INHERITED CANCER TEST REQUISITION FORM - Form #36752

PHYSICIANS ACCOUNT

PATIENT

PATIENT ID/ROOM #	SURGICAL ID	COMMENTS	❑ FASTING ❑ NON-FASTING
ENTRIES WILL SHOW ON REPORT			

NAME, LAST (OR CODE NAME) Please Print	FIRST	
STREET		APT. #

CITY	STATE	ZIP	DATE OF BIRTH MO|DAY|YEAR	AGE	M/F

PATIENT PHONE NO.	PATIENT CELL NO.	PATIENT EMAIL/FAX	COLLECTED (DATE/TIME) ❑ AM ❑ PM

RACE/ETHNICITY: ❑ AFRICAN AMERICAN ❑ ASHKENAZI JEWISH ❑ ASIAN ❑ CAUCASIAN ❑ HISPANIC ❑ NATIVE AMERICAN ❑ PACIFIC ISLANDER ❑ OTHER:_____

REFERRING PHYSICIAN

DIAGNOSIS		DX CODE	DX CODE
DX CODE	DX CODE	DX CODE	DX CODE

❑ Send Results Copy - 9991-1 ❑ Call Result - 9990-3 ❑ FaxResult - 9993-7

Name: _____

Street: _____

City:_____ State:____ Zip:_____

Phone:_____ Fax: _____

PATIENT STATUS – ONE MUST BE CHECKED

☐ HOSPITAL INPATIENT ☐ HOSPITAL OUTPATIENT ☐ NOT A HOSPITAL PATIENT

HOSPITAL PATIENT
DATE OF DISCHARGE _____/_____/_____

When ordering tests, providers should only order tests that are medically necessary for the diagnosis or treatment of a patient, generally not for screening. Only a few screening tests are covered by most government and third party payors for certain conditions at specific intervals.

_____ _____
Signature of Physician or Other Authorized NPI Provider Date

BILLING INFORMATION

BILL TO: ☐ CLIENT ☐ INSURANCE (complete insurance section & credit card info if necessary) INSURANCE CARRIER:_____
☐ MEDICARE ☐ PATIENT ☐ MEDICAID ☐ **HOLD SAMPLE FOR BENEFIT INVESTIGATION (ONLY IF OOP COST IS >$100). PLEASE ATTACH COPY OF REFERRAL/AUTHORIZATION**

If billing insurance, please include a copy of the front and back of the patient's insurance card. If two cards are submitted, indicate which is primary.

INS. ID #	GROUP #	SUBSCRIBER'S NAME	DATE OF BIRTH	RELATIONSHIP TO SUBSCRIBER ☐ SELF ☐ SPOUSE ☐ CHILD	PRIOR AUTHORIZATION #

INSURANCE ADDRESS	CITY	STATE	ZIP

If you would like to expedite an assessment of your possible eligibility for GeneDx's financial assistance program (FAP), please provide the number of your household members _____ and the annual income of your household $_____. GeneDx may require additional information from you to complete an application for GeneDx's financial assistance program. I represent that I am covered by insurance and authorize GeneDx, Inc. to give my designated insurance carrier, health plan, or third party administrator (collectively "Plan") the information on this form and other information provided by my healthcare provider necessary for reimbursement. I authorize GeneDx to inform my Plan of my test result only if test results are required for preauthorization of or payment for reflex/additional testing. I authorize Plan benefits to be payable to GeneDx. I understand that GeneDx will attempt to contact me if my out-of-pocket responsibility will be greater than $100 per test (for any reason, including co-insurance and deductible, or non-covered services). If GeneDx is unsuccessful in its attempts to contact me, I understand that it will be my responsibility to contact GeneDx to determine my out-of-pocket cost and to pay my out-of-pocket responsibility. I will cooperate fully with GeneDx by providing all necessary documents needed for Plan billing and appeals. I understand that I am responsible for sending GeneDx any and all of the money that I receive directly from my Plan in payment for this test. Reasonable collection and/or attorney's fees, including filing and service fees, shall be assessed if the account is sent to collection but said fees shall not exceed those permitted by state law. I permit a copy of this authorization to be used in place of the original.

Signature:_____ **Date:** _____

STATEMENT OF MEDICAL NECESSITY & PATIENT CONSENT

This test is medically necessary for the diagnosis or detection of a disease, illness, impairment, symptom, syndrome or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Provider is authorized by law to order the tests(s) requested herein. I confirm that I have provided genetic testing information to the patient and the patient has consented to genetic testing.

