OncoGeneDx Test Requisition Form

GeneDx an OPKO Health Company

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

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)
Fibroblasts are recommended for patients who had an allogenic bone marrow transplant. See www.genedx.com/specimen-requirements for details.
❒ Treatment-Related **RUSH**: _____ *(If known, please provide date)*

Clinical Diagnosis: _____ **ICD-10 Codes:** _____
Age at Initial Presentation: _____

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 #

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 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 (sign here)

I have read the attached 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. **More information is available on our website: www.genedx.com**

❒ 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

PATIENT STATUS – ONE MUST BE CHECKED: ❒ Hospital Inpatient ❒ Hospital Outpatient ❒ Not a Hospital Patient Hospital Patient Date of Discharge:_____

Payment Options

❒ Insurance Bill

Referral/Prior Authorization # _____
Please attach copy of Referral/authorization

Insurance Carrier Policy Name ❒ Hold sample for Estimated Benefit Investigation (only if OOP cost is >$100) GeneDx Benefit Investigation #_____

Insurance ID # Group # Name of Insured Date of Birth Insurance Address City State Zip

Secondary Insurance Carrier Name Insurance ID# Group # Name of Insured Date of Birth

Relationship to Insured ❒ Child ❒ Spouse ❒ Self ❒ Other _____
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)

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 estimated 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

Amount _____

If I have insurance coverage for this testing, I am electing to be treated as a self-pay patient for this testing. As such, I agree that neither GeneDx nor I will submit a claim to my insurance for this testing.

Please bill my credit card for the full amount stated above (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

GeneDx an OPKO Health Company

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(s)/Tumor(s) or Pancreatitis**

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:_____

❒ **Pancreatitis** Age(s) at Dx:_____
❒ Acute ❒ Chronic

❒ **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 ❒ Allogenic bone marrow transplant

* Fibroblasts may be the preferred specimen; visit www.genedx.com/specimen-requirements

❒ **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 ❒ Parathyroid ❒ Pituitary
❒ Pheochromocytoma (PCC) ❒ Paraganglioma (PGL) Location: _____
❒ Pathology/Diagnosis: _____

❒ **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: _____

Comments: _____

Genetic Testing History

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

Patient's Germline

❒ **No Personal History of Genetic Testing**

❒ **Prior Testing History Gene(s) Tested:** _____
Results: ❒ Negative ❒ Positive ❒ VUS
Gene(s): _____
c._____
p._____

Previous Familial Genetic Testing

❒ **No Known Family History of Genetic Testing**

❒ **Relationship to Proband:** _____
Results: ❒ Negative ❒ Positive ❒ VUS
Gene(s): _____
c._____
p. _____

Patient's Tumor Testing History

❒ **No Known Tumor Testing**

❒ **Lynch Screening:** Tumor Type: _____
MSI: ❒ Not Done ❒ High ❒ Stable ❒ Low
IHC: ❒ Not Done ❒ Present
❒ Absent IHC of: _____
MLH1 Methylation: ❒ Not Done ❒ Methylated - Tumor Only
❒ Methylated - Tumor and Normal Tissue ❒ Unmethylated
BRAF V600E: ❒ Not Done ❒ Present ❒ Absent
Other: _____

❒ **Other Tumor Testing:** Tumor Type: _____
Test Performed: _____
Results: _____

Family History of Cancer(s)/Tumor(s) or Relevant History

❒ **No Known Family History**

❒ 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. For pancreatitis history, please indicate acute or chronic, if available.

Relationship	Maternal	Paternal	Cancer/Tumor Site or Relevant History	Age at Dx
	❒	❒		
	❒	❒		
	❒	❒		
	❒	❒		

Commonly Used ICD-10 Codes

Commonly used ICD-10 Codes are listed below as a convenience. Please select or write any and all applicable ICD-10 code(s) to the highest level of specificity. 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):_____

OncoGeneDx Hereditary Cancer Testing

Account # Account Name

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

OncoGeneDx - Test Menu

Breast/Gynecologic Cancers

- ❒ **B361 *BRCA1/BRCA2* Ashkenazi Founder Panel**[1] (Three Targeted Pathogenic Variants)
  - ❒ Reflex to test code: _____
- ❒ **B362 *BRCA1/BRCA2* Sequencing and Deletion/Duplication Analysis**
  - ❒ Reflex to test code: _____
- ❒ **J055 Breast Cancer Management Panel (9 genes)**
- ❒ **B273 Breast/Gyn Cancer Panel (23 genes)**

