

## Tamoxitest Patient Information

*Information on tamoxifen resistance testing was posted by Dr. Susan M. Love on March 20, 2009 at the Dr. Susan Love Research Foundation website at [www.dsrlrf.org](http://www.dsrlrf.org). Dr. Love is a member of the faculty of UCLA School of Medicine and Director of the Santa Barbara Breast Cancer Institute. A trusted authority on women's health, she was appointed by President Clinton to the National Cancer Advisory Board and is a Board Member of the National Breast Cancer Coalition.*

One of the tests now available is the "tamoxifen resistance" or "CYP2D6" test. This test examines a gene called 2D6, which produces the enzyme CYP2D6. This enzyme is necessary for the body to metabolize a number of drugs, including tamoxifen.

Different people have different variations of this gene. Some variations metabolize 2D6 drugs very quickly, while others don't metabolize them as well. Still others don't metabolize them at all.

It is estimated that about 10 percent of women with breast cancer have a variation that keeps their bodies from properly metabolizing tamoxifen. At the 2008 San Antonio Breast Cancer Symposium, researchers from the University of Michigan and Mayo Clinic in Rochester, Minn., presented data showing that women who inherited this variation of the 2D6 gene were almost twice as likely to have their breast cancer recur, even though they were more likely to complete their tamoxifen treatment.

For this study, the researchers assessed the activity levels of the CYP2D6 enzyme in 297 women. Each woman was assigned a score based on this level; a score of zero meant the enzyme was not active.

The researchers found that all of the women with a zero score completed their tamoxifen treatment. They also found that these women rarely had any side effects from the drug. In contrast, the women with the highest scores were less likely to have remained on tamoxifen for five years. In addition, they were more likely to have not completed five years of tamoxifen therapy because of the side effects they were experiencing, such as hot flashes, night sweats, and nausea.

This finding confirms previous research which suggested that the side effects of tamoxifen were an indicator that the drug was working and that women who were not experiencing side effects were not getting the full benefit of the drug because their body was not metabolizing it properly.

They also support a 2006 recommendation from a **Food and Drug Administration** Clinical Pharmacology Subcommittee that the tamoxifen label carry a warning noting that the drug may not be as effective in women who carry a version of the 2D6 gene that does not metabolize the drug.

### **Susan says:**

Breast specialists have been aware of the tamoxifen resistance test for a number of years. However, most have considered the test to still be investigational, and were not recommending it to their patients.

**For immediate consultation Call 800-837-8362**

Hours 7:00 AM to 6:00 PM PST, 10:00 AM to 9:00 PM EST, fax 206-219-4000,

3000 First Avenue, Suite One, Seattle, WA 98121

E-mail: [info@genelex.com](mailto:info@genelex.com) Web: [www.HealthandDNA.com](http://www.HealthandDNA.com)

[www.Tamoxitest.com](http://www.Tamoxitest.com)

I felt the same way until I heard this data presented at San Antonio. Now, I think we do need to consider if and when it is appropriate to recommend that a patient be tested. However, we also have to take into account that only about 10 percent of women are actually resistant to tamoxifen. The test costs about \$300. Some, but not all, insurance companies are covering the cost. This means you should be sure to check with your insurance company to find out their specific policy about this genetic test before having it done. (Your doctor can do this for you.)

Given that more postmenopausal women are now using an aromatase inhibitor for their breast cancer treatment, tamoxifen resistance testing is less likely to be an issue for this group. However, it is something that premenopausal women, for whom tamoxifen remains the standard of care for breast cancer hormone therapy, should be aware of. The test may also be important for pre- and postmenopausal women who are using tamoxifen as part of their treatment for DCIS.

Depending on how easy it is for you to pay \$300 out-of-pocket for a genetic test, there are a couple of ways to proceed. If the cost is not an issue, and you are considering tamoxifen, you might want to go ahead and have the test. A cheek swab is all that is needed to obtain a DNA sample. The swab is then sent back to the testing company, which will send the test results to you and your doctor.

The other option is to start on the drug and see if you are having side effects. If you are, you know the drug is working. If you're not, you know it's not, and you can pursue other options with your oncologist.

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## Who Should Be Tested

The Tamoxitest tamoxifen resistance test is considered appropriate for women who are taking or considering taking tamoxifen to prevent the recurrence of breast cancer. It is especially important if the patient is also taking or considering co-administration with SSRIs.

