PHARMACOGENOMICS 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

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 | 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, and to be used as a de-identified sample for test development and improvement, internal validation, quality assurance, and training purposes. Otherwise, New York law requires GeneDx to destroy my sample after 60 days, and it cannot be used for the studies listed above.

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

Signature of patient (required) **Date**

STATEMENT OF MEDICAL NECESSITY

By submission of this test requisition and accompanying sample(s), I: (i) authorize and direct GeneDx to perform the testing indicated; (ii) certify that the person listed as the ordering provider is authorized by law to order the test(s) requested; (iii) the test results will determine my patient's medical management and treatment decisions of this patient's condition on this date of service; (iv) have obtained this patient's and relatives', when applicable, written informed consent to undergo any genetic testing requested.

Signature of provider (required) **Date**

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

PHARMACOGENOMICS TESTING OPTIONS

TEST CODE	TEST NAME	MEDICATION GROUPS/DISORDERS
◯ J909	PharmacoDx (~150 targeted variants)	Antiarrhythmics, Anticoagulants, Antidepressants, Antidiabetics, Antiepileptics, Antihypertensives, Antipsychotics, Antivirals/Antiretrovirals, Benzodiazepines, Chemotherapeutics, Corticosteroids, General Anesthetics, Immunosuppressants, Inhibitors, Muscle Relaxants, NSAIDS, Opioids, Platelet Aggregation, Proton Pump Inhibitors, Statins, Stimulants

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PHARMACOGENOMICS 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 changes in DNA or from changes in 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 diagnostic testing.

GeneDx's PharmacoDx test aids health care providers in the selection of medications that are most likely to be effective and least likely cause side effects. Finding the right drug for patients while trying to manage side effects via a "trial and error method" can be time consuming, expensive, and may result in delayed treatment.

The purpose of this test is to obtain information on predicted drug response to medications based on my genetic makeup. 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.

What could I learn from this genetic test?

The test results will include:

- Predicted response to certain medications, based on my genetic makeup
- Prescribing recommendations based on my predicted response to a medication
- A summary of the evidence behind the prescribing recommendations
- My genotype for each sequenced variant

What are the risks and limitations of this genetic 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 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.
- Occasionally, an additional sample may be needed if the initial specimen is not adequate.

Patient Confidentiality and Genetic Counseling

It is recommended that I consult with a physician, pharmacist, genetic counselor, and/or other health care professional before and after having this 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} 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 heath 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. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. No tests other than those authorized shall be performed on the biological sample.

Database Participation

De-identified heath 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 database, 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 healthcare 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 {my/my child} or {my/my child's} heirs.