Hereditary Breast and Ovarian Cancer Testing Patient FAQs

Most experts agree that hereditary cancer genetic testing should be performed when a patient or their family's history of certain cancers suggests the presence of a harmful genetic variant that may lead to cancer.

For women who have pathogenic variants in the *BRCA1* and *BRCA2* genes, the lifetime risk for developing breast cancer and ovarian cancer is greatly increased: their risk can increase up to approximately 80% for breast cancer and approximately 40% for ovarian cancer, by the age of 70.

Breast cancer is the second most common newly diagnosed cancer and the second leading cause of cancer death among women in the United States.

According to the National Cancer Institute and the American Cancer Society, in 2016 in the United States:

- About 246,660 new cases of breast cancer will be diagnosed in women.
- About 7 out of 100 women, or 7%, will develop breast cancer by age 70.
- The chance that breast cancer will be responsible for a woman's death is about 1 in 36, or about 3%.

What are BRCA and the Comprehensive Panel genes?

- BRCA1 and BRCA2 are genes that, when functioning normally, help repair damaged DNA allowing cells to grow normally.
- Inherited pathogenic variants in *BRCA1* or *BRCA2* may allow DNA damage to result in genetic alterations that may lead to cancer.
- The Comprehensive Hereditary Breast and Gynecologic Cancer Panel examines 17 additional genes associated with increased lifetime risks of developing breast, ovarian, endometrial (uterine) and other cancers.

Should you be tested?

If you answer yes to any of the following questions, you may want to discuss hereditary cancer genetic testing with your doctor.

Do you have:

- A family member that tested positive for a pathogenic variant in a known breast cancer susceptibility gene?
- A personal or family history of breast cancer at age 50 or younger?
- A personal or family history of bilateral breast cancer (cancer in both breasts)?
- A personal or family history of multiple related cancers such as breast, ovarian, pancreatic or prostate (Gleason Score of 7 or greater) cancers or endometrial (uterine) or colorectal cancers?
- A personal or family history of breast or pancreatic cancer and Ashkenazi Jewish heritage?
- A personal or family history of ovarian cancer or male breast cancer, regardless of age?

What are the benefits of testing?

Results of genetic testing will enable your physician to provide an individualized medical management plan for you. *BRCA*care[®] testing will:

- Identify at-risk individuals and family members.
- Provide information on the underlying causes of the pattern of cancers in the family.
- Allow family members without pathogenic variants to be identified, and so avoid unnecessary tests and procedures.
- Significantly improve medical outcome, as well as reduce overall medical costs, through earlier diagnosis and treatment of cancers.

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- Optimize cancer risk assessment, prevention, diagnosis and treatment.
- Enable proactive medical decisions regarding risk-reducing surgical treatment, preventive chemotherapy or fertility preservation for high-risk individuals.
- Enable you to make lifestyle decisions based on your specific genetic background

How is the testing done?

Collecting a specimen is as simple as using mouthwash or having your blood drawn. The sample is then sent to MDL for testing. Results will be sent to your physician and/or genetic counselor. Specimen collection instructions can be found at:

www.mdlab.com/forms/Other/Instructions_for_BRCA_ testing.pdf

What is Genetic Counseling?

Genetic testing is on the cutting edge of personalized medicine. Knowledge and new discoveries in the field are growing at a rapid pace. Therefore, healthcare providers and patients may feel it necessary to seek experts to fully understand their genetic information. Genetic counselors are healthcare professionals trained in genetics and are available to guide testing and follow-up.

Medical Diagnostic Laboratories offers healthcare providers and patients the genetic counseling services of InformedDNA. InformedDNA is a third-party service and is not affiliated with Medical Diagnostic Laboratories, L.L.C. (MDL). InformedDNA's genetic counselors are available by telephone and web-based technology to provide counseling nationwide.

InformedDNA provides three key elements for patient care:

- 1. Discussion of a patient's genetic health risks with appropriate guidance and counseling.
- 2. Determination of the appropriate testing according to the patient/family history and testing results.
- 3. Creation of a specific action plan for healthcare providers to help guide patient care.

IMPORTANT NOTE Some insurance providers require genetic counseling **prior** to genetic testing pre-authorization. In these instances, MDL will submit your information to InformedDNA on your behalf. InformedDNA will contact you directly to schedule pre-test counseling. You must then complete this pre-test counseling in order to determine your coverage.

Will insurance cover the cost of this test?

Hereditary cancer genetic testing determined to be medically necessary by physicians or genetic counselors is usually reimbursed by health insurance. However, some insurance carriers may not pay for this test unless specific criteria are met. Upon receipt of a specimen for testing, MDL will contact the insurance carrier on the patient's behalf to confirm coverage.

As a national reference laboratory, MDL participates in a large number of managed care contracts. **MDL will contact all** patients prior to performing this genetic test if the personal total financial responsibility will exceed \$149.00 for any reason including co-insurance, co-payments, deductibles or non-covered services.

If my insurance company does not cover testing, is financial assistance available?

MDL offers financial assistance for those who need help with the costs associated with hereditary cancer genetic testing. The patient financial assistance form may be downloaded at: http://mdlab.com/forms/Other/BRCA_Financial_Assistance

If you do not qualify for financial assistance, MDL offers interest-free payment plans.

Medical Diagnostic Laboratories, L.L.C. (MDL), founded in 1997, is a national reference laboratory that specializes in DNA-based testing in women's health. MDL is a CLIA-certified reference laboratory that is also accredited by the College of American Pathologists (CAP).

MDL is a member of the Genesis Biotechnology Group[®] (GBG) located in Hamilton, New Jersey.





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