



ASCO–CAP HER2 Patient Guide

Recommendations for Human Epidermal Growth Factor Receptor 2 (HER2) Testing in Breast Cancer: American Society of Clinical Oncology (ASCO) / College of American Pathologists (CAP) Clinical Practice Guideline Update

Introduction

About 1 in 5 breast cancers will test positive for increased levels of a protein called the human epidermal growth factor receptor 2 (HER2). While HER2-positive breast cancers tend to be more aggressive than other types of breast cancer, new advances in molecular testing and individualized treatment options have led to improved patient outcomes.

To help pathologists and oncologists provide the best possible patient care, the College of American Pathologists (CAP) and the American Society of Clinical Oncology (ASCO) have jointly released an updated evidence-based guideline aimed at improving the accuracy and reporting of HER2 testing and communications between physicians and patients.

This guide provides you, as a patient, an overview of the recommendations, the role of the pathologist in diagnosing HER2 positive breast cancer, as well as questions to ask your doctor.

Recommendations: What do they mean for patients?

To ensure breast cancer patients receive the right test, at the right time, for the right treatment, the guideline, Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: ASCO/CAP Clinical Practice Guideline Update, recommends:

- The HER2 tumor status (HER2 negative or positive) should be determined on all patients with invasive breast cancer (early stage or recurrence)
 - o If you have been diagnosed with invasive breast cancer, it is important for your doctors to know the HER2 status of your cancer to determine if you may benefit from HER2-targeted therapies, such as trastuzumab (Herceptin), lapatinib (Tykerb), pertuzumab (Perjeta), and T-DM1 (Kadcyla). These treatments can substantially improve survival in patients with HER2-positive invasive breast cancer.
 - o If your breast cancer is HER2-negative, you can avoid the side effects and costs associated with those drugs.

The updated guideline contains more detailed recommendations to empower you to take an active role in making decisions affecting your health. Other key points of the guideline include:

- The updated guideline addresses all aspects of HER2 testing in breast cancer, including fixation, testing, and reporting criteria for pathologists and recommendations for oncologists on HER2 targeted therapy based on pathology results.

- The updated recommendations include key points doctors should discuss with patients regarding HER2 status, such as reasons for HER2 testing, types of tests used, interpretation of test results, and the potential need for retesting.
- The updated recommendations also emphasize the critical need for a close collaboration by all physicians and health systems involved in the care of breast cancer patients and in the performance of tests that can be used to influence decisions about treatment.

The Role of Your Pathologist in Determining HER2 Status

Pathologists are medical doctors who use laboratory techniques and technology to diagnose and characterize disease. They work with other doctors on the patient care team to guide treatment plans.

For patients with invasive breast cancer, pathologists will further characterize the biology of their breast cancer, which includes HER2 testing. The two FDA-approved methods currently used in the United States to test for HER2 are immunohistochemistry (IHC) and in-situ hybridization (ISH).

Higher numbers (copies) of the *HER2* gene in cancer cells is called amplification. Amplification of the *HER2* gene leads to more copies of the HER2 protein on the surface of breast cancer cells. ISH testing measures how many copies of the *HER2* gene are present inside each cancer cell. IHC testing assesses how much HER2 protein is present on the surface of tumor cells.

Questions to Ask Your Doctor

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

- Has HER2 testing been performed on my cancer?
- What types of tests were used to determine the HER2 status?
- Can I see a copy of my pathology report?
- Is the HER2 test result clearly positive or negative? Is there anything borderline or unusual about my results? Is there any reason to consider retesting?
- How will you be using my HER2 test results in my treatment plan?
- If I still have questions, would it be possible to speak with my pathologist to help me understand my test results?
- Is the laboratory performing my testing an accredited laboratory?
- If my cancer has recurred or spread, should the HER2 status be checked again in the new sites of disease?

Patients can ask their physicians the name of the laboratory that performed their testing. Laboratories testing for HER2 should be accredited by an accrediting organization, such as the College of American Pathologists (CAP).

The CAP Laboratory Accreditation Program is an internationally recognized program designed to go well beyond regulatory compliance, and helps laboratories achieve the highest standards of excellence to positively impact patient care. Patients may search the CAP's online directory of accredited laboratories to see if their laboratory is CAP accredited.

Helpful Links

The updated guideline was published on October 7, 2013, in the CAP's peer-reviewed journal, *Archives of Pathology & Laboratory Medicine*, and ASCO's publication, *Journal of Clinical Oncology*. The joint guideline was prepared by an ASCO/CAP Update Committee consisting of experts in breast cancer and cancer biomarkers.

About the CAP

As the leading organization for board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. With more than 18,000 physician members, the CAP has led laboratory accreditation for more than 50 years with more than 7,500 CAP-accredited laboratories in 50 countries. Find more information about the CAP at cap.org. Follow the CAP on Twitter: @pathologists.

About ASCO

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs, and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds ground-breaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit www.asco.org. Patient-oriented cancer information is available at www.cancer.net.