Informed Consent for Pharmacogenomics Testing

This Informed Consent reviews the benefits, risks, and limitations of undergoing pharmacogenomics (PGx) testing provided through AccessDx Laboratory, and its contracted and/or affiliated companies ("AccessDx Lab") as indicated on the order form ("Test"). It also explains how your information and sample will be used after the Test is performed. In order for AccessDx to process your sample and provide you and your healthcare provider with your results, you must confirm by signing below or otherwise acknowledging that you have read, understood, and agreed to this Informed Consent. Prior to signing this Informed Consent, you may wish to speak with your ordering or referring healthcare provider, as well as a genetic counselor, about this Test.

ABOUT THIS TEST

A pharmacogenetics test analyzes small differences in your genetic material (in the DNA), which are called "gene variants" known to impact certain medications. For example, a gene variant may influence how a certain medication is metabolized by your body, or if there is an increased risk for toxicity, among other characteristics. This Test is carried out using molecular diagnostic methods and can then detect whether a particular gene variant is present or not.

Your results may show how the analyzed genes may affect how you process or respond to certain medications. This information may help your provider make more informed therapeutic decisions along with other assessed factors.

This test only analyzes a subset of genes that may affect how you process and respond to certain medications. This Test does **not** include a broad genetic screening. However, the test report may also include results related to inherited disease risk.

If a list of current medications are submitted with the Test, your provider may also be provided with information about specific potential drug–gene interactions or drug–drug interactions related to that submitted list. Your authorized healthcare provider(s) may also utilize clinical decision support tools that provide references to drug or dose changes that may be advisable based on the Test result and current medications.

LABORATORY INFORMATION

AccessDx Lab operates a clinical testing laboratory that is accredited by a College of American Pathologists (CAP) and meets the certification requirements for high-complexity testing established under the Clinical Laboratory Improvement Amendments (CLIA) as well as the New York State Department of Health (NYSDOH). For the most up to date information about AccessDx's genetic testing options, please ask your provider or visit the AccessDx Lab website (www.accessdxlab.com).

SAMPLE COLLECTION AND TESTING

An authorized provider will review your information, and, upon their determination that this Test is appropriate for you, they will order the Test for you. You will be asked to provide a sample in accordance with AccessDx's collection procedures, and to provide your Personal and Family Health Information (PFHI). Your sample and PFHI will then be transferred to AccessDx's laboratory in Texas, USA, for analysis. In order for the Test to perform as intended, you must provide accurate and correct information. If another person is submitting your PFHI or related information on your behalf, by signing this Informed Consent, you represent and warrant that such person is authorized to provide such information and that all such information is accurate and correct. Upon successful completion of the Test, you hereby request that a report be made available to you and your ordering provider for review. We recommend that you further consult with a genetic counselor or your healthcare provider about your results.

TEST RESULTS AND INTERPRETATION

The specific list of reportable gene variants will be available in a report that will be provided to your ordering physician. Your physician will evaluate and discuss with you the results of your pharmacogenomics genetic Test to determine the best course of action.

Knowledge of genetic information improves continuously, so new information may become available in the future that could impact the interpretation of your Test results. AccessDx may notify you or your provider of such clinical updates to be reviewed in consultation with your ordering healthcare provider.

Disease RISKS and Other Implications for Genes Tested

Some tested genes have inherited disease risk implications, such as APOE, which can show an elevated, though not definite, risk of developing Alzheimer's and can be associated with Type III hyperlipoproteinemia, and F2/F5 for hereditary thrombophilia, which increases clotting risk. Some results may be designated for informational purposes only, as evidence is still developing and may have implications in the future that are not currently fully known. The U.S. Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, certain exceptions apply, and you are encouraged to review GINA and related laws and regulations, as well as state-specific laws governing prohibition of discrimination in life insurance, disability insurance, or long-term care insurance. Be sure to discuss any concerns with your ordering healthcare provider prior to taking the Test.

RISKS AND LIMITATIONS

The Test is a genetic test that may cause you to discover sensitive information about your health, specifically related to your ability to metabolize or respond to certain medications.

