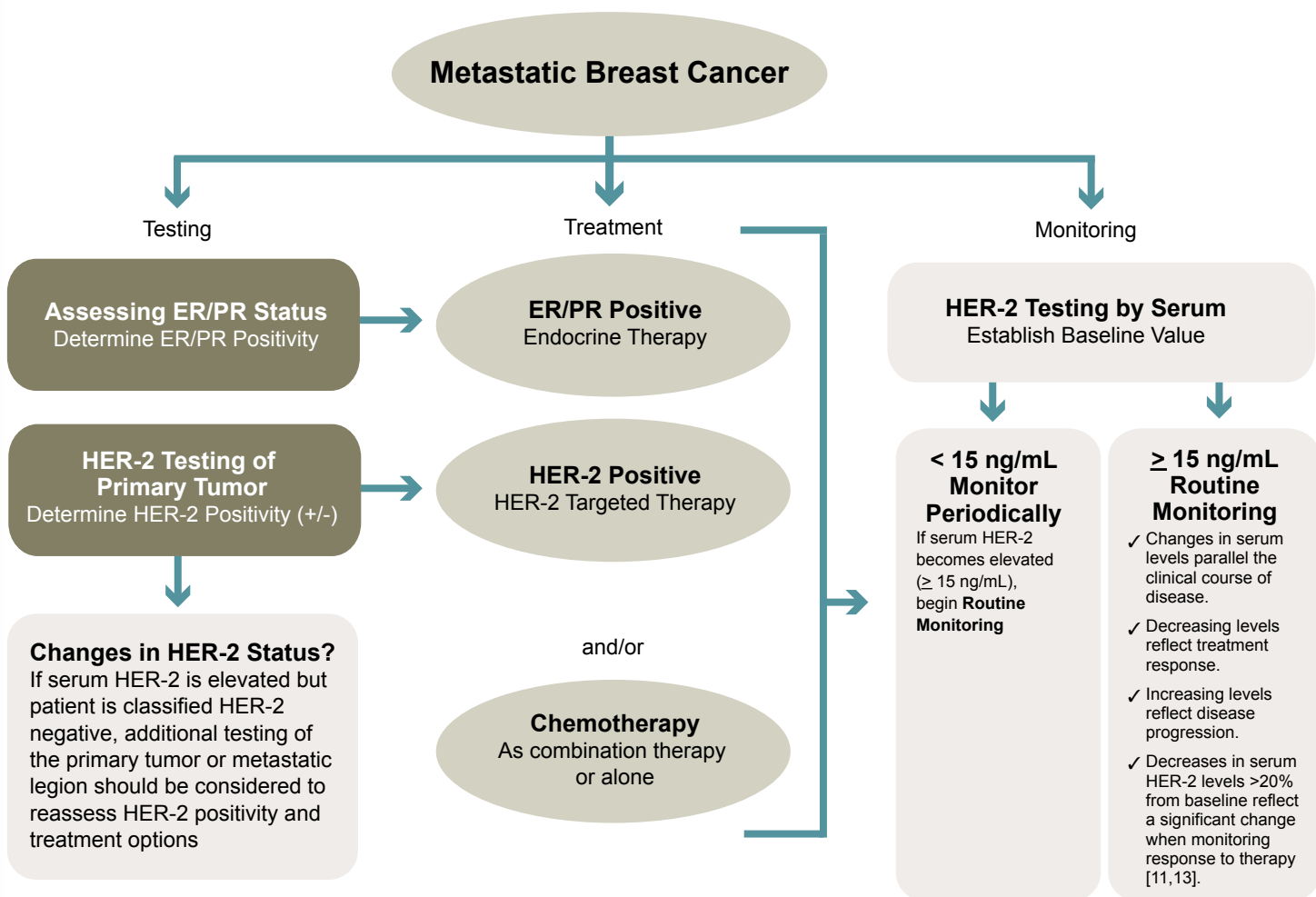
→ Monitor the course of disease regardless of therapy

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.