Signature of Physician or Other Authorized NPI Provider (required): _____ **Date:** _____

Patient Consent: I have read the Informed Consent document and I give permission to GenPath and GeneDx, a BioReference company, to perform genetic testing as described. I also give permission for my specimen and clinical information to be used in de-identified studies at GeneDx to improve genetic testing and for publication, if appropriate. My name or other personal identifying information will not be used in or linked to the results of any studies and publications. I also give GeneDx permission to inform me or my health care provider in the future about research opportunities, including treatments for the condition in my family.

☐ **Check this box, if you wish to opt out of being contacted for research studies.**

☐ **Check this box, if you are a New York state resident, and give permission for GeneDx to retain any remaining sample longer than 60 days after the completion of testing.**

Patient/Guardian Signature: _____ **Date:**_____

Medicare Patients: A completed Advance Beneficiary Notice (ABN) is required for patients that do not meet Medicare criteria. In addition, please sign the informed consent on the back of this form.

PATIENT CLINICAL HISTORY (DETAILED MEDICAL RECORDS MUST BE ATTACHED)

☐ **No Personal History of Cancer**

☐ **Breast Cancer(s)** Age at Dx:_____ ER: + / - PR: + / - HER2: + / - Triple Negative ☐
☐ Bilateral ☐ Two Primaries ☐ Invasive Ductal ☐ Invasive Lobular
☐ DCIS ☐ LCIS ☐ Other:_____

☐ **Ovarian Cancer(s)** Age at Dx: _____ ☐ Serous ☐ Mucinous ☐ Endometrioid
☐ Clear Cell ☐ LPM/Borderline ☐ Other:_____

☐ **Endometrial Cancer(s)** Age at Dx: _____ ☐ Serous ☐ Mucinous ☐ Endometrioid
☐ Clear Cell ☐ Sarcoma ☐ Other:_____

☐ **Pancreatic Cancer(s)** Age at Dx: _____
☐ Adenocarcinoma ☐ IPMN ☐ Neuroendocrine ☐ Other: _____

☐ **Prostate Cancer** Age at Dx: _____ Gleason Score:_____

☐ **Hematologic Disease** Age(s) at Dx: _____ Diagnosis:_____
Status: ☐ Active/Residual Disease ☐ Remission

☐ **Gastric Cancer(s)/Tumor(s)** Age at Dx:_____ Pathology: _____

☐ **Melanoma(s)** Age(s) at Dx:_____
☐ Invasive ☐ In-Situ

☐ **Colorectal Cancer(s)** Age at Dx: _____ Pathology:_____
Location: ☐ Right ☐ Left ☐ Transverse ☐ Rectum
MSI: ☐ Not Done ☐ High ☐ Stable ☐ Low
IHC: ☐ Not Done ☐ Present ☐ Absent IHC of: _____
MLH1 Methylation: ☐ Not Done ☐ Unmethylated
☐ Methylated – Tumor Only ☐ Methylated – Tumor and Normal Tissue
BRAF V600E: ☐ Not Done ☐ Positive ☐ Negative

☐ **Polyps** Age of first polyp:_____ Adenomatous – total #: _____
☐ Other Pathology: _____ Other – total #: _____

☐ **Renal Cancer(s)/Tumor(s)** Age at Dx: _____ _____ ☐ Bilateral
☐ Papillary Type (I or II): _____ ☐ Transitional Cell ☐ Clear Cell: _____
☐ Other: _____

☐ **Other Cancer(s)/Tumor(s):**_____ Age at Dx:_____

FAMILY HISTORY OF CANCER

☐ No Known Family History of Cancer(s)/Tumor(s) ☐ Adopted ☐ Pedigree Attached

Please include clinical details, such as bilateral, pathology (including triple negative breast cancer), premenopausal breast cancer, and Gleason score for prostate cancer, if available.

Relationship	Maternal	Paternal	Cancer Site	Age at Dx
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____

PREVIOUS GENETIC TESTING

☐ No history of genetic testing ☐ Patient Tested ☐ Relative Tested: _____
Gene(s) Tested: _____ ☐ Positive: _____
☐ Negative: _____ ☐ VUS: _____
Please include copies of family members' previous test results.