This Test cannot analyze all genetic causes for variability in medication response, nor is there any guarantee that a) the results will be directly applicable to you or b) will the results directly lead to a specific health outcome. This Test does not provide information regarding response to all medications that are currently prescribed in the U.S. nor dietary and herbal supplements.

Test results and clinical interpretation may be inaccurate for individuals who have undergone or are receiving non-autologous blood transfusions, tissue, and/or organ transplant therapies. Test results should always be interpreted in the context of other factors which may affect your response to medications. Examples of such factors include comedications, smoking status, diet, and medical conditions. The Test may yield uninterpretable results for the following reasons: sample contamination, insufficient sample collection, incomplete knowledge of the available genetic markers, or technical reasons.

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Analysis of results is based on currently available information in scientific literature and databases, as well as laboratory informatics and algorithms that may be subject to change. New information may replace or add to the information that was used to analyze your results. You understand and agree that our laboratory may, at its sole discretion, amend or modify your Test report. AccessDx will attempt to notify you of any material amendments or modifications.

BILLING AND REIMBURSEMENT

AccessDx Lab and or/its designees shall bill in accordance with all applicable regulations and agreements. Unless designated as a self-pay test, you hereby agree to appoint AccessDx and/or its designees the power to a) file claims and related activities; b) pursue and collect payment of any and all applicable proceeds from medical benefits (including private insurers, Medicaid and Medicare) and any related appeals; and c) convey all rights in connection with a claim, cause of action, reimbursement, appeal or rights to claims on your behalf; to the fullest extent permissible under the law. In doing so, AccessDx Lab and/or its designees shall have the right to obtain and release applicable medical records, supporting detail, and insurance information as necessary to process claims and related activities.

PRIVACY AND DATA SECURITY

Your privacy is AccessDx Lab's priority. Details about AccessDx Lab's policies governing patient privacy and health information, including patient rights regarding such information, can be found at www.accessdxlab.com, or will be made available to you upon request by emailing info@accessdxlab.com. AccessDx Lab complies with the applicable requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (as amended) regarding Personally Identifiable Information (PII). AccessDx Lab implements certain physical, managerial, and technical safeguards that are designed to protect the integrity and security of your PII. AccessDx Lab cannot, however, guarantee the security of any information you transmit to AccessDx Lab or store on the AccessDx Lab website, and you do so at your own risk. You agree that AccessDx Lab is not liable for the unauthorized release of your PII, results, or medical information unless such release was the result of gross negligence or willful misconduct on the part of AccessDx Lab.

In the event of a data breach, we intend to comply with all federal and state reporting requirements. If you are domiciled outside of the US, you should consult with your physician because genetic testing may be subject to specific regulatory constraints, or be prohibited, in certain countries. By agreeing to this Informed Consent, you agree that the laws and regulations of the U.S. regarding data privacy and collection, use, processing, and storage of patient information shall govern AccessDx's performance of the Test and handling of your sample and information, even if they may differ from those of your country of residence. You further agree that by providing your sample, you are not violating any export ban or other legal restrictions in your country.

USE OF INFORMATION AND SAMPLES

After your personal information is removed, the data/specimen may be stored indefinitely to be used for quality assurance, studies, research and development or medical education (New York State residents: sample shall be destroyed within 60 days of collection). You can withdraw consent at any time and have your sample destroyed by contacting AccessDx Lab at 346-571-6627.

AccessDx Lab may contact you to solicit feedback (including through optional surveys, interviews, or testimonials), and describe new tests and services developed by AccessDx Lab and its collaborators that may be of interest to you. You can opt out of such communications at any time.

Patient Authorization

I have read and fully understand the above and give my consent to the **performance of this pharmacogenomics test** and accept the consequences of this decision. My healthcare provider has explained the effectiveness and limitations of the test, and I understand that the test results may not provide definitive conclusions regarding current or future medications.

Patient Name: _____ Patient Signature: _____

Patient's Legal Guardian Signature: _____ Relationship to Patient: _____

Date: _____

Referring Physician

I confirm that I have provided appropriate consultation to the above-named person regarding the planned test and answered this person's questions. I confirm that the patient has voluntarily decided to have this test performed by AccessDx Lab.

Full name: _____ NPI#: _____

Signature: _____ Date: _____