PREVENTEST™ Cancer Risk Analysis

Test Request Form and Statement of Medical Necessity

TO AVOID DELAYS PLEASE COMPLETE ENTIRE FORM

ADVANCED MOLECULAR DIAGNOSTICS, LLC

136 SUMMIT AVE • MONTVALE, NJ 07645 • ☎ (201) 825-0186 • (201) 825-0191 • Info@GeneIDLab.com • www.GeneIDLab.com

ORDERING PHYSICIAN				**SEND RESULTS TO** (IF OTHER THAN ORDERING PHYSICIAN)			
NAME (LAST, FIRST, DEGREE)		NPI #		NAME (LAST, FIRST, DEGREE)		NPI #	
ADDRESS	CITY	STATE	ZIP	ADDRESS	CITY	STATE	ZIP
OFFICE PHONE	FAX	EMAIL		OFFICE PHONE	FAX	EMAIL	

PATIENT INFORMATION (COMPLETE INFORMATION REQUIRED FOR INSURANCE COVERAGE)

PATIENT NAME (LAST, FIRST, INITIAL)	☐ FEMALE ☐ MALE	BIRTH DATE (MM/DD/YYYY)	PHONE	BEST TIME TO CALL (IF NEEDED)
ADDRESS	CITY	STATE	ZIP	CAN WE LEAVE A DETAILED MESSAGE AT THIS NUMBER? (YES) (NO)

ANCESTRY AND CLINICAL HISTORY – CHECK ALL THAT APPLY

☐ CAUCASIAN ☐ DUTCH ☐ SWEDISH ☐ HUNGARIAN ☐ ICELANDIC ☐ AFRICAN/AMERICAN ☐ MIDDLE EASTERN ☐ ADOPTED
☐ ASHKENAZI JEWISH ☐ LATIN AMERICAN/CARIBBEAN ☐ ASIAN ☐ NATIVE AMERICAN ☐OTHER_____

PATIENT PERSONAL HISTORY OF CANCER
PLEASE INCLUDE ALL RELEVANT MEDICAL RECORDS TO SUPPORT THE INFORMATION BELOW

☐ PATIENT HAS A PERSONAL HISTORY OF CANCER CANCER TYPE(S) _____ DX AGE(S) _____ ICD-10 CODE(S) _____

PATIENT FAMILY HISTORY OF CANCER
PLEASE INCLUDE ALL RELEVANT MEDICAL RECORDS TO SUPPORT THE INFORMATION BELOW

Relation to Patient	Maternal	Paternal	Cancer/Polyp Type	Dx age	Relation to Patient	Maternal	Paternal	Cancer/Polyp Type	Dx age
1)					5)				
2)					6)				
3)					7)				
4)					8)				

• For Breast Cancer Patients note if Triple Negative (ER-, PR-, HER2-), Invasive, DCIS, Bilateral, Premenopausal • For Prostate Cancer Patients include Gleason Score

☐ IS PATIENT CURRENTLY BEING TREATED FOR CANCER (FOR PATIENTS WITH A PERSONAL HISTORY OF CANCER)
☐ COLON POLYPS (K63.5) # OF POLYPS _____ ☐ BONE MARROW TRANSPLANT RECIPIENT
☐ KNOWN FAMILIAL MUTATION: **GENE** _____ **MUTATION** _____

ICD10 CODES

ICD10 DIAGNOSIS CODES: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
FOR A LIST OF COMMONLY USED ICD10 CODES PLEASE SEE BACK OF FORM

TEST REQUESTED

☐ ***PREVENTEST™ Hereditary Cancer Risk Analysis*** - **APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, ELAC2, EPCAM, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTCH1, PTEN, RAD50, RAD51C, RAD51D, RECQL4, RET, RINT1, SMAD4, STK11, TP53**

☐ ***CUSTOM (specify genes from PrevenTest panel)*** _____

PAYMENT INFORMATION (PATIENT MUST SIGN BELOW AND ALSO INITIAL CONSENT ON THE BACK)