SAMPLE INFORMATION

Specimen Type:
☐ Blood in EDTA (5-6 mL in lavender top tube) ☐ Oral Rinse in 50 mL centrifuge tube
☐ Buccal Swab
☐ DNA (>20 ug) – Tissue Source:_____ Concentration: _____ (ug/mL)
Total volume:_____(ul) Treatment-Related RUSH:_____(if known please provide date)
☐ Other:_____ (Call Lab)

Specimens are not accepted for patients who have had allogeneic bone marrow transplants. For patients who have had blood transfusions, please list the date of last transfusion:____ / ____ / ____ (2-4 weeks of wait time is required for some testing)

HEREDITARY CANCER TESTS & PANELS

☐ B362-5 *BRCA1/BRCA2* Sequencing and Deletion/Duplication Analysis
☐ Reflex to test code: _____
☐ B361-7 *BRCA1/BRCA2* Ashkenazi Founder Panel (Three Targeted Pathogenic Variants)[1]
☐ Reflex to test code: _____
☐ J055-5 Breast Cancer Management Panel (9 genes)
☐ B273-4 Breast/Gyn Cancer Panel (23 genes)
☐ B399-7 Melanoma Panel (9 genes)
☐ B394-8 Renal Cancer Panel (18 genes)
☐ B275-9 Comprehensive Common Cancer Panel (46 genes)
☐ B751-9 Common Cancer Management Panel (37 genes)
☐ B522-4 Lynch/Colorectal High Risk Panel (7 genes)
☐ B274-2 Colorectal Cancer Panel (20 genes)
☐ B343-5 Pancreatic Cancer Panel (15 genes)
☐ J665-1 Hereditary Prostate Cancer Panel (12 genes)
☐ B363-3 Rest of Comprehensive Common Cancer Panel, if subpanel is negative

TARGETED VARIANT TESTING

☐ B370-8: Testing for a Previously Identified Variant Gene: _____ Variant:_____
Relationship to Proband: _____ Proband Name: _____ Proband GenPath Accession #: _____
☐ Positive Control Included/Will Be Sent ***(Positive control is recommended if previous test was performed at another lab)***
☐ Positive Control Not Available. Please initial to acknowledge acceptance of caveat language on a negative report _____
☐ Family Member Test Report Included ***(A clear copy of the test report on the positive family member is recommended if previous test completed at another lab)***

VARIANT TESTING PROGRAM (Requires lab approval)

☐ B753-5 Previously Identified Variant of Uncertain Significance Gene(s):_____ Variant(s):_____
Proband Name:_____ Relationship to Proband: _____ Proband GenPath Accession #: _____

1. Reflex to Rest of Comprehensive Common Cancer Panel (B363-3), if subpanel is negative, is not available.

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GenPath is a business unit of BioReference Laboratories, Inc.

Informed Consent

I understand that my health care provider has ordered the following genetic testing for {me/my child}: _____

Patient/Guardian Signature (sign here or on page 1 of the test requisition form) _____ **Date:**_____

If I wish to change my decisions or have any questions, I understand that I may contact the laboratory via email at genedx@genedx.com or by phone at +1-301-519-2100, or if I am located in the United States, toll free at +1-888-729-1206.

General Information About Genetic Testing

What is genetic testing?

DNA provides instructions for our body's growth and development. Genes are distinct sequences of DNA, and are arranged on chromosomes. The DNA in a gene contains instructions for making proteins, which determine things like growth and metabolism as well as traits like eye color and blood type. Genetic disorders are caused by harmful changes in DNA or from changes in the structure or number of chromosomes. Genetic testing is a laboratory test that tries to identify these harmful changes in chromosomes or the DNA. Genetic testing can be a diagnostic test, which is used to identify or rule out a specific genetic condition. Genetic screening tests are used to assess the chance for a person to develop or have a child with a genetic condition. Genetic screening tests are not typically diagnostic and results may require additional diagnostic testing.

The purpose of this test is to see if I, or my child, may have a genetic variant or chromosome rearrangement causing a genetic disorder or to determine the chance that I, or my child, will develop or pass on a genetic disorder in the future. 'My child' can also mean my unborn child, for the purposes of this consent.

Additional information about the specific test being ordered is available from my health care provider or I can go to the GeneDx website, www.genedx.com. This information includes the specific types of genetic disorders that can be identified by the genetic test, the likelihood of a positive result, and the limitations of genetic testing.

If {I/my child} already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I will inform the laboratory of this information.

What could I learn from this genetic test?

The following describes the possible results from the test:

1) Positive: A positive result indicates that a genetic variant has been identified that explains the cause of {my/my child's} genetic disorder or indicates that {I/my child} am at increased risk to develop the disorder in the future. It is possible to test positive for more than one genetic variant.

