PREVENTEST™ Cancer Risk Analysis

ADVANCED MOLECULAR DIAGNOSTICS, LLC

Test Request Form and Statement of Medical Necessity

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 – CHECK ALL THAT APPLY

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

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) _____

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** _____

GS denotes *gleason score* **MP** denotes *multiple primaries*
3x- denotes *triple negative* **HR** denotes *high-risk ethnicity*
MT denotes *metachronous tumor* **ST** denotes *synchronous tumor*

PREMM$_5$

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*** _____

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

ICD10	DESCRIPTION	ICD10	DESCRIPTION	ICD10	DESCRIPTION
☐ Z80.3	Family history of malignant neoplasm, breast	☐ Z80.8	Family history of malignant neoplasm,other specified	☐ Z80.59	Family history of malignant neoplasm of other urinary tract organ
☐ Z80.41	Family history of malignant neoplasm, ovary	☐ Z80.42	Family history of prostate cancer	☐ Z84.81	Family history of BRCA or Lynch Syndrome gene mutation
☐ Z80.0	Family history of malignant neoplasm- colon or GI cancers	☐ Z80.49	Family history of cancer of genital system	☐ Z80.9	Family history of malignant neoplasm, unspecified

PATIENT PERSONAL HISTORY OF CANCER ICD-10 CODES

BREAST CANCER

ICD10	DESCRIPTION
☐ C50.919	Malignant neoplasm, breast (female), unspecified site
☐ 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

OVARIAN CANCER

ICD10	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

UTERINE CANCER

ICD10	DESCRIPTION
☐ C55.0	Malignant neoplasm of the uterus, part unspecified
☐ C54.9	Malignant neoplasm of the corpus uteri (uterine body)
☐ Z85.42	Personal history of malignant neoplasm of uterus

PROSTATE CANCER

ICD10	DESCRIPTION
☐ C61.0	Malignant neoplasm of prostate
☐ Z85.46	Personal history of malignant neoplasm of prostate

GASTRIC CANCER

ICD10	DESCRIPTION
☐ C16.9	Malignant neoplasm of the stomach, NOS
☐ C17.9	Malignant neoplasm of small intestine, NOS
☐ C24.9	Malignant neoplasm of biliary tract, unspecified
☐ Z85.068	Personal history of other malignant neoplasm of small intestine
☐ Z85.00	Personal history of malignant neoplasm of digestive organ, NOS

PANCREATIC CANCER

ICD10	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
☐ Z85.07	Personal history of malignant neoplasm of pancreas

COLORECTAL CANCER

ICD10	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
☐ K63.5	Polyp of colon
☐ Z86.010	Personal history of colonic polyps
☐ Z85.038	Personal history of other malignant neoplasm of large intestine…

OTHER CANCERS

ICD10	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
☐ C65.9	Malignant neoplasm of renal pelvis
☐ C66.9	Malignant neoplasm of ureter
☐ C68.9	Malignant neoplasm of urinary system, NOS
☐ C71.0	Malignant neoplasm of the brain
☐ C73	Malignant neoplasm of the thyroid
☐ Z85.528	Personal history of other malignant neoplasm of kidney
☐ Z85.53	Personal history of malignant neoplasm of renal pelvis
☐ Z85.54	Personal history of malignant neoplasm of ureter
☐ Z85.50	Personal history of malignant neoplasm of urinary tract organ, NOS
☐ Z85.841	Personal history of malignant neoplasm of brain

CORRESPONDING ICD-10 CODES BASED ON PATIENT'S PERSONAL AND FAMILY HISTORY

ICD10	DESCRIPTION

INFORMED CONSENT AND STATEMENT OF MEDICAL NECESSITY – TEST REQUESTS WITHOUT A SIGNATURE WILL NOT BE PROCESSED

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.

_____ **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 healthcare 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 removed.

Patient / Responsible Party Signature **Date**

PAYMENT INFORMATION

☐ **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 card(s)

☐ **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)