☐ **OPTION 1: PLEASE BILL MY INSURANCE** (requires patient signature and enlarged copy of both sides of insurance card(s). If two cards are submitted, indicate which is primary)

Name of Policy Holder: _____ **DOB:** _____ **Insurance Carrier:** _____
Patient Relationship to Policy Holder: ☐ **Self** ☐ **Spouse** ☐ **Child** ☐ **Other** **Insurance ID #:** _____

I hereby represent that I am covered by insurance and authorize Advanced Molecular Diagnostics, LLC to furnish my designated insurance carrier, health plan, or third party administrator the information on this form and other information provided by my healthcare provider necessary for reimbursement. I authorize Advanced Molecular Diagnostics, LLC to utilize a licensed third party laboratory for test processing when deemed necessary. I authorize Plan benefits to be payable to Advanced Molecular Diagnostics, LLC.. If requested, I agree to assist Advanced Molecular Diagnostics, LLC in resolving insurance claim issues and if I do not assist, I may be responsible for the full test cost. I permit a copy of this authorization to be used in place of the original. I authorize Advanced Molecular Diagnostics, LLC to inform my plan of my test result ONLY if test results are required for reimbursement for testing or preauthorization of or payment for reflex/ additional testing.

Please include a copy of both sides of all insurance

☐ **In the event that my insurance company requires pre-test genetic counseling to consider reimbursing for the test, I authorize GeneID to share my information with a certified genetic counselor, who will contact me to arrange for counseling. (Not a requirement for testing)**

_____ _____
Patient / Responsible Party Signature **Date**

☐ **OPTION 2: PATIENT PAYMENT** (Patient will be contacted for secure credit card information and to arrange payment plan)

INFORMED CONSENT AND STATEMENT OF MEDICAL NECESSITY

I have supplied information to the patient regarding genetic testing and the patient has given consent for genetic testing to be performed. I further confirm that this test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder, and the results will be used in the medical management and treatment decisions for the patient. I confirm that the person listed in the Ordering Physician space above is authorized by law to order the test(s) requested herein.

(Note: Test requests without a signature will not be processed) _____ _____
Medical Professional Signature **Date**

INFORMED CONSENT: CANCER SCREENING

General information about genetic testing for hereditary cancer:

1) Genetic disorders may be caused by mutations in the DNA sequence of a gene.
2) The purpose of genetic testing is to evaluate for changes in the DNA sequence of a gene and, when clinically indicated, to look for mutations. This test may help determine if I am affected with, or am at risk to someday develop, a form of hereditary cancer.
3) The genes included on this test are associated with several different types of cancer and with varying levels of cancer risk.
4) This test cannot identify all types of mutations, deletions, or duplications causing hereditary cancers or other genetic disorders. Specifically, this test cannot identify any genetic changes involving genes not included in the specific test(s) ordered by my health care provider.
5) I understand that this test is not the only way to look for genetic abnormalities. My health care provider may recommend this test before or after ordering other genetic or laboratory tests.
6) This test requires high-quality DNA. In some cases, an additional sample may be needed if the volume, quality and/or condition of the initial specimen is not adequate.

What could I learn from this genetic test?

1) Negative result - I may learn that no genetic abnormality was identified by this test. This reduces the likelihood, but does not exclude a hereditary form of cancer.
2) Positive result - I may learn that a genetic abnormality was identified that explains either the cause of cancer that I have and/or the risk that I have to develop cancer in the future. The type(s) of cancer for which I am at risk depends on the gene involved. These results may aid my physician in making decisions about my medical management, including but not limited to cancer screening, risk-reducing surgeries and preventive medication strategies.
3) Variant of uncertain significance (VUS) - I may learn that a VUS was identified by this test. This means that a genetic change (variant) was identified, but it is unknown whether the variant may cause cancer. The variant could be a normal genetic difference that does not cause medical problems, or it could be a cancer-causing abnormality. Without further information, the effects of the variant may not be known, and an inconclusive result may be reported. Testing other affected family members may be necessary to determine the significance of the variant. The laboratory will provide additional information to my healthcare provider who is ordering this testing if this variant is determined to be benign or risk-causing.