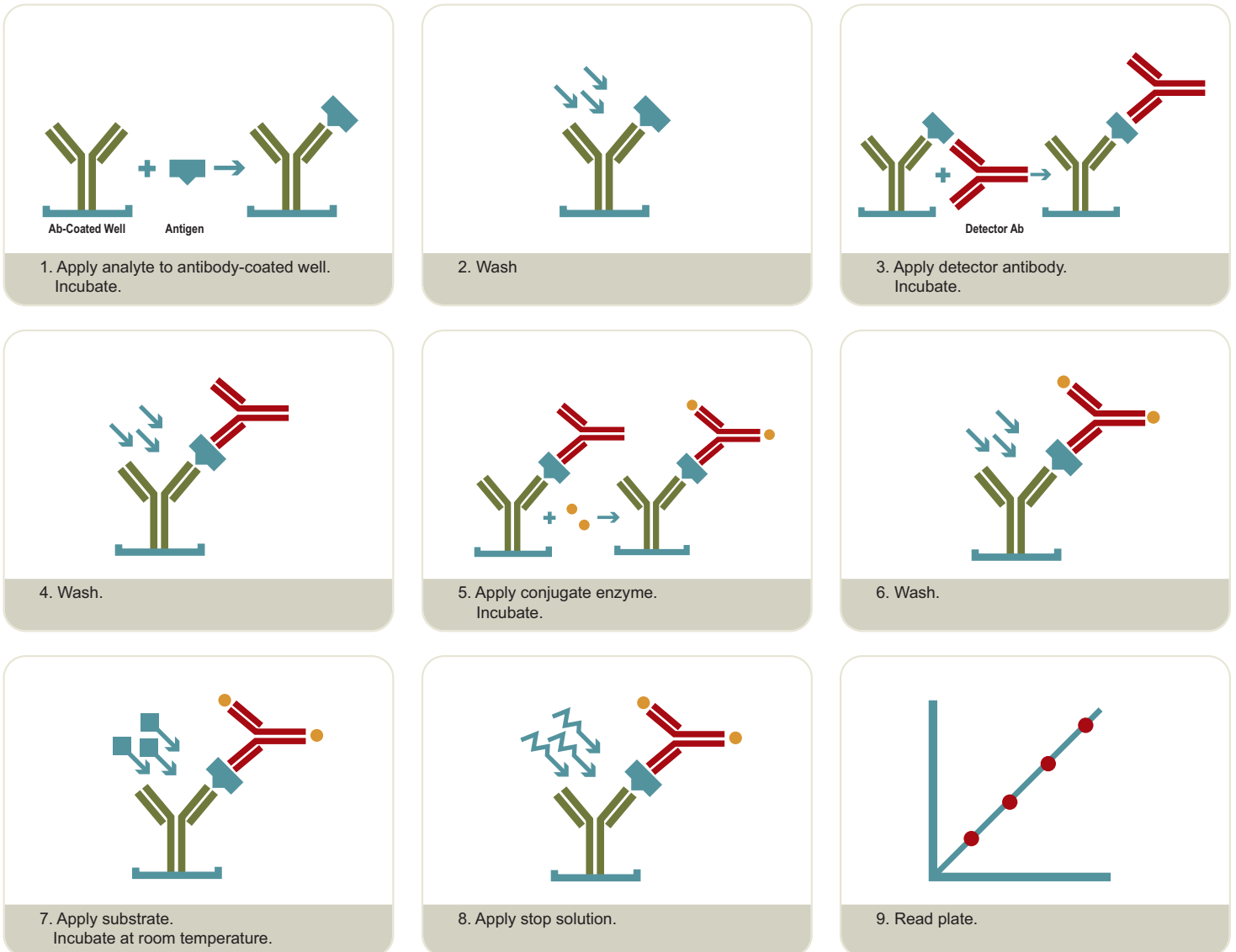
Serum HER-2/neu ELISA - A Monitoring Device Complementary to Tissue Testing



The Serum HER-2/neu ELISA can be used as an aid in the follow-up and management of metastatic breast cancer patients whose initial HER-2/neu value is 15 ng/mL or greater. The correspondence between HER-2/neu values and the patient's clinical course of disease demonstrate that this test may be used in conjunction with other clinical indicators to monitor disease progression and response to therapy. Recent reports indicate that decreases in serum HER-2/neu levels >20% from baseline reflect a significant change when monitoring response to therapy [11,13].

HER-2/neu ELISA Procedure

Results are available in one day for customers who require a standardized, reliable result for comparing values within the laboratory or between laboratories.



The HER-2/neu ELISA also includes the following required materials to ensure accurate, consistently reproducible results:

- Microtiter plate
- HER-2/neu Standards
- Sample Diluent
- Detector Antibody
- Conjugate Diluent
- Conjugate Concentrate
- Substrate Diluent
- Substrate
- Stop Solution
- Platewash Concentrate (20X)



→ For additional product information or to place an order, please visit www.oncogene.com.

Ordering Information

Part Number Description

06489876	HER-2/neu ELISA (IVD/CE Mark)*	1 Plate	96 Wells	38 Samples†
06489884	HER-2/neu ELISA Controls (IVD/CE Mark)*	0.5 mL		3 Levels

Each plate contains 96 antibody-coated test wells (12 strips of 8).

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

†Tests to be run in duplicate.

→ Reimbursement

Effective January 1, 2002, the American Medical Association (AMA) approved a unique Current Procedural Terminology (CPT) code for HER-2/neu oncoprotein testing for most health insurance programs.

CPT Code:

- HER-2/neu oncoprotein: 83950



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