MEDICAL DIAGNOSTIC LABORATORIES

PATIENT INFORMED CONSENT AND INSURANCE ACKNOWLEDGEMENT

Important – Please Read Carefully: This Patient Informed Consent and Insurance Acknowledgement describes the purpose, procedure, benefits, limitations and possible risks of genetic testing for inherited susceptibility to cancer. This is a voluntary test and you may wish to seek genetic counseling prior to signing this form.

Purpose: The primary purpose of this test is to detect the specific alteration (changes) of the gene(s), called mutations, associated with inherited susceptibility to cancer. A mutation is the changing of the structure of a gene, resulting in a variant form that may be transmitted to subsequent generations. This test is an assessment of an individual's risk for hereditary cancer and is used in conjunction with the clinical evaluation of the personal or family cancer history and all other risk factors.

Test Procedure: This is a non-invasive test requiring only the collection of a saliva or whole blood sample. Cells from the inside of the cheeks are collected in the saliva solution and will be processed for DNA analysis. In some instances, an additional sample may be needed if the volume, quality and/or condition of the initial specimen is not adequate for testing. A whole blood specimen is also acceptable from all states other than New York.

Important - **Test Results and Interpretation:** Your physician and/or genetic counselor will evaluate and discuss with you the results of your hereditary cancer genetic testing taking into consideration your personal and family cancer history, clinical information and laboratory data in order to determine the best course of medical management. The possible results of the hereditary cancer genetic testing are:

Positive Test Result (**Pathogenic or Likely Pathogenic Mutation)**: A mutation in a gene or genes associated with an increased risk for hereditary cancer was identified.

Negative Test Result (Benign or Likely Benign Mutation): No harmful mutation was identified.

Uncertain Test Result (VUS, Variant of Uncertain Significance): Genetic alteration(s)/change(s) were detected, but it is not known if these changes pose a cancer risk based on current scientific information. VUS may be re-classified over time.

The results of this test is considered protected health information pursuant to the Health Insurance Portability and Accountability Act (HIPAA) and remains confidential to the extent allowed by federal and state law. The results of this test becomes a part of your medical record, and may be made available to individuals/organizations with legal authorization to access your medical record including, but not limited to, the physicians and nursing staff directly involved in your care, your genetic counselor, and your current or future insurance carrier. MDL maintains the confidentiality of your tests results in full compliance with HIPAA and applicable state laws.

The Federal Genetic Information Nondiscrimination Act of 2008 (GINA) protects individuals from any type of discrimination by health insurers and employers based on the results of genetic testing; however, there is currently no federal laws that prohibit life insurance, long term care or disability insurance companies from discriminating based on genetic information. Your state may have a more comprehensive law that protects against discrimination based on genetic information. For additional information about GINA and the state laws that also protect against discrimination based on the results of genetic testing, visit www.ginahelp.org.

Because the results of hereditary cancer genetic testing have implications for your blood relatives, in consultation with your physician or genetic counselor, you may wish to discuss sharing your test results with certain blood relatives who may be at risk. Genetic testing may provide previously unknown information about relationships in families.

Test Benefits: The results of this genetic testing will assist you and your physician in making more informed choices relevant to your medical management including screening, medications, surgical options and treatment. This testing analyzes if a person has an increased risk of developing certain cancers due to mutation(s) associated with a particular hereditary cancer. If the results of this testing are positive, you should discuss with your physician or genetic counselor how hereditary cancer is inherited and the possibility that your children and blood relatives may have the same mutation(s) in the gene(s) tested. If the results of this testing are negative, you cannot pass a mutation to your children and you have at least the same cancer risk as the general population. In this case, your personal risk of developing cancer without the identification of the tested mutations will be individually calculated based on all other risk factors present.

Test Risks: There is minor risk from the venipuncture required for this test. The patient may experience pain, soreness, and bruising at the site of the venipuncture.

Test Limitations: This test determines the presence of mutations in only select important gene(s) associated with a specific hereditary cancer. This test is not the only way to detect genetic abnormalities. Your healthcare provider may also recommend other genetic, imaging or laboratory tests.