What are the limitations and risks of this genetic test?

1) In some cases, testing may not identify an abnormality even though a genetic abnormality may exist. This may be due to limitations in current knowledge about a gene's complete structure. It may be due to the fact that some types of genetic abnormalities causing a specific hereditary cancer have not yet been identified. I understand that the methods used by Advanced Molecular Diagnostics are highly accurate. However, the chance of a false positive or false negative result, due to laboratory errors incurred during any phase of testing, or due to unusual circumstances (bone marrow transplantation, blood transfusion, presence of change(s) in such a small fraction of cells that they may not be detectable (mosaicism) or incorrect reporting of family history or relationships), cannot be completely excluded.
2) Accurate interpretation of the test results requires knowledge of the true biological relationships in a family. Failure to accurately disclose the biological relationships in a family may result in incorrect interpretation of results and/or inconclusive test results.
3) You may be concerned about discrimination based on genetic test results. The federal government enacted the Genetic Nondiscrimination Act (GINA) of 2008 prohibiting this type of discrimination by health insurers and employers. Furthermore, genetic test results are deemed "Protected Health Information" per the Health Insurance Portability and Accountability Act (HIPAA) of 1996 which prohibits unauthorized disclosure of such information. These laws set a minimum standard of protection across the nation. Some states may have laws limiting the use of genetic information by other types of insurers as well. For additional information about these regulations, visit http://www.genome. gov/10002077.

Patient confidentiality and counseling

1) To maintain confidentiality, I understand that results will be reported to the indicated healthcare provider or ordering laboratory and upon request copied to additional health- care provider(s) indicated on the test requisition form. I understand that results may only be disclosed to others by my written consent and/ or if demanded by an order of a court of competent jurisdiction.
2) Information obtained from the test may be used in scientific publications or presentations, but the identity of all individuals studied will not be revealed in such publications or presentations.
3) It is recommended that I receive genetic counseling before and after having this test. Further testing or additional consultations with physicians may be necessary.

Specimen retention

1) DNA samples are not returned to individuals or to referring physicians.
2) In some cases, if further diagnostic tests are needed, a referring physician may request in writing that additional tests be performed on an existing DNA sample (additional costs apply). Additional testing will not be performed unless requested by an authorized healthcare professional.
3) In some cases, de-identified DNA may be used by the laboratory for new test development and/or laboratory quality assurance purposes after all identifiers have been re- moved.

Patient Signature _____

Appropriate Common Diagnosis COMPATIBLE ICD-10 - Insurance coverage is not required for genetic testing. The diagnostic code (ICD-10) information provided herein is for insurance information purposes only and does not guarantee insurance coverage for any genetic test, nor is it intended to be a definitive list of diagnosis codes that may be applicable for any individual patient. The testing laboratory will pursue reimbursement directly from the patient should the patient's insurance carrier deny coverage.

Family History of Cancer and Genetic Mutation ICD-10 Codes

ICD 10 Code	DESCRIPTION	ICD 10 Code	DESCRIPTION	ICD 10 Code	DESCRIPTION
Z80.3	Family history of malignant neoplasm, breast	Z80.49	Family history of cancer of genital system	Z84.81	Family history of genetic disease carrier/Family history of BRCA Mutation/Family History of gene mutation for Lynch Syndrome
Z80.41	Family history of malignant neoplasm, ovary	Z80.42	Family history of prostate cancer	Z80.8	Family history of other specified malignant neoplasm
Z80.0	Family history of malignant neoplasm- colon or GI cancers	Z80.8	Family history of malignant neoplasm, other specified (breast, male)	Z80.9	Family history of malignant neoplasm, unspecified

