HER2 TESTING

This handout explains why breast cancers are tested for HER2 and how the testing is done. It also describes the different types of HER2 tests and what the results of each test mean.

Your health care team is your primary resource for information. Only your health care team can give you medical advice about your treatment.

Why Are Breast Cancers Tested for HER2?

Breast cancer cells are tested for HER2 (human epidermal growth factor receptor 2) to give you and your doctor information about how your cancer might behave and which treatments might be most appropriate. Breast cancer that tests positive for HER2 is more likely to grow quickly and spread to other parts of the body. There are treatments available just for HER2-positive breast cancer, and they can help slow or stop the cancer’s growth. These targeted treatments are often given together with conventional chemotherapy, and they can affect both cancer cells and normal cells.

How, When, and Where Is HER2 Testing Done?

After your biopsy, the breast tissue that was removed goes to a laboratory. Here, a doctor called a pathologist studies cells from the tissue sample for many factors in order to make a diagnosis. One of the tests performed on the cells is a HER2 test.

HER2 testing should be done for all cases of invasive breast cancer (cancer that has spread from its original place to nearby breast tissue), including recurring cancer that previously tested HER2-negative. The result of the HER2 test should be shown on the pathology report, which is a report that the pathologist sends to your doctor to describe the characteristics of your cancer.

What Are the Different Kinds of HER2 Tests?

Laboratories usually use the following types of HER2 tests. All of the tests involve looking at the cancer cells under a microscope, but they look for different things.

IHC, which stands for immunohistochemistry, is a test that shows whether the cancer cells have too much of the HER2 protein. This protein causes cells to grow. The result of the IHC test can be one of the following: 0, 1+, 2+, or 3+. A result of 0 or 1+ is reported as HER2-negative, a result of 2+ is reported as borderline (or “equivocal”), and a result of 3+ is reported as HER2-positive.

ISH, which stands for in situ hybridization, is a kind of test that shows whether the cancer cells have too many copies of the HER2 gene. This gene tells cells to make the HER2 protein. The result of an ISH test (also called FISH or CISH) is either positive or negative.
**What Do the Results Mean?**

**Positive**
A positive HER2 test result means the cancer cells have large amounts of the HER2 gene or protein. HER2-positive cancer may be eligible for treatment with one of several drugs that work by blocking the HER2 protein’s ability to make cells grow. These drugs are known as HER2-targeted treatments. They are often given along with conventional chemotherapy, and they can affect both cancer cells and normal cells.

**Negative**
A negative HER2 test result means the cancer cells do not have large amounts of the HER2 gene or protein. HER2-negative cancer may not be eligible for HER2-targeted treatments, so if your cancer is HER2-negative, you and your doctor should discuss other options.

**Borderline**
A borderline HER2 test result (IHC 2+) means it is unclear whether the cancer is HER2-positive or HER2-negative. If you have a borderline result, your tissue sample must be tested again with a different HER2 test, or a new sample tested with the same HER2 test. All tests used should be FDA-approved.

**Note:** This is general information only. Each laboratory is responsible for its own testing methods.

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**HER2 Testing Recommendations**

**From the American Society of Clinical Oncology and the College of American Pathologists**

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>What it Counts</th>
<th>Possible Results</th>
<th>How the Results May Affect Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHC</td>
<td>HER2 proteins</td>
<td>0 (negative)</td>
<td>Oncologist must not recommend HER2-targeted treatment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1+ (negative)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2+ (borderline)</td>
<td>Oncologist must delay decision to recommend HER2-targeted treatment. Pathologist must retest the same sample with a different test, or test a new sample with the same test.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3+ (positive)</td>
<td>Oncologist should recommend HER2-targeted treatment.*</td>
</tr>
<tr>
<td>ISH</td>
<td>HER2 genes</td>
<td>Negative</td>
<td>Oncologist must not recommend HER2-targeted treatment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Positive</td>
<td>Oncologist should recommend HER2-targeted treatment.*</td>
</tr>
</tbody>
</table>

*HER2-targeted treatments are often given together with conventional chemotherapy.

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**What Else Should I Consider?**

Because the HER2 status of your cancer affects your treatment options, it’s important for you and your doctor to have this information before deciding on a treatment plan. Sometimes test results don’t all come back at once, and sometimes it can be a few weeks until you have all the results. If your pathology report doesn’t show the HER2 status, be sure to ask your doctor about waiting for the HER2 test result.

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