XOMEDX*INSIGHTS* TEST REQUISITION FORM

GeneDx an OPKO Health Company

PATIENT INFORMATION

First name | Last name

Sex ◯ Male ◯ Female
Gender identification (optional): _____ | Date of birth (mm/dd/yy)

Ancestry ◯ White/Caucasian ◯ Hispanic ◯ Black/African American
◯ Native American ◯ East Asian ◯ South Asian
◯ Middle Eastern ◯ Ashkenazi Jewish
◯ Other: _____

Email

Address

City | State | Zip code

Primary phone | Is this patient deceased? ◯ Yes ◯ No
Deceased date: _____

SAMPLE INFORMATION

Date sample obtained (mm/dd/yy) | Medical record #

◯ Blood ◯ Buccal swab
◯ Other: _____
◯ DNA: tissue source _____

Patient has had a blood transfusion ◯ Yes ◯ No Date of last transfusion: _____
(2-4 weeks of wait time is required for some testing)

Patient has had an allogenic bone marrow transplant ◯ Yes ◯ No
Fibroblasts are recommended for patients who had an allogenic bone marrow transplant.
See www.genedx.com/specimen-requirements for details.

◯ Treatment-Related **RUSH** Date: _____

ACCOUNT INFORMATION

Account number | **Account name**

Phone | Fax

Address | City

State | Zip code | Country

Ordering provider

Name | Role/Title

Phone (verbal results) | NPI

Email address (for report access)

Reporting Preference: ◯ Portal ◯ Fax ◯ Email ◯ Care Evolve *If unmarked, we will use the account's default preferences or fax to new clients.*

Additional Reporting Providers ◯ Same as ordering provider

Name | Role/Title

Phone | NPI

Email address (for report access)

Additional clinical or laboratory contact (optional)

Name | Email address (for report access)

SEND ADDITIONAL REPORT COPIES TO

Healthcare provider/Acct # | Fax #/Email

PATIENT CONSENT

By signing this form I acknowledge as the patient that I have read the attached informed consent document and that I authorize GeneDx to perform genetic testing as described. I have been informed that GeneDx may contact me or my healthcare provider about research opportunities in the future. More information, including the GeneDx Notice of Privacy Policies, is available on GeneDx's website: www.genedx.com

◯ By checking this box, I confirm that I am a New York state resident, and I give permission for GeneDx to retain any remaining sample longer than 60 days after the completion of testing.

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

◯ Check this box if you do not wish to receive information from genes in the CNS Disorder Opt-Out List.

◯ Check this box if you would like to receive more information about the PeopleSeq study.

_____
Signature of patient (required) **Date**

ICD-10 codes:

Clinical diagnosis: | **Age at initial presentation:**

PATIENT STATUS – ONE MUST BE CHECKED: ◯ **Hospital outpatient** ◯ **Hospital inpatient** **Date of discharge:** _____ ◯ **Not a hospital patient**

PAYMENT OPTIONS

◯ **Patient Bill** | Amount _____

If Patient Bill is selected, I am electing to be treated as a self-pay patient for this testing. I agree that neither GeneDx nor I will submit a claim to my insurance for this testing, if I have insurance. GeneDx will send an invoice to the patient listed above.

◯ **GeneDx Affiliate Code:**

◯ **Institutional Bill**

GeneDx account # | Hospital/Lab name

Place sticker/stamp here

TEST MENU

◯ J775 XomeDx*Insights*

If sending partner in for concurrent testing, please provide the following information:
Partner's Information: ◯ Not available ◯ To be sent within three weeks*

First Name Last Name DOB

***PARTNER'S SAMPLE MUST BE RECEIVED WITHIN 3 WEEKS IF CONCURRENT ANALYSIS IS DESIRED.**
Please submit a separate requisition for partner.

207 Perry Parkway, Gaithersburg, MD 20877 • T: (888) 729-1206 (Toll-Free), (301) 519-2100 • F: (201) 421-2010 • www.genedx.com

CLINICAL INFORMATION

Account #	Account Name

First Name	Last Name	Date of Birth

CLINICAL INFORMATION CAN AID IN THE ACCURATE INTERPRETATION OF RESULTS. PLEASE ATTACH RELEVANT MEDICAL RECORDS. PLEASE CHECK ALL THAT APPLY.