Patient Personal History of Cancer ICD-10 Codes

Breast Cancer

ICD 10 Code	DESCRIPTION
C50.019	Malignant neoplasm, nipple and areola of female breast
C50.119	Malignant neoplasm, central portion of female breast
C50.219	Malignant neoplasm, upper-inner quadrant of female breast
C50.319	Malignant neoplasm, lower-inner quadrant of female breast
C50.419	Malignant neoplasm, upper-outer quadrant of female breast
C50.519	Malignant neoplasm, lower-outer quadrant of female breast
C50.619	Malignant neoplasm, axillary tail of female breast
C50.819	Malignant neoplasm, other specified sites of female breast
C50.919	Malignant neoplasm, breast (female), unspecified site
C50.029	Malignant neoplasm, nipple and areola of male breast
C50.929	Malignant neoplasm, other & unspecified sites of male breast
C79.81	Secondary malignant neoplasm, breast
D05.9	Carcinoma in situ, breast
Z85.3	Personal history of malignant neoplasm, breast
Z84.81	Known familial BRCA mutation

Other Cancer Sites

ICD 10 Code	DESCRIPTION
C49.9	Malignant neoplasm of connective & other soft tissue, NOS (sarcoma)
C67.9	Malignant neoplasm of the bladder, NOS
C64.9	Malignant neoplasm of kidney, except pelvis
C64.9	Malignant neoplasm of renal pelvis
C66.9	Malignant neoplasm of ureter
C71.0	Malignant neoplasm of the brain
C73	Malignant neoplasm of the thyroid
E03.9	Unspecified acquired hypothyroidism

Ovarian Cancer

ICD 10 Code	DESCRIPTION
C56.9	Malignant neoplasm, ovary
C79.60	Secondary malignant neoplasm, ovary
D07.39	Carcinoma in situ, ovary
N95.1	Symptomatic menopausal or female climacteric states
Z85.43	Personal history of malignant neoplasm, ovary
Z80.41	Malignant neoplasm, ovary

Prostate Cancer

ICD 10 Code	DESCRIPTION
C61.0	Malignant neoplasm of prostate
Z85.46	History of prostate cancer

Gastric Cancer

ICD 10 Code	DESCRIPTION
C16.9	Malignant neoplasm of the stomach, NOS
C17.9	Malignant neoplasm of small intestine, NOS

Melanoma

ICD 10 Code	DESCRIPTION
C43.0	Malignant melanoma of skin of lip
C43.10	Malignant melanoma of skin of eyelid, including canthus
C43.2	Malignant melanoma of skin ear and external auditory canal
C43.3	Malignant melanoma of skin of other and unspecified parts of face
C43.4	Malignant melanoma of skin of scalp and neck
C43.59	Malignant melanoma of skin of trunk, except scrotum
C43.6	Malignant melanoma of skin of upper limb, including shoulder
C43.7	Malignant melanoma of skin of lower limb, including hip
C43.8	Malignant melanoma of other specified sites of skin
D03.9	Melanoma of skin, site unspecified

Colorectal Cancer

ICD 10 Code	DESCRIPTION
C18.4	Malignant neoplasm of transverse colon
C18.9	Malignant neoplasm of colon, unspecified
C20	Malignant neoplasm of Rectum
C21.0	Malignant neoplasm Anus Unspecified

Pancreatic Cancer

ICD 10 Code	DESCRIPTION
C25.0	Malignant neoplasm of body of pancreas
C25.1	Malignant neoplasm of tail of pancreas
C25.2	Malignant neoplasm of pancreatic duct
C25.3	Malignant neoplasm of islets of Langerhans)
C25.4	Malignant neoplasm of other specified sites of pancreas
C25.7	Malignant neoplasm of pancreas, part unspecified
C25.0	Malignant neoplasm of head of pancreas

Uterine Cancer

ICD 10 Code	DESCRIPTION
C55.0	Malignant neoplasm of the uterus, part unspecified
C54.9	Malignant neoplasm of the corpus uteri (uterine body)