Colorectal Cancer

- ❒ **B274 Colorectal Cancer Panel (20 genes)**
- ❒ **B522 Lynch/Colorectal High Risk Panel (7 genes)**

Multiple Cancers

- ❒ **B275 Comprehensive Common Cancer Panel (46 genes)**
- ❒ **B751 Common Cancer Management Panel (37 genes)**
- ❒ **B363 Rest of Comprehensive Common Cancer Panel (if first test is negative)**[1]

Specialty Panels

- ❒ **T830 Hereditary MDS/Leukemia Panel (10 genes)**[1]
- ❒ **J899 Hereditary Pancreatitis Panel (5 genes)**[1]
- ❒ **T828 Hyperparathyroidism/Endocrine Tumor Panel (11 genes)**[1]
- ❒ **J318 Pediatric Tumor Panel (27 genes)**[1]

Tumor Specific Panels

- ❒ **T831 Brain Tumor Panel (23 genes)**[1]
- ❒ **J665 Hereditary Prostate Cancer Panel (16 genes)**
- ❒ **B399 Melanoma Panel (9 genes)**
- ❒ **B343 Pancreatic Cancer Panel (15 genes)**
- ❒ **B395 PGL/PCC Panel (12 genes)**
- ❒ **B394 Renal Cancer Panel (18 genes)**

[1] *Rest of Comprehensive Common Cancer Panel is not available after test codes B361, J318, J899, T830, T828 or T831.*

B749 OncoGeneDx Custom Panel

Please select one or more genes to create a custom panel (no minimum). Up to 64 genes are available.

B749 OncoGeneDx Custom Panel - Include all genes from test code(s) _____ in addition to gene(s) selected below.

❒ *ALK*	❒ *BMPR1A*	❒ *CDK4*	❒ *FH*	❒ *MITF**	❒ *NF1*	❒ *POLD1*	❒ *RAD51C*	❒ *SDHA**	❒ *SMARCA4*	❒ *TSC1*
❒ *APC*	❒ *BRCA1*	❒ *CDKN2A*	❒ *FLCN*	❒ *MLH1*	❒ *NF2*	❒ *POLE*	❒ *RAD51D*	❒ *SDHAF2*	❒ *SMARCB1*	❒ *TSC2*
❒ *ATM*	❒ *BRCA2*	❒ *CHEK2*	❒ *HOXB13*	❒ *MSH2*	❒ *NTHL1*	❒ *POT1*	❒ *RB1*	❒ *SDHB*	❒ *STK11*	❒ *VHL*
❒ *AXIN2*	❒ *BRIP1*	❒ *DICER1*	❒ *MAX*	❒ *MSH6*	❒ *PALB2*	❒ *PRKAR1A*	❒ *RECQL*	❒ *SDHC*	❒ *SUFU*	❒ *WT1*
❒ *BAP1*	❒ *CDC73*	❒ *EPCAM**	❒ *MEN1*	❒ *MUTYH*	❒ *PHOX2B**	❒ *PTCH1*	❒ *RET**	❒ *SDHD*	❒ *TMEM127*	
❒ *BARD1*	❒ *CDH1*	❒ *FANCC*	❒ *MET*	❒ *NBN*	❒ *PMS2*	❒ *PTEN*	❒ *SCG5/GREM1**	❒ *SMAD4*	❒ *TP53*	

