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HER2 Testing for Breast Cancer [1]

To help doctors give their patients the best possible care, the American Society of Clinical Oncology (ASCO) asks its medical experts to develop recommendations for specific areas of cancer care. In 2013, ASCO and the College of American Pathologists (CAP) issued an updated joint clinical practice guideline about human epidermal growth receptor 2 (HER2) testing for breast cancer. This guide for patients is based on ASCO and CAP?s recommendations.

Key Messages:

- HER2 is a specialized protein found on breast cancer cells that controls cancer growth and spread.
- All patients with invasive breast cancer should have their tumors tested for HER2 with at least one of the two approved testing methods.
- If the cancer has spread to other parts of the body, HER2 testing should be done on the areas where the cancer has spread, if it is possible, and especially if results would influence a patient?s treatment options.
- This testing should be performed by an accredited laboratory that follows specific testing procedures.

Larger Image [2]

Cancer.Net

Diagnosing Breast Cancer:
Human Epidermal Growth Factor (HER2) Testing

HER2, or human epidermal growth factor 2, is a special protein on the surface of breast cells that controls the growth of cancer.

The levels of HER2 in your tumor help your doctor plan your treatment options.

When is HER2 testing done?

- You have been newly diagnosed with breast cancer
- You have breast cancer that has come back after treatment
- Your cancer has spread to other parts of the body

How is HER2 testing done?

- **Immunohistochemistry (IHC)** measures the levels of HER2 protein on the surface of the cancer cells.
- **In-situ hybridization (ISH)** measures the copies of the HER2 gene within one cancer cell.

HER2 test results can be

HER2 POSITIVE

High levels of the HER2 protein and/or many copies of the HER2 gene are found in your tumor sample.

Treatment Options

HER2-targeted therapy, such as trastuzumab (Herceptin), lapatinib (Tykerb), pertuzumab (Perjeta), and ado-trastuzumab emtansine (T-DM1; Kadcyla)

HER2 NEGATIVE

No or low levels of the HER2 protein and/or few copies of the HER2 gene are found in your tumor sample.

Treatment Options

HER2-targeted therapy is not recom-mended. Your doctor will suggest other treatment options.

Sometimes, retesting is needed

The levels of the HER2 protein and/or the number of copies of the HER2 gene fall between the limits for HER2 positive and HER2 negative.

Testing may need to be done again, either on a different tu-mor sample or with a different test. Even then, results may not be conclu-sive. You and your doctor will discuss what this means for treatment.

- Find more at www.cancer.net/recommendations or read the full guideline from ASCO and the College of American Pathologists at www.asco.org/guidelines/her2

- **RESOURCES**
  Guide to Breast Cancer (www.cancer.net/breast)
  Understanding a Pathology Report (www.cancer.net/pathology)
  After a Biopsy: Making the Diagnosis (www.cancer.net/afterbiopsy)

ASCO
American Society of Clinical Oncology

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Background

HER2 is a receptor (specialized protein) on the surface of all breast cells. When a breast cell has abnormally high levels of HER2, it can drive breast cancer growth and spread. Usually, a breast cell has two copies of the *HER2* gene, which controls production of the HER2 protein. About 15% to 20% of patients with invasive breast cancer have abnormally high levels of the *HER2* gene and/or the HER2 protein. These cancers, referred to as HER2-positive, tend to be higher risk cancers, but certain types of chemotherapy and targeted therapy work well to treat these cancers.

Drugs that specifically block HER2 to stop the growth of cancer cells are called HER2-targeted therapies. Examples of these drugs include trastuzumab (Herceptin), lapatinib (Tykerb), pertuzumab (Perjeta), and ado-trastuzumab emtansine (T-DM1; Kadcyla). These drugs are effective against HER2-positive invasive cancers, but they are costly. Rarely, these drugs cause serious side effects, such as heart problems, liver inflammation, diarrhea, and skin problems. Therefore, it is important to accurately determine how much HER2 your cancer makes so you can receive these drugs if the cancer is HER2 positive, or avoid receiving ineffective drugs if it is HER2 negative.

The two FDA-approved methods currently used in the United States to test for HER2 are immunohistochemistry (IHC) and in-situ hybridization (ISH). IHC testing can show how much of the HER2 protein is present on the cancer cell surface, while ISH testing measures the number of copies of the *HER2* gene inside each cell. There are two main types of ISH tests: fluorescence and bright-field ISH.

Recommendations for HER2 testing

To help your doctor decide if HER2-targeted therapy is a treatment option for you, ASCO recommends the following:

- If you have been diagnosed with invasive breast cancer, HER2 testing must be done on your cancer when first diagnosed to determine whether HER2-targeted therapy is a treatment option for you. In addition, if the breast cancer has spread to another part of your body or comes back after treatment, testing should be done again on the new tumor or areas where the cancer has spread, especially if results would influence your treatment options.
- Either IHC or ISH testing may be used, as long as it is correctly performed, validated, and reproducible. The pathology laboratories that perform HER2 testing should follow specific testing procedures and handle tissue samples consistently.
- Most HER2 tests are clearly negative or positive, meaning that your cancer has either a high or low level of HER2. If your test results are not clearly positive or negative, testing may need to be done again, either on a different tumor sample or with a different test. Sometimes even with repeated testing, the results may not be conclusive so you and your doctor will have to discuss the best treatment.
- If the cancer is HER2 positive, HER2-targeted therapy is a recommended treatment option for

you. If the cancer is HER2 negative, HER2-targeted therapy is not a treatment option for you, and your doctor will give you other options for treating the breast cancer.

What This Means for Patients

It is important that you and your doctor know if your breast cancer is HER2 positive or negative, whether the cancer is newly diagnosed, has spread, or has come back after treatment. Your doctor will use the results of HER2 testing to make sure you receive the appropriate treatment and avoid the side effects of a treatment that is unlikely to work. Use this information to talk with your doctor about the results of your HER2 testing, including what they mean and how they affect your treatment options.

Questions to Ask Your Doctor

To learn more about HER2 testing for breast cancer, consider asking your doctor the following questions:

- Are the results of HER2 testing on my tumor clearly negative or positive? What does this mean?
- What test was used and does the lab that did the testing follow the ASCO/CAP guideline?
- Will the test need to be repeated? If so, is another tumor sample needed?
- If my cancer has spread, will HER2 testing be done on the metastases? If so, what does this involve?
- Can I obtain a copy of my pathology report (laboratory test results)? Is my HER2 status indicated on the pathology report?
- Are you comfortable with the results?
- Based on these test results, what treatments do you recommend? Why?
- What are the possible side effects of these treatments?

Helpful Links

Read the entire clinical practice guideline at www.asco.org/guidelines/her2 [3].

Guide to Breast Cancer [4]

Understanding a Pathology Report [5]

After a Biopsy: Making the Diagnosis [6]

Links:
[1] http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/her2-testing-breast-cancer
[2] http://www.cancer.net/sites/cancer.net/files/her2-testing_infographic_large.pdf
[3] http://www.asco.org/guidelines/her2
[4] http://www.cancer.net/node/18618
[5] http://www.cancer.net/node/24715
[6] http://www.cancer.net/node/24371