



Clinical Trial for HER2-Negative Breast Cancer Patients

The **CELsignia HER2 Activity Test** may help your doctor decide if you are eligible to participate in a clinical trial evaluating a new option for the treatment of your breast cancer. Clinical trials are now underway to evaluate whether this test can potentially help you and thousands more breast cancer patients in the future.

The CELsignia Test may find that you are eligible to receive a targeted therapy

Breast cancer patients routinely receive a HER2 test to determine if their cancer is HER2-positive or HER2-negative. Patients with HER2-positive breast cancer are typically treated with anti-HER2 targeted therapies that are intended to stop the growth of cancer tumor cells.

The new CELsignia HER2 Activity Test is now available to help identify HER2-negative patients who may also potentially benefit from anti-HER2 targeted drugs.

Research from Celcuity, a leader in dynamic tumor analysis, has shown that **approximately 1 in 5 breast cancer patients who are HER2-negative have abnormal HER2 activity that anti-HER2 targeted drugs may block.**



Patients diagnosed with abnormal HER2 activity are now eligible to receive anti-HER2 targeted therapies in a clinical trial setting.

Why is my participation in this study important?

Doctors hope treatment with anti-HER2 targeted therapies will be of benefit to HER2- negative patients with abnormal HER2 activity.

If these clinical trials find that enrolled patients like you respond favorably, up to 45,000 additional breast cancer patients annually may benefit from anti-HER2 targeted therapy.

However, there is no proof yet that this will mean a benefit for you. This study, though, will provide doctors with important information about whether more cancer patients can benefit from anti-HER2 targeted therapies.

This is why your participation in this study could help many future breast cancer patients.



Together we can fight breast cancer

Why would I be interested in receiving anti-HER2 targeted therapies?

A clinical trial with HER2+ early breast cancer patients found that almost twice as many people who received the anti-HER2 therapies, Perjeta + Herceptin, before surgery had no detectable cancer cells in the lymph nodes and breast tissue (39.3%), compared with people who received other treatment (21.5%).

(Source: Genentech Perjeta patient brochure)

CELsignia

HER2 Activity Test | breast



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How do I find out if I am eligible to receive this additional treatment?

Your doctor will ask if you are willing to undergo an additional biopsy procedure to provide a sample of your tumor tissue.

If you undergo a biopsy, Celcuity will use their CELsignia Test to analyze your tumor cells.

If your tumor cells have abnormal HER2 activity, and you meet all other criteria, you may be eligible to enroll in a clinical trial that offers anti-HER2 targeted therapy.

How is the CELsignia test performed?

The CELsignia Test utilizes the cancer tissue obtained from your biopsy and extracts the tumor cells in a laboratory. The lab then analyzes these live tumor cells to determine if HER2 activity is at normal or abnormal levels. Your test results will be sent to your doctor in 10-14 days. This is typical for tests like these so your treatment will not be delayed.

The CELsignia Test results are reported as either “Normal” or “Abnormal”:

- **HER2 Activity NORMAL** means HER2 does not play a role in your cancer. Your physician will discuss treatment options for your breast cancer that do not include anti-HER2 targeted therapies.
- **HER2 Activity ABNORMAL** means HER2 may play a role in your breast cancer. Your physician may recommend you enroll in this clinical trial so that you can be treated with anti-HER targeted therapies.

How do I get more information about this trial?

Your doctor and healthcare team will discuss all study specifics with you, including potential risks and side effects of HER2 therapies, and ask your permission through an informed consent process before you decide whether or not to participate in this important study. Taking part in this study is your choice. If you are found to be eligible for the trial, you will be under no obligation to participate.

How will my treatment be affected?

If you enroll in one of these clinical trials, you will receive standard chemotherapy PLUS the same anti-HER2 targeted therapies that many HER2-positive breast cancer patients receive.

Are there any costs associated with testing?

No. There is no charge to you for the CELsignia testing or the anti-HER2 drugs.