GENETICS CENTER

Informed Consent For Hereditary Cancer Molecular Genetic Testing (GCBRCA)

1. Test Overview:

The majority of hereditary breast and ovarian cancer is associated with mutations in the *BRCA1* and *BRCA2* genes, which belong to a class of genes known as tumor suppressors. Individuals with mutations in these genes are at a significantly higher risk for developing cancer over his or her lifetime. **GC**BRCA analyzes the *BRCA1* and *BRCA2* genes by various methods looking for mutation(s) that increase cancer susceptibility. It is highly recommended that you seek pre-and post-test genetic counseling to discuss the benefits, risks, and limitations of this test.

2. Possible Results:

Your personal and family health history, other relevant laboratory tests, results of physical examination, and the clinical impression of your doctor should all be taken into consideration when interpreting the results of this test. Only final test results will be provided.

GCBRCA may yield one of the following possible results:

- *Positive:* a mutation is found in a gene that is associated with an increased risk for developing cancer. This may allow you to make informed decisions about your health, including more frequent screening, preventive medication strategies, and preventative surgery to reduce risk.
- *Negative:* no currently relevant mutations are identified in the genes tested. The likelihood of having a mutation in the genes tested is greatly reduced.
- *Variant of Unknown Significance*: a variant is identified, but it is currently unknown if the variant is associated with an increased risk for developing cancer.

These test results could have implications for you and your family members, which should be discussed with the appropriate healthcare provider. If you have a positive test result, you are recommended to discuss the result with your healthcare provider as well as receive genetic counseling to discuss the risk of your children and/or biological relatives inheriting the same mutation(s).

Participation in molecular testing is completely voluntary, and the results are confidential. Because of the complexity of DNA based testing and the important implications of the test, upon request, the results will be reported to me only through my physician, genetic counselor, or other health care specialist whom I have designated. The results will only be released to other medical professionals or other parties including insurance carriers with my written consent. Genetics Center is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) and other relevant regulations.

3. Test Limitations:

Any incorrect diagnosis in a family member can lead to an inaccurate diagnosis for other related individuals. Generally, these genetic tests are relatively new and are being improved and expanded continuously. These tests only clarify cancer risks for those cancers related to the genes being tested. There may be additional mutations and/or genes that other tests could cover and/or will be known in the future as these tests evolve. Genetic testing is often complex and utilizes specialized methods and materials, thus there is always a small possibility that the test may not work properly, or that an error will occur.

4. Other:

Once my test result is completed an aliquot of my DNA may be made anonymous (name and all other identifiers removed) and used for quality control or research purposes. No compensation will be given for any invention(s) resulting from the use of my DNA in research and development. You may refuse to have your specimen used in this way, and your refusal will in no way affect the present testing results. Please indicate your consent or denial below. If left blank, it will be assumed that you consent to the use of your DNA sample as described above.

☐ I consent to the use of my DNA for quality control or research purposes

☐ I *do not* consent to the use of my DNA for quality control or research purposes

5. Patient Consent:

My signature below acknowledges that my doctor, genetic counselor, or other health care specialist has explained the limitations and benefits of molecular testing to me and I have had the opportunity to ask questions I might have regarding this test. I have read this entire document, and I give my consent for sample collection and genetic testing and acknowledge that I am ultimately responsible for payment.

Test Ordered (circle one):	**GC**BRCA	**GC**BRCA 3 variants	**GC**BRCA1 variant	**GC**BRCA2 variant
CPT Code(s):	81162	81212	81215	81217

Name of Patient:_____ **Date of Birth:**_____

Signature of Patient:_____ **Date:**_____
(or guardian)

BILLING/INSURANCE INFORMATION
(Attach copy of insurance card front and back)

☐Hospital/Institution ☐HMO ☐PPO ☐Medicare ☐Cash/Payment Enclosed ☐Other Insurance

*Insurance Co._____

Billing Address_____

City, State, Zip_____

*HMO Medical Group Name_____

Name of Insured_____

Test Preauthorization no._____

Relationship to Patient: ☐Self ☐Spouse ☐Child ☐Other

Insured's Employer_____

Policy no._____Group no._____

I hereby authorize Genetics Center to furnish my designated insurance carrier such information concerning my laboratory tests that is relevant or requested for reimbursement. I also authorize benefits to be paid directly to Genetics Center. I understand that my insurance coverage is a contract between me and my insurance carrier, and I am responsible for any amount not paid by my insurance (including co-pays, unmet deductibles, lack of coverage and/or authorization, etc). *Genetics Center may not be contracted with my insurance company, in which case I will be responsible for payment in full. The charges for these services are ultimately my responsibility. I permit a copy of this consent to be used in place of the original.

Patient (or Guardian) _Signature_ X _____ **Date**_____