GeneType for Breast Cancer

Informed Consent Form

Request Molecular Genetic Testing For: GeneType for Breast Cancer

General Description and Purpose of GeneType for Breast Cancer: GeneType for Breast Cancer is a test that combines clinical risk factors (such as your age) with those from genetic markers to derive a personalized risk assessment for the development of breast cancer over the next 5 years and over the rest of your life.

Informed Consent/Advance Beneficiary Notice: Please read carefully and discuss with your requesting Healthcare Provider before signing consent.

1. The description and purpose of the test have been discussed in detail.
2. You may wish to obtain genetic counseling prior to signing this consent form in order to understand the testing and what the results may mean.
3. GeneType for Breast Cancer is a risk assessment test only. This means that it can provide the risk that you develop breast cancer over the next 5 years and over the rest of your life. It cannot diagnose cancer or advise with certainty that you will develop cancer.
4. Because of the complexity of genetic testing and the important implications of the test results, results will only be reported to the patient through your Healthcare Provider. The result reports are kept strictly confidential. Participation in genetic testing is completely voluntary.
5. An increased risk test result will help your Healthcare Provider determine if you may be a candidate for additional measures to help prevent breast cancer. Not all cancers can be prevented even with medications or other measures. An increased risk test result does not mean that you will get cancer. Rather, it does mean that you are at an increased risk compared to the general population. You may consider further consultation with your Healthcare Provider or a genetic counselor to understand the results and what additional testing or suggested care plans may be available to you.
6. If the test does not show an increased risk for breast cancer, there still remains a risk that you may develop breast cancer. It is important for you to continue your Healthcare Provider's advice regarding breast cancer screening, such as appropriately scheduled mammograms.
7. The results of the above test become part of the patient's medical record. They may be made available to individuals/organizations with legal access to the patient's medical records, on a strict "need to know" basis, including, but not limited to the physicians, genetic counselors and nursing staff directly involved in the patient's care, and others specifically authorized by the patient to gain access to the medical records.
8. No tests other than the tests specifically authorized above will be performed on this sample. The sample will be discarded 90 days after the report has been released from the laboratory or it may be kept without identifiers and used for control purposes.
9. Advanced Beneficiary Notice: This is a self-pay test. Medicare/Insurance carriers may not pay for the test, you will be billed directly.
10. The patient has read and fully understands the above.

To be signed by the Patient (or Legal Guardian)

☐ I consent to testing as described above.

☐ I decline testing at this time.

Patient Name _____

Legal Guardian _____

Relationship to Patient _____

Signature of Patient or Legal Guardian _____

Date DD / MMM / YYYY

To be signed by the Healthcare Provider

The above information has been discussed with the patient and informed consent obtained. This form was signed in my presence.

Provider's Full Name _____

NPI Number _____

Phone Number _____

Signature _____

Date DD / MMM / YYYY

PHENOGEN SCIENCES
Testing conducted by
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