## The Testing Process

The process is simple. We mail a cheek swab collection kit directly to you. Simply collect the samples and return them to our laboratory with the prepaid shipping included.

Included with each Genelex tamoxifen resistance DNA test is 90-days access to GeneMedRx drug and gene interaction software so your healthcare providers can see the effect of the genotype on all of your medications, herbals, and over-the counter medicines.

## Insurance and Payment Information

You must get a prescription from your physician with relevant diagnostic (ICD9) codes for insurance billing, or include payment information with the testing. To confirm insurance coverage prior to submitting a sample, see instructions on the prescription form that follows.

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## Physician Referral Prescription for Tamoxitest™ CYP2D6 Tamoxifen Resistance DNA Test

Your physician thinks that you will benefit from having the Tamoxitest™, and has included a prescription for this testing below. Tamoxitest™ determines your genetic ability to convert tamoxifen to endoxifen; endoxifen is responsible for helping to prevent breast cancer recurrence in the body. About 10% of patients cannot convert tamoxifen to endoxifen and need an alternative therapy. Another 35% have a reduced ability to convert tamoxifen to endoxifen and may require higher doses and need to be very careful about taking other medications, over-the-counters and herbals that can interfere with this conversion. Testing is covered by many insurance plans. Preauthorization instructions are on the back of the form if you would like to confirm coverage in advance.

Please call a DNA Testing Consultant at 800 TEST-DNA (800-837-8362) with this prescription in hand to obtain the cheek swab collection kit for the Tamoxitest™. The consultant can also answer any questions you may have at that time. Alternatively, you can fax this form with a copy of both sides of your insurance card, and your mailing address and phone number to 206-219-4000 and your kit will be mailed.

<b>Patient's Name:</b> _____		
Date of Prescription: _____	Phone: _____	DOB: _____
To: Genelex Corporation 3000 First Ave., Suite One Seattle, WA 98121 Phone: 800-523-3080 <b>Fax: 206-219-4000</b>		
<b>From (Referring Physician):</b>		
Name: _____		
Address: _____		
City, State, Zip: _____		
Phone: _____		Fax: _____
Email: _____		
<b>TESTING IS MEDICALLY NECESSARY.</b> Please perform the TamoxiTest™ on this patient to determine tamoxifen resistance for the diagnosis codes noted below.		
Physician Signature: _____		
License #: _____		UPIN: _____
<b>Diagnosis Codes:</b>		
<input type="checkbox"/> 174.9	<input type="checkbox"/> 174.8	_____

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### Is the testing covered by insurance?

Genelex has seen pharmacogenetic testing coverage by the insurers listed below however coverage benefits can vary by plan. To confirm coverage prior to submitting a sample, see preauthorization instructions at the bottom of this page. Alternatively, we have a patient safeguard program that limits patient out of pocket expense to \$295.00. If the out-of-pocket expense determined by the insurance company is less than the prepaid discount price, the difference will be refunded. This is also the option available for patients with no insurance or who do not want their insurance to be billed. For patients with financial hardship, please call 800-523-6487 to request a financial consideration form.

Medicare	Blue Cross	Aetna	Cigna
Humana	United Healthcare	DWI Holding	Group Health
Farm Bureau	Tricare	Oxford HMO	

### Optional Preauthorization Instructions

Call the number on your insurance card and provide them with:

1. The CPT codes for requested testing:  
1 x 83891, 2 x 83892, 1 x 83900, 14 x 83914, 1 x 83909, 1 x 83912, 1 x 83912-26
2. The ICD-9 diagnosis codes provided by your physician.
3. Your physician's name and other requested information.

Record the following information about your insurance company call(s):

1. Date of phone call \_\_\_\_\_ Phone number with extension \_\_\_\_\_
2. Name of person you spoke with \_\_\_\_\_
3. Preauthorization number \_\_\_\_\_ Valid dates: \_\_\_\_\_

If preauthorization is denied, Genelex encourages patients to appeal. Contact Kristine Ashcraft at [kashcraft@genelex.com](mailto:kashcraft@genelex.com) or call 800 TEST-DNA (800 837-8362) for help with this process. We have successfully handled appeals before and have materials we can provide on your behalf.

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