

## Patient Information

First name \_\_\_\_\_ Last name \_\_\_\_\_  
 Gender  Male  Female Date of birth (mm/dd/yy) \_\_\_\_\_  
 Ancestry  Caucasian  Eastern European  Northern European  
 Western European  Native American  Middle Eastern  
 African American  Asian  Pacific Islander  
 Caribbean  Central/South American  
 Ashkenazi Jewish  Hispanic  Other: \_\_\_\_\_

Mailing address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip code \_\_\_\_\_  
 Home phone \_\_\_\_\_ Work phone \_\_\_\_\_  
 Email \_\_\_\_\_ Patient's primary language if not English \_\_\_\_\_

## Ordering Account Information

Acct # \_\_\_\_\_ Account Name \_\_\_\_\_  
 Reporting Preference\*:  Care Evolve  Fax  Email  
*\*If unmarked, we will use the account's default preferences or fax to new clients.*

Physician \_\_\_\_\_ NPI # \_\_\_\_\_  
 Genetic Counselor \_\_\_\_\_  
 Street address 1 \_\_\_\_\_  
 Street address 2 \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip code \_\_\_\_\_  
 Phone \_\_\_\_\_ Fax (important) \_\_\_\_\_  
 Email \_\_\_\_\_ Beeper \_\_\_\_\_

**Send Additional Report Copies To:**

Physician or GC/Acct # \_\_\_\_\_ Fax#/Email/CE # \_\_\_\_\_  
 Physician or GC/Acct # \_\_\_\_\_ Fax#/Email/CE # \_\_\_\_\_

## Sample Information

Medical record # \_\_\_\_\_ Specimen ID \_\_\_\_\_ Date sample obtained (mm/dd/yy) \_\_\_\_\_  
 Blood in EDTA (5-6 mL in lavender top tube)  
 DNA (>20 ug): Tissue source \_\_\_\_\_ concentration \_\_\_\_\_ (ug/ml) total Volume \_\_\_\_\_ (ul)  
 Oral Rinse (At least 30 mL of Scope oral rinse in a 50 mL centrifuge tube)  
 Buccal Swab  
 Other \_\_\_\_\_ (Call lab)  
 Patient has had a blood transfusion  Yes  No Date of last transfusion \_\_\_/\_\_\_/\_\_\_  
 (2-4 weeks of wait time is required for some testing) Specimens are not accepted for patients who have had allogeneic bone marrow transplants  
 Treatment-Related **RUSH:** \_\_\_\_\_ (If known, please provide date)  
**Clinical Diagnosis:** \_\_\_\_\_ **ICD-10 Codes:** \_\_\_\_\_  
**Age at Initial Presentation:** \_\_\_\_\_

## Statement of Medical Necessity

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 Physician 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.

**Medical Professional Signature (required)** \_\_\_\_\_ Date \_\_\_\_\_

## Patient Consent (sign here or on the consent document)

I have read the Informed Consent document and I give permission to GeneDx 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 \_\_\_\_\_

## Payment Options

**Insurance Bill** PATIENT STATUS — ONE MUST BE CHECKED  Hospital Inpatient  Hospital Outpatient  Not a Hospital Patient Referral/Prior Authorization # \_\_\_\_\_  
 GeneDx Benefit Investigation # \_\_\_\_\_  
 Insurance Carrier \_\_\_\_\_ Policy Name \_\_\_\_\_  Hold sample for Benefit Investigation (only if OOP cost is >\$100) **Please attach copy of Referral/authorization**  
 Insurance ID # \_\_\_\_\_ Group # \_\_\_\_\_ Name of Insured \_\_\_\_\_ Date of Birth \_\_\_\_\_ Insurance Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Relationship to Insured  Child  Spouse  Self  Other \_\_\_\_\_  
 Secondary Insurance Carrier Name \_\_\_\_\_ Insurance ID# \_\_\_\_\_ Group # \_\_\_\_\_ Name of Insured \_\_\_\_\_ Date of Birth \_\_\_\_\_  
 Relationship to Insured  Child  Spouse  Self  Other \_\_\_\_\_

**Please include a copy of the front and back of the patient's insurance card (include secondary when applicable)**  
 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 health care provider necessary for reimbursement. 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.