Does the patient have a known or suspected chronic medical condition? ○ No ○ Yes

If yes, please describe: _____

(Note that XomeDx*Insights* is for adults who are generally healthy. Individuals seeking a diagnosis for a current medical condition should consider the XomeDx test.)

Prior genetic testing performed on patient: _____

Personal and/or family history of known genetic condition? ○ No ○ Yes

If Yes, please indicate relationship to patient being testing and diagnosis, including gene mutation if known: _____

_____

PREGNANCY HISTORY

Is the patient/partner currently pregnant? ○ No ○ Yes (If Yes, EDD: _____)

Infertility ○ No ○ Yes

Recurrent pregnancy loss ○ No ○ Yes

Prior intrauterine fetal demise (IUFD) ○ No ○ Yes

Current and/or prior pregnancy with anomalies: ○ No ○ Yes

If Yes, please describe and/or provide diagnosis:

OPTIONAL INFORMATION

Is the patient adopted? ○ No ○ Yes

Does the patient consider themselves to work in health care? ○ No ○ Yes

Additional relevant clinical information: _____

_____

_____

_____

_____
Signature of provider (required) Date

INFORMED CONSENT

Account #	Account Name

First Name	Last Name	Date of Birth

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 complete gene lists, 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.

INFORMED CONSENT

Account #	Account Name

First Name	Last Name	Date of Birth

XomeDx*Insights* Information and Reporting Options

XomeDxInsights can provide information in three different categories: personal health, reproductive risk, and drug metabolism (also known as pharmacogenomic information). As many different genes and conditions are analyzed, this test may reveal unanticipated findings.

1. Personal Health: Reported personal health information includes variants in genes known to cause childhood and/or adult onset disease. This includes variants that significantly increase the risk for cancer, heart disease, and neurological conditions. **You may choose to opt out of personal health information from genes associated with progressive, central nervous system (CNS) diseases such as Parkinson's disease or dementia, for which there may not be currently available treatments, by checking the box below. Please refer to the latest version of the CNS Disorder Opt-Out List on our website for the complete list of genes and associated genetic disorders. If opting out, a list of the genes not analyzed for personal health risk will also be attached to the report.**
2. Reproductive Risk: Reported reproductive risk information includes carrier status for pathogenic and likely pathogenic variants in known recessive and X-linked disease genes. Variants of uncertain significance are reported only if the person's reproductive partner is known to GeneDx to carry a pathogenic or likely pathogenic variant in the same gene. Variants contributing to infertility or other adverse reproductive outcomes will also be reported.
3. Pharmacogenomic (drug metabolism) Information: The pharmacogenomic portion of the test targets known genetic changes associated with the body's response to certain medications that may be prescribed for a variety of clinical indications.

Limitations

- Pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. **The absence of a reportable variant for any particular gene does not mean there are no pathogenic variants in or affecting that gene.**
- Only changes at the sequence level will be included in the report. Larger deletions/duplications, abnormal methylation, repeat expansion variants, or other variants not routinely identified by exome sequencing will not be reported.

OPTIONAL: The Personal Genome Sequencing Outcomes "PeopleSeq" Study

The Personal Genome Sequencing Outcomes Study (PeopleSeq) is one of the first large-scale studies to examine the experiences, attitudes, and outcomes of healthy adults who have pursued personal genomic sequencing. Our hope is that the knowledge gained through this study will play an integral role in shaping the future of genomic sequencing practice and policy.

Several thousand ostensibly healthy individuals in the U.S. have already had whole exome or whole genome sequencing, and several thousands more are projected to have personal genome sequencing in the next few years. While early adopters who seek personal genome sequencing may not be representative of the general population, they can provide unique insight about the individual and societal impact personal genome sequencing may have once such testing becomes widespread. A number of these projects have been organized into the "PeopleSeq Consortium" and piloted a web-based survey instrument to better understand the medical, behavioral and economic impacts of sequencing ostensibly healthy adults.

Participation is completely optional and will not impact test results of XomeDx*Insights*. By agreeing to receive more information about this study, a patient agrees to direct contact from PeopleSeq via email.

○ Yes, you may send me more information about the study.

Patient email (required): _____

○ No, I do not want information about the study.