Informed Consent for DNA Testing

Patient's Name _____ **Date of Birth** _____ /_____ /_____ **Gender** ☐ **Male** ☐ **Female**

What is Drug Sensitivity Testing? The Cytochrome P450 family of genes plays a key role in the metabolism of many drugs. The Cytochrome P450 tests can detect small differences (variants) in your DNA, which can affect the way drugs work and are broken down in your body. These tests can help to detect potential side effects from medications.

What are the Factor II, Factor V, and MTHFR genes? Factor II, Factor V, and MTHFR are genes known to play a role in the development of serious blood clots (thrombosis). Changes (mutations) in any of these genes can increase your risk of blood clots.

What is Cystic Fibrosis? Cystic Fibrosis (CF) is an inherited disease that results from mutations in a gene called, "CFTR". Although severity varies, affected patients may have both lung disease and impaired digestion, as well as problems in other organ systems.

How can the testing help me and what will the test(s) show? Your doctor can use the information derived from these tests to decide on your treatment plan and more effectively prescribe medications for you.

Test Ordered	Description of the test and meaning of the results
Cytochrome P450 2C19	Detects variants in genes that may affect an individual's response to 5-10% of medications.
Cytochrome P450 2C9 VKORC1	Detects variants in genes that may affect an individual's response to ~15% of all medications.
Cytochrome P450 2D6	Detects variants in genes that may affect an individual's response to ~25% of all medications.
Cytochrome P450 3A4 & 3A5	Detects variants in genes that may affect an individual's response to approximately 40-45% of all medications.
Factor II Prothrombin Mutation Testing	Detects a genetic change in the Factor II (Prothrombin) gene. The risk is approximately 3-10 times higher in individuals who have one copy of the genetic variant.
Factor V Leiden Mutation Testing	Detects a genetic change in the Factor V gene called Factor V Leiden. Individuals who have this variant are at an increased risk of blood clot formation. This risk is approximately 2-10 times higher in individuals who have one copy of the genetic variant, and greater than 10 times higher for individuals who carry two copies of the genetic variant.
MTHFR Mutation Testing	Detects two genetic changes in the MTHFR gene. Individuals who are found to have two mutations are at an increased risk for serious blood clot formation. Individuals who have only one or no copies of either genetic change in the MTHFR gene may still be at increased risk.
Cystic Fibrosis Testing	Detects 60 genetic changes in the CFTR gene. Everyone has two copies of this CFTR gene; an individual may have two normal copies (unaffected non-carrier), two abnormal copies (affected with CF), or one normal and one abnormal (CF carrier).

What is required to perform this test? The DNA tests in the panel above use a cheek (buccal) swab to obtain enough cells to get a genetic profile. Special swabs (provided by GENETWORx) are used to rub the inside of your cheek.

What are the limitations of the test(s)? The Drug Sensitivity Testing does not take into account non-genetic factors that can affect medication dosing. The results should not be used as the sole means for clinical diagnosis or patient management decisions. If mutations are not found during CF Testing, it does not mean that the risk of carrying or developing CF is not present. It simply means that these specific mutations have not been found, although other mutations may be present. Where possible and appropriate, negative results will be used to calculate revised carrier risks.

Is there a cost for this test(s)? GENETWORx will bill your health insurance for the cost of testing. You will be responsible for any co-pay, co-insurance, or deductibles associated with your plan. If you choose to self-pay for the testing, you will receive a bill from GENETWORx for the self-pay fee and will be responsible for that amount. In the case of financial hardship, GENETWORx can work with you to establish a payment plan.

How will I get the results of my testing? Because of the complexity of the test information, GENETWORx will release the results to the ordering health care provider or those entitled to them by state and local laws. Genetic counseling is recommended prior to, as well as following, genetic testing. Your results may suggest that further testing or doctor consults are needed.

Can this test help my family? If you are found to have one or more of the genetic variants being tested, your family members may as well. You may wish to talk to them about your test results so they can consider whether testing is appropriate for them.

What will happen to my DNA once the test is complete? No additional tests will be performed on this sample. Following testing the sample will be destroyed within one month. The results of your testing may be used for internal validation studies or in research. Your results will only be used after all identifiers have been removed.

I request and authorize GENETWORx to perform the genetic tests selected and described above on my DNA sample.

My signature constitutes my acknowledgement that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health care professional. By signing this consent form, I also agree to allow GENETWORx to request and use my prescription medication history from my other healthcare providers and/or third party pharmacy benefit payers for medication review. This medication review will allow GENETWORx to provide information to my physician about the effectiveness of my current medications based on my test results.

Parent/Guardian Signature _____ **Date** ____ /____ /____

Healthcare Professional:

I have explained DNA testing and its limitations to the patient or legal guardian and answered all questions.

Printed Name of Healthcare Professional _____ **Date** ____ /____ /____

Signature _____ **Phone Number** _____