**Patient Signature (required)** \_\_\_\_\_ Date \_\_\_\_\_

## Institutional Bill

GeneDx Account # \_\_\_\_\_  
 Hospital/Lab Name \_\_\_\_\_  
 Contact Name \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
 Phone \_\_\_\_\_ Fax \_\_\_\_\_

## Patient Bill

I understand that my credit card will be charged the full amount for the testing. Amount \_\_\_\_\_  
**Please bill my credit card (all major cards accepted)**  
 MasterCard  Visa  Discover  American Express  
 Name as it appears on card \_\_\_\_\_  
 Account Number \_\_\_\_\_ Expiration date \_\_\_\_\_ CVC \_\_\_\_\_  
**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

## For GeneDx Use Only



# OncoGeneDx Hereditary Cancer Testing

Account # \_\_\_\_\_ Account Name \_\_\_\_\_

First Name \_\_\_\_\_ Last Name \_\_\_\_\_ Date of Birth (mm/dd/yy) \_\_\_\_\_

## Patient Clinical Information DETAILED MEDICAL RECORDS MUST BE ATTACHED

No Personal History of Cancer/Tumor

Clinical Diagnosis: \_\_\_\_\_ ICD-10 Codes: \_\_\_\_\_ Diagnosis Age(s): \_\_\_\_\_

- Breast Cancer(s)** Age(s) at Dx: \_\_\_\_\_ ER \_\_\_ PR \_\_\_ HER2 \_\_\_  triple negative
  - Bilateral  Two Primaries  Invasive Ductal  Invasive Lobular
  - DCIS  LCIS  Other: \_\_\_\_\_
- Ovarian Cancer(s)** Age(s) at Dx: \_\_\_\_\_
  - Serous  Mucinous  Endometrioid  Clear Cell
  - LMP/Borderline  Other: \_\_\_\_\_
- Endometrial Cancer(s)** Age(s) at Dx: \_\_\_\_\_
  - Serous  Mucinous  Endometrioid  Clear Cell
  - Sarcoma  Other: \_\_\_\_\_
- Pancreatic Cancer(s)** Age(s) at Dx: \_\_\_\_\_
  - Adenocarcinoma  IPMN  Neuroendocrine  Other: \_\_\_\_\_
- Prostate Cancer** Age at Dx: \_\_\_\_\_ Gleason Score: \_\_\_\_\_
- Melanoma(s)** Age(s) at Dx: \_\_\_\_\_  Invasive  In-Situ
- Hematologic Disease** Age(s) at Dx: \_\_\_\_\_ Diagnosis: \_\_\_\_\_
  - Status:  Active/Residual Disease  Remission

- Colorectal Cancer(s)** Age(s) at Dx: \_\_\_\_\_ Pathology: \_\_\_\_\_
  - Location:  Right  Left  Transverse  Rectum
- Polyp(s)** Age of first polyp: \_\_\_\_\_  Adenomatous - total #: \_\_\_\_\_
  - Other - Pathology: \_\_\_\_\_ Other - total #: \_\_\_\_\_
- Gastric Cancer(s)/Tumor(s)** Age(s) at Dx: \_\_\_\_\_ Pathology: \_\_\_\_\_
- Endocrine Cancer(s)/Disease** Age(s) at Dx: \_\_\_\_\_
  - Thyroid  Pathology/Diagnosis: \_\_\_\_\_
  - Pheochromocytoma (PCC)  Paraganglioma (PGL) Location: \_\_\_\_\_
  - Bilateral
- Renal Cancer(s)/Tumor(s)** Age(s) at Dx: \_\_\_\_\_  Bilateral
  - Clear Cell  Papillary Type (I or II): \_\_\_\_\_
  - Transitional Cell  Other: \_\_\_\_\_
- Brain Cancer(s)/Tumor(s)** Age(s) at Dx: \_\_\_\_\_ Pathology: \_\_\_\_\_
- Other Cancer/Tumor** \_\_\_\_\_ Age at Dx: \_\_\_\_\_

## Patient Genetic Testing History

No Personal History of Genetic Testing

Gene(s) Tested: \_\_\_\_\_  Positive \_\_\_\_\_  VUS \_\_\_\_\_  Negative

## Patient Tumor Testing History

No Known Tumor Testing

Tumor Type Tested: \_\_\_\_\_

MSI:  Not Done  High  Stable  Low  
 IHC:  Not Done  Present  
 Absent IHC of: \_\_\_\_\_  
 Other: \_\_\_\_\_

MLH1 Methylation:  Not Done  Methylated - Tumor Only  
 Methylated - Tumor and Normal Tissue  Unmethylated  
 BRAFV600E:  Not Done  Present  Absent

Please include copies of all previous genetic test results, tumor test results and detailed medical records.

## Family History of Cancer(s)/Tumor(s)

No Known Family History of Cancer(s)/Tumor(s)

Pedigree Attached  Adopted

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/Tumor Site	Age at Dx
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

## Previous Familial MLH1 Genetic Testing

No Known Family History of Genetic Testing

Relative Tested: \_\_\_\_\_  Gene(s) Tested: \_\_\_\_\_  Positive \_\_\_\_\_  VUS \_\_\_\_\_  Negative

Please include copies of family members' previous test results.