Additional information about this hereditary cancer genetic testing can be found on the Medical Diagnostic Laboratories, LLC (MDL) patient website at www.mdlab.com/BRCA.

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Patient Statement of Informed Consent:
By signing below, I have read and fully understand this form, and acknowledge the following:

- I have or will receive genetic counseling provided by my physician or a licensed genetic counselor. If I notify my physician of my interest, he/she will arrange for genetic counseling services at no cost to me through Medical Diagnostic Laboratories..
- I have been informed by my physician or genetic counselor of the purpose, procedure, benefits, limitations and possible risks of this genetic test. I have been given the opportunity to ask and have all my questions answered about this genetic test.
- I have discussed with my physician or genetic counselor ordering this test the reliability of the positive or negative test results and the level of certainty that a positive test result for the gene mutation(s) tested serves as a predictor of hereditary cancer.
- I have read this entire document and have been informed that I may retain a copy for my records.
- I consent to this testing for hereditary cancer predisposition and I will discuss the results and appropriate medical management with my physician and/or genetic counselor.
- I understand that my medical history and these test results will not be discussed or disclosed to a third party, unless related to my treatment or payment for my treatment, without my express written authorization.

I have read and fully understand the above, and give my consent to the **performance of this genetic test** and accept the consequences of this decision.

Patient Name: _____ Patient/Legal Guardian Signature: _____

Date: _____

Patient Consent to Use Sample for Research

Information obtained from your DNA samples may be used in scientific publications or presentations; all samples will be processed in a de-identified manner. The identity of all individuals who consented to the use of samples for research will not be revealed in any publication or presentation. Your refusal to consent to medical research will not affect your results. All DNA samples are discarded after 60 days unless used for research purposes in which case they are retained indefinitely.

Initial your selection below:

_____ **YES**, I consent to the use of my DNA sample for research purposes.

_____ **NO,** I do not consent to the use of my DNA sample for research purposes.

Patient Insurance Acknowledgement

Hereditary cancer genetic testing determined to be medically necessary by your physician or genetic counselor is usually reimbursed by health insurance. However, Medicare, Medicaid and some insurance carriers may not pay for this test. Certain insurance plans for example, **CIGNA**, **UNITED HEALTHCARE** and **BLUE CROSS BLUE SHIELD FEDERAL**, in order to receive prior authorization to perform the test, require the patient to participate in pre-test genetic counseling. **AETNA** covers the test to detect the mutations in the BRCA1 and BRCA2 genes associated with inherited susceptibility to cancer, but does not cover the BRCA1 and BRCA2 duplication/deletion variant analysis and the breast cancer extended panel analysis. Patients with **AETNA** insurance may request to have the BRCA1 and BRCA2 duplication/deletion variant analysis and the breast cancer extended panel analysis performed at their own expense.

I further understand that I am financially responsible for any amounts not covered by my insurer for this genetic test. MDL will perform the genetic test and bill me without further contact if my total financial responsibility will not exceed $150.00 for any reason, including co-insurance, co-payments, deductibles or non-covered services. If the out-of-pocket expense will exceed $150.00, I will be contacted to discuss my financial responsibility.

I understand that MDL will honor test cancellations received prior to the initiation of the testing. Once the genetic testing process has been initiated, no cancellation request will be honored and a claim for the services performed will be submitted to the patient's insurance company and the test result will be provided to the ordering physician.

I acknowledge that the information provided by me is true to the best of my knowledge. For direct insurance/third-party billing, I hereby authorize my insurance benefits to be paid directly to MDL and authorize MDL to release medical information concerning my testing to my insurer. If applicable, I authorize MDL to be my Designated Representative for purposes of appealing any denial of benefits.

I understand that if I am a patient with Medicare insurance, I may be required to complete an Advance Beneficiary Notice.

I also fully understand that I am legally responsible for sending MDL any money received from my health insurance company for the performance of this genetic test.

Patient Name: _____ Patient/Legal Guardian Signature: _____

Date: _____

I fully **understand and agree to my financial responsibilities** concerning the performance of this genetic test.

Patient Name: _____ Patient/Legal Guardian Signature: _____

Date: _____

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