2) Negative: A negative result indicates that no disease-causing genetic variant was identified for the test performed. It does not guarantee that {I/my child} will be healthy or free from genetic disorders or medical conditions. If {I/my child} test negative for a variant known to cause the genetic disorder in other members of {my/my child's} family, this result rules out a diagnosis of the same genetic disorder in {me/my child} due to this specific change.

3) Inconclusive/Variant of Uncertain Significance (VUS): A finding of a variant of uncertain significance indicates that a genetic change was detected, but it is currently unknown whether that change is associated with a genetic disorder either now or in the future. A variant of uncertain significance is not the same as a positive result and does not clarify whether {I/my child} is at increased risk to develop a genetic disorder. The change could be a normal genetic variant or it could be disease-causing. Further analysis may be recommended, including testing both parents and other family members. Detailed medical records or information from other family members also may be needed to help clarify results.

4) Unexpected results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may tell me about the risk for another genetic condition {I/my child} is not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. This information may be disclosed to the ordering health care provider if it likely impacts medical care.

Result interpretation is based on currently available information in the medical literature, research and scientific databases. Because the literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may replace or add to the information GeneDx used to interpret {my/my child's} results. Providers can contact GeneDx at any time to discuss the classification of an identified variant. In addition, I or {my/my child's} health care providers may monitor publicly available resources used by the medical community, such as ClinVar (www.clinvar.com), to find current information about the clinical interpretation of my/my child's variant(s).

For tests that evaluate data from multiple family members, my spouse, or partner concurrently, results may be included in a single comprehensive report.

What are the risks and limitations of this genetic test?

- Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.
- Accurate interpretation of test results may require knowing the true biological relationships in a family. Failing to accurately state the biological relationships in {my/my child's} family may result in incorrect interpretation of results, incorrect diagnoses, and/or inconclusive test results. In some cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. This includes non-paternity (the stated father of an individual is not the biological father) and consanguinity (the parents of an individual are related by blood). It may be necessary to report these findings to the health care provider who ordered the test.
- Genetic testing is highly accurate. Rarely, inaccurate results may occur for various reasons. These reasons include, but are not limited to: mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or unusual circumstances such as bone marrow transplantation, or the presence of change(s) in such a small percentage of cells that the change(s) may not be detectable by the test (mosaicism).
- This test does not have the ability to detect all of the long-term medical risks that {I/my child} might experience. The result of this test does not guarantee my health or the health of my child/fetus. Other diagnostic tests may still need to be done, especially when only a genetic screening test has been performed previously.
- Occasionally, an additional sample may be needed if the initial specimen is not adequate.

Patient Confidentiality and Genetic Counseling

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area here: www.nsgc.org. Further testing or additional consultations with a health care provider may be necessary.

To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to me, to other health care providers involved in {my/my child's} diagnosis and treatment, or to others as entitled by law. The United States Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, I understand that I can visit www.genome.gov/10002077.

International Specimens

If {I/my child} reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of {my/my child's} residence..

Specimen Retention

After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring health care providers unless specific prior arrangements have been made.

I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by my selection below. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language.

Database Participation

De-identified health history and genetic information can help health care providers and scientists understand how genes affect human health. Though {I/my child} may not personally benefit, sharing this information helps health care providers to provide better care for their patients and researchers to make discoveries. GeneDx shares this type of information with health care providers, scientists, and health care databases. No personal identifying information will be shared, as it will be replaced with a unique code.

Even though only a code is used for the reporting to the databases, there is a risk that {I/my child} could be identified based on the genetic and health information that is shared. GeneDx believes that this is unlikely, though the risk is greater if I have already shared {my/my child's} genetic or health information with public resources, such as genealogy websites.

Recontact for Research Participation

Separate from the above, GeneDx may collaborate with scientists, researchers and drug developers to advance knowledge of genetic diseases and to develop new treatments. If there are opportunities to participate in research relevant to the disorder in {my/my child's} family, and if I have consented for recontact, GeneDx may allow my health care provider to be recontacted for research purposes, such as the development of new testing, drug development, or other treatment modalities. In some situations, such as if my health care provider is not available, I may be contacted directly.

Any research that results in medical advances, including new products, tests or discoveries, may have potential commercial value and may be developed and owned by GeneDx or the collaborating researchers. If any individuals or corporations benefit financially from these studies, no compensation will be provided to {me/my child} or {my/my child's} heirs.