## Frequently Used ICD-10 Codes

Please select or write the applicable ICD-10 code(s) below.

### Breast and Ovarian Cancer

- C50.411: Malignant neoplasm of upper-outer quadrant of right female breast
- C50.412: Malignant neoplasm of upper-outer quadrant of left female breast
- D05.11: Intraductal carcinoma in situ of right breast
- D05.12: Intraductal carcinoma in situ of left breast
- Z80.3: Family history of malignant neoplasm of breast
- Z80.41: Family history of malignant neoplasm of ovary
- Z85.3: Personal history of malignant neoplasm of breast
- Z85.43: Personal history of malignant neoplasm of ovary

### Colorectal Cancer

- Z80.0: Family history of malignant neoplasm of digestive organs
- Z83.71: Family history of colonic polyps
- Z86.010: Personal history of colonic polyps

### Other

- C54.1: Malignant neoplasm of endometrium
- Z80.42: Family history of malignant neoplasm of prostate

Other ICD-10 Codes (please specify): \_\_\_\_\_

Account # \_\_\_\_\_ Account Name \_\_\_\_\_

First Name \_\_\_\_\_ Last Name \_\_\_\_\_ Date of Birth (mm/dd/yy) \_\_\_\_\_

## OncoGeneDx - Hereditary Cancer Test Menu

<p><b>Breast/Ovarian Cancer</b></p> <p><input type="checkbox"/> <b>B361 BRCA1/BRCA2 Ashkenazi Founder Panel</b> (Three Targeted Pathogenic Variants) Reflex to test code: _____</p> <p><input type="checkbox"/> <b>B362 BRCA1/BRCA2 Sequencing and Deletion Duplication Analysis</b> Reflex to test code: _____</p> <p><input type="checkbox"/> <b>J055 Breast Cancer High/Moderate Risk Panel (8 genes)</b></p> <p><input type="checkbox"/> <b>J662 Breast Cancer Surgical Panel (3 genes)</b></p> <p><input type="checkbox"/> <b>B273 Breast/Ovarian Cancer Panel (20 genes)</b></p>	<p><b>Multiple Cancers</b></p> <p><input type="checkbox"/> <b>B275 Comprehensive Cancer Panel (32 genes)</b></p> <p><input type="checkbox"/> <b>B751 High/Moderate Risk Panel (23 genes)</b></p> <p><input type="checkbox"/> <b>B363 Rest of Comprehensive Cancer Panel (if first test is negative)<sup>1</sup></b></p> <p><b>Colorectal Cancer</b></p> <p><input type="checkbox"/> <b>B274 Colorectal Cancer Panel (19 genes)</b></p> <p><input type="checkbox"/> <b>B522 Lynch/Colorectal High Risk Panel (7 genes)</b></p> <p><input type="checkbox"/> <b>J006 MSH2 Exons 1-7 Inversion Analysis<sup>1</sup></b></p>	<p><b>Other Cancers</b></p> <p><input type="checkbox"/> <b>B344 Endometrial Cancer Panel (12 genes)</b></p> <p><input type="checkbox"/> <b>B399 Melanoma Panel (9 genes)<sup>1</sup></b></p> <p><input type="checkbox"/> <b>B343 Pancreatic Cancer Panel (16 genes)</b></p> <p><input type="checkbox"/> <b>J318 Pediatric Tumor Panel (27 genes)<sup>1</sup></b></p> <p><input type="checkbox"/> <b>B395 PGL/PCC Panel (12 genes)<sup>1</sup></b></p> <p><input type="checkbox"/> <b>J665 Prostate Cancer Panel (12 genes)</b></p> <p><input type="checkbox"/> <b>B394 Renal Cancer Panel (18 genes)<sup>1</sup></b></p>
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<sup>1</sup>Rest of Comprehensive Cancer Panel is not available after BRCA1/BRCA2 (test codes B361 and B362) or test codes B394, B395, B399, J006 or J318.

## B749 OncoGeneDx Custom Panel

Please select one or more genes to create a custom panel (no minimum). Up to 62 genes are available.

