

PATIENT ID/ROOM # SURGICAL ID COMMENTS PATIENT STATUS - ONE MUST BE CHECKED

REFERRING PHYSICIAN DIAGNOSIS DX CODE

PATIENT STATUS - ONE MUST BE CHECKED HOSPITAL INPATIENT HOSPITAL OUTPATIENT

BILLING INFORMATION

BILL TO: CLIENT INSURANCE MEDICARE MEDICAID SUBSCRIBER'S NAME DATE OF BIRTH

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.

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.

PATIENT CLINICAL HISTORY (DETAILED MEDICAL RECORDS MUST BE ATTACHED)

No Personal History of Cancer Breast Cancer(s) Ovarian Cancer(s) Endometrial Cancer(s) Pancreatic Cancer(s) Prostate Cancer Age at Dx: Hematologic Disease Age(s) at Dx: Gastric Cancer(s)/Tumor(s) Colorectal Cancer(s) Polyps Renal Cancer(s)/Tumor(s) Other Cancer(s)/Tumor(s)

FAMILY HISTORY OF CANCER

Table with columns: Relationship, Maternal, Paternal, Cancer Site, Age at Dx

HEREDITARY CANCER TESTS & PANELS

B362-5 BRCA1/BRCA2 Sequencing and Deletion Duplication Analysis B361-7 BRCA1/BRCA2 Ashkenazi Founder Panel J055-5 Breast Cancer High/Moderate Risk Panel B273-4 Breast/Ovarian Cancer Panel J662-8 Breast Cancer Surgical Panel B344-3 Endometrial Cancer Panel B399-7 Familial Cutaneous Malignant Melanoma B275-9 Comprehensive Cancer Panel B751-9 High/Moderate Risk Panel B522-4 Lynch/Colorectal High Risk Panel B274-2 Colorectal Cancer Panel B890-5 Lynch Syndrome Custom Panel B343-5 Pancreatic Cancer Panel J665-1 Hereditary Prostate Cancer Panel B394-8 Renal Cancer Panel B363-3 Rest of Comprehensive Cancer Panel, if subpanel is negative

TARGETED VARIANT TESTING

VARIANT TESTING PROGRAM (Requires lab approval)

1. Reflex to Rest of Comprehensive Cancer Panel, if subpanel is negative, is not available. 2. Lynch Syndrome single gene tests include sequencing and deletion/duplication except for EPCAM which only includes deletion/duplication analysis.

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 High/Moderate Risk Panel (8 genes)

ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, TP53

Breast/Ovarian Cancer Panel (20 genes)

ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM*, FANCC, MLH1, MSH2, MSH6, NBN, PALB2, PMS2, PTEN, RAD51C, RAD51D, TP53, XRCC2

Breast Cancer Surgical Panel (3 genes)

BRCA1, BRCA2, PALB2

Colorectal Cancer Panel (19 genes)

APC, ATM, AXIN2, BMPR1A, CDH1, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SCG5/GREM1*, SMAD4, STK11, TP53

Comprehensive Cancer Panel (32 genes)

APC, ATM, AXIN2, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM*, FANCC, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, POLD1, POLE, PTEN, RAD51C, RAD51D, SCG5/GREM1*, SMAD4, STK11, TP53, VHL, XRCC2

Endometrial Cancer Panel (12 genes)

BRCA1, BRCA2, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, PTEN, TP53

Familial Cutaneous Malignant Melanoma (2 genes)

CDK4, CDKN2A

High/Moderate Risk Panel (23 genes)

APC, ATM, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDKN2A, CHEK2, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PALB2, PMS2, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53, VHL

Lynch/Colorectal High Risk Panel (7 genes)

APC, EPCAM*, MLH1, MSH2, MSH6, MUTYH, PMS2

Pancreatic Cancer Panel (16 genes)

APC, ATM, BRCA1, BRCA2, CDK4, CDKN2A, EPCAM*, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53, VHL, XRCC2

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

This list is intended to assist ordering physicians in providing ICD-10 Diagnostics codes as required by Medicare and other insurers. It includes some commonly found ICD-10 codes. This list was compiled from the ICD-10-CM 2017 AMA manual. A current ICD-10-CM book should be used as complete reference. The ultimate responsibility for correct coding belongs to the ordering physician.

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

Pancreatic Cancer

- Z85.07: Personal history of malignant neoplasm of pancreas

Prostate Cancer

- Z85.46: Personal history of malignant neoplasm of prostate
- Z80.42: Family history of malignant neoplasm of prostate

Renal Cancer

- Z85.51: Personal history of malignant neoplasm, bladder
- V16.52: Family history of malignant neoplasm, bladder

Other

- C54.1: Malignant neoplasm of endometrium
- Z80.42: Family history of malignant neoplasm of prostate
- Other ICD-10 Codes (please specify): _____