Informed Consent for TheraGuide 5-FU™

NOTE: Some states may have additional requirements for informed consent.

Introduction. This form describes the benefits, risks, and limitations of genetic testing to determine risk for developing toxicity to the family of drugs related to *5-fluorouracil (5-FU*). Examples of these drugs include 5-FU, and Xeloda (capecitabine). This is a voluntary test and you may wish to seek genetic counseling prior to signing this form. Read this form carefully before making your decision about testing.

Purpose. This test analyzes a specific gene or gene(s) for genetic changes called variations. The genes analyzed are associated with 5-FU toxicity. This test will help determine if a person has a significantly increased risk of developing toxicity to 5-FU related therapies.

Test Procedure. Usually, a tube(s) of your blood will be drawn and sent to Myriad Genetic Laboratories, Inc. ("Myriad"). In some instances however, other types of cells will be submitted. Myriad will analyze the DNA of a specific gene(s) to look for variations associated with 5-FU toxicity. Additional information about testing can be found on Myriad's patient website at http://www.myriadtests.com.

Test Results and Interpretation. Your results should be evaluated in the context of personal health history, the results of physical examination, laboratory and hospital tests, and the clinical impression of your healthcare provider. Possible result outcomes include the following;

- High Risk – A variant that is associated with an increased risk for 5-FU toxicity was identified. Knowing this information may help you and your doctor make more informed choices about your health care.
- Low Risk – A variant was identified and in previous studies, patients with this genotype experienced no increased risk of 5-FU toxicity compared to the general population. You may still be at greater than average risk due to a genetic predisposition that cannot be detected by this test, either in the gene(s) that were tested, or in another gene linked to 5-FU toxicity.
- Indeterminate– A genetic change was detected but it is not known if this change is linked to 5-FU toxicity. You still have at least the same risk of toxicity as the general population. In addition, you may still be at greater than average risk due to this change or a genetic predisposition that cannot be detected by this test, either in the gene(s) that were tested or in another gene linked to 5-FU toxicity.

You may wish to share your test results with blood relatives so that they may understand their risks in case they are considered for 5-FU related therapy in the future.

Myriad keeps test results confidential and is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) regulations. Myriad will only release your test results to your healthcare provider, his or her designee, or to another healthcare provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required by federal and state laws.

Benefits. Your genetic test results may help you and your doctor make more informed choices about your health care.

Risks. Genetic testing requires DNA most often provided from a sample of blood. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and rarely infection.

Limitations. This test analyzes only certain important gene(s) associated with specific 5-FU toxicity. Genetic testing clarifies toxicity risks for only the related genes analyzed.

If you are found to have a variant that predisposes you to 5-FU toxicity, there may be differing opinions among physicians about the best steps to take. Your medical care is best determined by you in consultation with your healthcare provider.

Analysis for a specific indeterminate result may be considered investigational and may not provide additional toxicity information to blood relatives.

For the State of New York. The State of New York requires that samples be destroyed at the end of the testing process or not more than sixty days after the sample was taken.

Financial Responsibility. Genetic testing of appropriate individuals is typically reimbursed by health insurance or covered by HMOs. You are responsible for any cost of the genetic test not reimbursed by insurance.

Future Correspondence. Due to the dynamics of this field, there continues to be new information and data. It is recommended that you keep in contact with your healthcare provider, at least annually, to learn of any new developments in the genetics of 5-FU toxicity.

Patient Consent Statement.
By signing below, I, the patient having the test performed, acknowledge that:

- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and limitations of the genetic test(s) to be performed as indicated on the associated test request form or follow-on tests ordered by my healthcare provider.
- I have read this document in its entirety and realize I may retain a copy for my records.
- I have discussed with the medical practitioner ordering this test the reliability of positive or negative test results and the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease.
- I have been informed about the availability and importance of genetic counseling and provided with written information identifying an appropriate healthcare provider from whom I might obtain such counseling.
- I consent to being tested for predisposition to 5-FU toxicity and I will discuss the results and appropriate medical management with my healthcare provider/genetic counselor.

_____	_____
Name of patient having testing (please print)	Date of Birth
_____	_____
Signature of patient (or legal guardian*)	Date

*Genetic testing on children under the age of 18 requires that the ordering healthcare provider obtain an informed consent from a parent or legal guardian. If legal guardian, specify relationship to the patient: _____