<input type="checkbox"/> ALK	<input type="checkbox"/> BRCA1	<input type="checkbox"/> CHEK2	<input type="checkbox"/> MAX	<input type="checkbox"/> MUTYH	<input type="checkbox"/> POLD1	<input type="checkbox"/> RBI	<input type="checkbox"/> SDHD	<input type="checkbox"/> TP53
<input type="checkbox"/> APC	<input type="checkbox"/> BRCA2	<input type="checkbox"/> DICER1	<input type="checkbox"/> MEN1	<input type="checkbox"/> NBN	<input type="checkbox"/> POLE	<input type="checkbox"/> RET*	<input type="checkbox"/> SMAD4	<input type="checkbox"/> TSC1
<input type="checkbox"/> ATM	<input type="checkbox"/> BRIP1	<input type="checkbox"/> EPCAM*	<input type="checkbox"/> MET	<input type="checkbox"/> NF1	<input type="checkbox"/> PRKARIA	<input type="checkbox"/> SCG5/GREM1*	<input type="checkbox"/> SMARCA4	<input type="checkbox"/> TSC2
<input type="checkbox"/> AXIN2	<input type="checkbox"/> CDC73	<input type="checkbox"/> FANCC	<input type="checkbox"/> MITF*	<input type="checkbox"/> NF2	<input type="checkbox"/> PTCH1	<input type="checkbox"/> SDHA*	<input type="checkbox"/> SMARCB1	<input type="checkbox"/> VHL
<input type="checkbox"/> BAP1	<input type="checkbox"/> CDH1	<input type="checkbox"/> FH	<input type="checkbox"/> MLH1	<input type="checkbox"/> PALB2	<input type="checkbox"/> PTEN	<input type="checkbox"/> SDHAF2	<input type="checkbox"/> STK11	<input type="checkbox"/> WT1
<input type="checkbox"/> BARD1	<input type="checkbox"/> CDK4	<input type="checkbox"/> FLCN	<input type="checkbox"/> MSH2	<input type="checkbox"/> PHOX2B*	<input type="checkbox"/> RADS1C	<input type="checkbox"/> SDHB	<input type="checkbox"/> SUFU	<input type="checkbox"/> XRCC2
<input type="checkbox"/> BMPRIA	<input type="checkbox"/> CDKN2A	<input type="checkbox"/> HOXB13	<input type="checkbox"/> MSH6	<input type="checkbox"/> PMS2	<input type="checkbox"/> RADS1D	<input type="checkbox"/> SDHC	<input type="checkbox"/> TMEM127	

If OncoGeneDx Custom Panel is negative, reflex to test code: \_\_\_\_\_

## Other Hereditary Cancers Test Menu

<input type="checkbox"/> <b>714 Birt-Hogg-Dube syndrome (FLCN)</b> (Seq & Del/Dup)	<input type="checkbox"/> <b>718 Li-Fraumeni syndrome (TP53)</b> (Seq & Del/Dup)
<input type="checkbox"/> <b>372 Bloom syndrome (BLM)</b> (Seq)	<input type="checkbox"/> <b>719 Multiple endocrine neoplasia, type 1 (MEN1)</b> (Seq & Del/Dup)
<input type="checkbox"/> <b>715 Carney complex (PRKARIA)</b> (Seq & Del/Dup)	<input type="checkbox"/> <b>1771 Multiple endocrine neoplasia, types 2A and 2B (RET)</b> (Seq)
<input type="checkbox"/> <b>205 Gorlin syndrome (PTCH1)</b> (Seq & Del/Dup)	<input type="checkbox"/> <b>195 PTEN hamartoma tumor syndrome (PTEN)</b> (Seq & Del/Dup)
<input type="checkbox"/> <b>713 Hereditary leiomyomatosis and renal cell cancer (FH)</b> (Seq & Del/Dup)	<input type="checkbox"/> <b>2071 Peutz-Jeghers syndrome (STK11)</b> (Seq & Del/Dup)
<input type="checkbox"/> <b>721 Hyperparathyroidism-jaw tumor syndrome (CDC73)</b> (Seq & Del/Dup)	<input type="checkbox"/> <b>332 Von Hippel-Lindau syndrome (VHL)</b> (Seq & Del/Dup)
<input type="checkbox"/> <b>717 Juvenile polyposis syndrome (BMPRIA, SMAD4)</b> (Seq & Del/Dup)	

## Targeted Variant Testing

**B370 Testing for a previously identified variant**

Gene: \_\_\_\_\_ Variant: \_\_\_\_\_

Proband Name: \_\_\_\_\_ Relationship to proband: \_\_\_\_\_

Proband GeneDx 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 was performed at another lab.