Hereditary Cancer Testing Panel Components

Breast Cancer Management Panel (9 genes)
ATM, BRCA1, BRCA2, CDH1, CHEK2, NBN, PALB2, PTEN, TP53

Breast/Gyn Cancer Panel (23 genes)
ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, FANCC, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, PTEN, RAD51C, RAD51D, RECQL, TP53*

Colorectal Cancer Panel (20 genes)
APC, ATM, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, NTHL1, PMS2, POLD1, POLE, PTEN, SCG5/GREM1*, SMAD4, STK11, TP53*

Comprehensive Common Cancer Panel (46 genes)
APC, ATM, AXIN2, BAP1, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FANCC, FH, FLCN, HOXB13, MET, MITF*, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, NTHL1, PALB2, PMS2, POLD1, POLE, POT1, PTEN, RAD51C, RAD51D, RECQL, SCG5/GREM1*, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL*

Melanoma Panel (9 genes)
BAP1, BRCA2, *CDK4, CDKN2A, MITF*, POT1, PTEN, RB1,TP53*

Common Cancer Management Panel (37 genes)
APC, ATM, AXIN2, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM, FH, FLCN, MLH1, MSH2, MSH6, MUTYH, NBN, NF1, NTHL1, PALB2, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, SCG5/GREM1*, SDHB, SDHC, SDHD, SMAD4, STK11, TP53, TSC1, TSC2, VHL*

Lynch/Colorectal High Risk Panel (7 genes)
APC, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2*

Pancreatic Cancer Panel (15 genes)
APC, ATM, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, VHL*

Hereditary Prostate Cancer Panel (12 genes)
ATM, BRCA1, BRCA2, CHEK2, EPCAM, HOXB13, MLH1, MSH2, MSH6, NBN, PMS2, TP53*

Renal Cancer Panel (18 genes)
BAP1, EPCAM, FH, FLCN, MET, MITF*, MLH1, MSH2, MSH6, PMS2, PTEN, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL*

Testing includes sequencing and deletion duplication for all genes except EPCAM (del/dup only), MITF (evaluation of c.952G>A only), and SCG5/GREM1 (del/dup only).

Frequently Used ICD-10 Codes

Please select or write the applicable ICD-10 codes(s). Ordering providers should always select the ICD-10 code(s) that are most appropriate for the test ordered for the patient. Patients of Ashkenazi Jewish descent with only family history require one code from box 2.

Box 1 — ICD-10 codes that do not require an accompanying secondary code:

- ❒ C50.411 Malignant neoplasm of upper-outer quadrant of right female breast
- ❒ C50.412 Malignant neoplasm of upper-outer quadrant of left female breast
- ❒ C50.911 Malignant neoplasm of unspecified site of right female breast
- ❒ C50.912 Malignant neoplasm of unspecified site of left female breast
- ❒ C54.1 Malignant neoplasm of endometrium
- ❒ D05.11 Intraductal carcinoma in situ of right breast
- ❒ D05.12 Intraductal carcinoma in situ of left breast
- ❒ Z83.71 Family history of colonic polyps
- ❒ Z85.038 Personal history of other malignant neoplasm of large intestine
- ❒ Z86.010 Personal history of colonic polyps

Box 2 — ICD-10 codes that require a secondary ICD-10 code from Box 3 or Other:

- ❒ Z80.0 Family history of malignant neoplasm of digestive organs
- ❒ Z80.3 Family history of malignant neoplasm of breast
- ❒ Z80.41 Family history of malignant neoplasm of ovary
- ❒ Z80.42 Family history of malignant neoplasm of prostate
- ❒ Z85.07 Personal history of malignant neoplasm of pancreas
- ❒ Z85.3 Personal history of malignant neoplasm of breast
- ❒ Z85.43 Personal history of malignant neoplasm of ovary
- ❒ Z85.46 Personal history of malignant neoplasm of prostate

Box 3 — ICD-10 codes that require a secondary ICD-10 code from Box 2 or Other:

- ❒ C25.0 Malignant neoplasm of head of pancreas
- ❒ C25.1 Malignant neoplasm of body of pancreas
- ❒ C25.4 Malignant neoplasm of endocrine pancreas
- ❒ C25.8 Malignant neoplasm of overlapping site of pancreas
- ❒ C25.9 Malignant neoplasm of pancreas, unspecified
- ❒ C61 Malignant neoplasm of prostate

❒ Other ICD-10 Codes (please specify):_____