❒ If OncoGeneDx Custom Panel is negative, reflex to test code: _____

Other Hereditary Cancers Test Menu

- ❒ **714 Birt-Hogg-Dube syndrome** (*FLCN*) (Seq & Del/Dup)
- ❒ **372 Bloom syndrome** (*BLM*) (Seq)
- ❒ **715 Carney complex** (*PRKAR1A*) (Seq & Del/Dup)
- ❒ **205 Gorlin syndrome** (*PTCH1*) (Seq & Del/Dup)
- ❒ **713 Hereditary leiomyomatosis and renal cell cancer** (*FH*) (Seq & Del/Dup)
- ❒ **721 Hyperparathyroidism-jaw tumor syndrome** (*CDC73*) (Seq & Del/Dup)
- ❒ **717 Juvenile polyposis syndrome** (*BMPR1A, SMAD4*) (Seq & Del/Dup)
- ❒ **718 Li-Fraumeni syndrome** (*TP53*) (Seq & Del/Dup)
- ❒ **719 Multiple endocrine neoplasia, type 1** (*MEN1*) (Seq & Del/Dup)
- ❒ **1771 Multiple endocrine neoplasia, types 2A and 2B** (*RET*) (Seq)
- ❒ **195 *PTEN* hamartoma tumor syndrome** (*PTEN*) (Seq & Del/Dup)
- ❒ **2071 Peutz-Jeghers syndrome** (*STK11*) (Seq & Del/Dup)
- ❒ **332 Von Hippel-Lindau syndrome** (*VHL*) (Seq & Del/Dup)
- ❒ **Other Test** (include test code and name): _____

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**

Gene(s): _____

Variant(s): _____

Proband Name: _____

Relationship to proband: _____

Proband GeneDx Accession #: _____

OncoGeneDx Hereditary Cancer Testing

GeneDx an OPKO Health Company

Account # Account Name

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

OncoGeneDx Panel Components

Breast/Gynecologic Cancers		
J055	Breast Cancer Management Panel (9 genes)	*ATM, BRCA1, BRCA2, CDH1, CHEK2, NBN, PALB2, PTEN, TP53*
B273	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 Cancers		
B274	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*
B522	Lynch/Colorectal High Risk Panel (7 genes)	*APC, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2*
Multiple Cancers		
B275	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*
B751	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*
Specialty Panels		
T830	Hereditary MDS/Leukemia Panel (10 genes)	*ANKRD26, CEBPA, DDX41, ETV6, GATA2, RUNX1, SRP72, TERC, TERT, TP53*
J899	Hereditary Pancreatitis Panel (5 genes)	*CASR, CFTR, CTRC, PRSS1*, SPINK1*
T828	Hyperparathyroidism/Endocrine Tumor Panel (11 genes)	*AIP, APC, CASR, CDC73, CDKN1B, CHEK2, DICER1, MEN1, PRKAR1A, PTEN, RET*
J318	Pediatric Tumor Panel (27 genes)	*ALK, APC, CDC73, DICER1, EPCAM*, MEN1, MLH1, MSH2, MSH6, NF1, NF2, PHOX2B*, PMS2, PRKAR1A, PTCH1, PTEN, RB1, RET*, SMARCA4, SMARCB1, STK11, SUFU, TP53, TSC1, TSC2, VHL, WT1*
Tumor Specific Panels		
T831	Brain Tumor Panel (23 genes)	*APC, CDKN1B, CDKN2A, DICER1, EPCAM, MEN1, MLH1, MSH2, MSH6, NF1, NF2, PMS2, POT1, PTCH1, PTEN, SMARCA4, SMARCB1, SMARCE1, SUFU, TP53, TSC1, TSC2, VHL*
J665	Hereditary Prostate Cancer Panel (16 genes)	*ATM, BRCA1, BRCA2, BRIP1, CHEK2, EPCAM*, HOXB13, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, RAD51C, RAD51D, TP53*
B399	Melanoma Panel (9 genes)	*BAP1, BRCA2, CDK4, CDKN2A, MITF*, POT1, PTEN, RB1, TP53*
B343	Pancreatic Cancer Panel (15 genes)	*APC, ATM, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM*, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, VHL*
B395	PGL/PCC Panel (12 genes)	*FH, MAX, MEN1, NF1, RET*, SDHA*, SDHAF2, SDHB, SDHC, SDHD, TMEM127, VHL*
B394	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), PHOX2B (seq only), PRSS1 (seq only), RET (seq only), SCG5/GREM1 (del/dup only), SDHA (seq only).*

Informed Consent

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 certain changes in DNA affecting the structure or number of chromosomes. Genetic testing is a laboratory test that tries to identify these 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 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.

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 by 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 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.

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, the limitations of genetic testing, as well as information about how specimens and information are stored and used.

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.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

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.

I. Signature:	J. Date:

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