## Variant Testing Program (requires lab approval)

**B753 Previously identified variant of uncertain significance**

VTP Family ID: F \_\_\_\_\_

Gene(s): \_\_\_\_\_

Variant(s): \_\_\_\_\_

Proband Name: \_\_\_\_\_

Relationship to proband: \_\_\_\_\_

Proband GeneDx Accession #: \_\_\_\_\_

## Hereditary Cancer Testing Panel Components

<b>J055</b>	<b>Breast Cancer High/Moderate Risk Panel (8 genes)</b>	ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, TP53
<b>J662</b>	<b>Breast Cancer Surgical Panel (3 genes)</b>	BRCA1, BRCA2, PALB2
<b>B273</b>	<b>Breast/Ovarian Cancer Panel (20 genes)</b>	ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM*, FANCC, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RADS1C, RADS1D, TP53, XRCC2
<b>B274</b>	<b>Colorectal Cancer Panel (19 genes)</b>	APC, ATM, AXIN2, BMPRIA, CDH1, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SCG5/GREM1*, SMAD4, STK11, TP53
<b>B275</b>	<b>Comprehensive Cancer Panel (32 genes)</b>	APC, ATM, AXIN2, BARD1, BMPRIA, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM*, FANCC, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTEN, RADS1C, RADS1D, SCG5/GREM1*, SMAD4, STK11, TP53, VHL, XRCC2
<b>B344</b>	<b>Endometrial Cancer Panel (12 genes)</b>	BRCA1, BRCA2, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, PTEN, TP53
<b>B399</b>	<b>Melanoma Panel (9 genes)</b>	BAP1, BRCA2, CDK4, CDKN2A, MITF*, POT1, PTEN, RB1, TP53
<b>B751</b>	<b>High/Moderate Risk Panel (23 genes)</b>	APC, ATM, BMPRIA, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PALB2, PMS2, PTEN, RADS1C, RADS1D, SMAD4, STK11, TP53, VHL
<b>B522</b>	<b>Lynch/Colorectal High Risk Panel (7 genes)</b>	APC, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2
<b>B343</b>	<b>Pancreatic Cancer Panel (16 genes)</b>	APC, ATM, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM*, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, VHL, XRCC2
<b>J318</b>	<b>Pediatric Tumor Panel (27 genes)</b>	ALK, APC, CDC73, DICER1, EPCAM*, MEN1, MLH1, MSH2, MSH6, NF1, NF2, PHOX2B*, PMS2, PRKARIA, PTCH1, PTEN, RB1, RET*, SMARCA4, SMARCB1, STK11, SUFU, TP53, TSC1, TSC2, VHL, WT1
<b>B395</b>	<b>PGL/PCC Panel (12 genes)</b>	FH, MAX, MEN1, NF1, RET*, SDHA*, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL
<b>J665</b>	<b>Prostate Cancer Panel (12 genes)</b>	ATM, BRCA1, BRCA2, CHEK2, EPCAM*, HOXB13, MLH1, MSH2, MSH6, NBN, PMS2, TP53
<b>B394</b>	<b>Renal Cancer Panel (18 genes)</b>	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), PHOX2B (seq only), RET (seq only), SCG5/GREM1 (del/dup only), SDHA (seq only)

Account # \_\_\_\_\_ Account Name \_\_\_\_\_

First Name \_\_\_\_\_

Last Name \_\_\_\_\_

Date of Birth (mm/dd/yy) \_\_\_\_\_

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

## 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](http://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](http://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](http://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](http://www.genome.gov/10002077).



# Informed Consent and Authorization Form

Account # \_\_\_\_\_ Account Name \_\_\_\_\_

First Name \_\_\_\_\_

Last Name \_\_\_\_\_

Date of Birth (mm/dd/yy) \_\_\_\_\_

## 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.

## Patient Consent (sign here or on page 1 of the test requisition form)

I have read the Informed Consent document and I give permission to GeneDx 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 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 (mm/dd/yyyy)

**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](mailto: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.**

**A. Notifier:**

**B. Patient Name:**

**C. Identification Number:**

## Advance Beneficiary Notice of Noncoverage (ABN)

**NOTE:** If Medicare doesn't pay for **D.** \_\_\_\_\_ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** \_\_\_\_\_ below.

<b>D.</b>	<b>E. Reason Medicare May Not Pay:</b>	<b>F. Estimated Cost</b>

**WHAT YOU NEED TO DO NOW:**

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** \_\_\_\_\_ listed above.  
**Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

**G. OPTIONS: Check only one box. We cannot choose a box for you.**

- OPTION 1.** I want the **D.** \_\_\_\_\_ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- OPTION 2.** I want the **D.** \_\_\_\_\_ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**
- OPTION 3.** I don't want the **D.** \_\_\_\_\_ listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

**H. Additional Information:**

**This notice gives our opinion, not an official Medicare decision.** If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

<b>I. Signature:</b>	<b>J. Date:</b>
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