

DPD-5FU GenotypR™ INFORMED CONSENT

1. What is DPD-5FU Genotyping? The assay detects the dihydropyrimidine dehydrogenase (DPD) gene mutation IVS14+1 G>A. This gene produces an enzyme that helps the body process a widely used chemotherapeutic drug, 5-fluorouracil (5-FU).

2. What is the purpose of this test and what are its limitations? Dihydropyrimidine dehydrogenase (DPD) is the initial and rate-limiting enzyme in the catabolism of 5-fluorouracil (5-FU). Patients with a partial deficiency of this enzyme due to mutation are at risk from developing severe 5-FU-associated toxicity. Identification of the DPD gene mutation, IVS14+1 G>A, can help doctors predict which cancer patients are likely to experience severe side effects from the chemotherapy drug 5-FU.

Everyone has two copies of the DPD gene; an individual may have two normal copies (unaffected), two abnormal copies (homozygous), or one normal and one abnormal (heterozygous). It is recommended that screening for IVS14+1 G>A mutation be performed prior to start of 5-FU therapy. Heterozygotes should receive only a limited dose of 5-FU, while homozygotes, who are at high risk to develop severe complications, should be treated with alternative therapeutic drugs.

This assay is not a substitute for a physician's judgment and clinical experience. Other important clinical factors that may affect dosing should be considered.

3. What is required to perform this test? You will be asked to provide 5 mL of blood, which is equal to about one tablespoon. DNA will be extracted from this blood sample and tested. The only discomfort that you may feel is the stick of the needle in your arm. You may also experience a small bruise at the site of the needle puncture. You will also be asked to provide information regarding your medical history, which is necessary for proper interpretation of your test result. In the unlikely event that you should be injured in the course of being tested, your physician will provide any necessary medical care. However, you would be expected to bear the cost of such medical care. Compensation will not be provided in the event of any injury.

4. Is there a cost for this test? This is a routine clinical laboratory test and the results may aid in your diagnosis; thus, you or your health insurer will be billed for this procedure.

5. What will happen to the DNA once the test is complete? The original blood sample will be discarded at the end of the testing process or stored not more than 60 days. The DNA will be retained for a minimum of 6 months. In some circumstances, a patient's DNA may be used anonymously as a negative or positive control sample in future testing, but, in this circumstance, all identifiers will be removed prior to re-testing and the DNA sample and results obtained will remain anonymous.

I understand and agree that my DNA remaining after testing may be stored for up to 6 months should additional testing be required. *Please initial.*

6. How will I obtain results from this test? DNA testing and interpretation of results are complex. The information from this test will be provided in the form of a written report to your physician who will inform you of the results. The laboratory will not provide results directly to patients. Your physician may suggest genetic counseling prior to performing this test or if your results are abnormal. Consult with your physician about the availability of genetic counseling in your area. To the extent permitted by law, all of your laboratory records and results are confidential and shall not be disclosed without your written authorization.

Patient Attestation of Informed Consent:

My signature below indicates that I have received information about this test, **DPD-5FU GenotypR™**, and that I have read and understood the material in this document. I have been given a full opportunity to ask questions that I may have about the testing procedure and related issues. I agree to undergo this testing.

Patient Signature

Date

Signature of Parent/Guardian if Patient is a minor

Print Name of Parent/Guardian

For the Physician:

As the referring physician, I understand the benefits and limitations of this study and have requested that the above-named patient be tested. I attest to the fact that I have provided the patient with the information contained above and fully answered any questions. I believe that the patient understands the information and is voluntarily signing this informed consent.

Signature of Physician/Health Care Professional

Print Name of Physician/Health Care Professional

