

Informed Consent for TPMT Enzyme Activity Test

Patient's Name: _____

Patient's ID Number: _____

Patient's Date of Birth: _____

Ordering Provider's Name: _____

Physician/Health Care Provider: Please ask your patient or his/her legal guardian to read and complete this consent form for biochemical genetic testing. Endocrine Sciences, an entity of the LabCorp Specialty Testing Group, will perform this biochemical genetic testing only when this form has been completed.

I have counseled Mr/Ms _____ regarding this test and have obtained his/her or the legal guardian's informed consent for the TPMT enzyme activity test.

I understand the following and freely give my consent to this biochemical genetic testing.

- **Reason for Medical Referral** — Thiopurine drugs (eg, azathioprine, 6-mercaptopurine, 6-thioguanine) are used to treat acute lymphoblastic leukemia and autoimmune diseases and to prevent post-transplant organ rejection. The TPMT enzyme, thiopurine S-methyltransferase, prevents a toxic buildup of the active forms of these drugs. Variants in the TPMT gene that lead to low enzyme activity can lead to an increased risk of thiopurine toxicity. Because of the potentially severe bone marrow toxicity that can occur even with standard thiopurine dosages in patients with TPMT enzyme deficiency, testing for the TPMT enzyme activity is recommended before beginning treatment. The information can be used to adjust the drug dosage or can suggest the use of an alternative treatment.
- **Description of the test** — A blood sample is taken from you. This may cause you some pain and discomfort. The blood sample is sent to the laboratory where red blood cells, which contain the enzyme, are isolated. The enzyme activity is measured to see if it is normal, or has low or high activity.
- **Limitations of the test** — This test measures the activity of the TPMT enzyme in your blood at the time your blood was taken. If you have recently received a transfusion of red blood cells that were not yours, the results will not reflect your normal activity. The test is also sensitive to environmental factors and drug interactions. Intermediate and low normal activities can be difficult to distinguish.
- **Meaning of a positive test result** — Reduced TPMT enzyme activity may indicate the presence of a clinically important variation in your TPMT gene. If you have an intermediate level of TPMT enzyme activity, you have an increased risk for thiopurine toxicity and a lower drug dosage is recommended. If you have a very low level of TPMT enzyme activity, your physician may consider an alternative drug or a drastic dose reduction. If you have a higher than normal level of TPMT enzyme activity, you may metabolize the drug at a higher rate.

- **Meaning of a negative test result** — A normal test result indicates that no clinically important reduction of activity was detected in your sample. A negative result does not guarantee that you will not develop any toxic effects associated with thiopurine drugs, as other genes and non-genetic factors are not evaluated by this test. Therapeutic drug monitoring or the TPMT genetic test is recommended.
- **Confidentiality and distribution of your test result** — Stringent laboratory processes are in place to keep your personal information and your TPMT enzyme activity test results strictly confidential. Only the TPMT enzyme activity test will be performed on your specimen. The TPMT enzyme activity test results will be released only to your physician or to the referring institution.
- **Genetic counseling, further testing, additional physician consults** — As a patient you may seek the advice of a physician and/or professional genetic counselor prior to signing this form. Once your test has been completed, further consultation with your physician and/or genetic counselor may be warranted.
- **Specimen retention** — Endocrine Sciences may retain your blood specimens for up to 60 days after completion of testing. At the end of this time, the specimens will be destroyed.

I have read the information provided above and I have discussed the TPMT enzyme activity test with my physician/health care provider. I have had the opportunity to ask any questions regarding this test, and all questions have been answered to my satisfaction. In no way does this waive my legal rights or release anyone from their legal and professional responsibilities.

Signature of Patient or
Patient's Authorized Representative

Date

Relationship to Patient
(If the Patient's Authorized Representative)

Date

Signature of Ordering Health Care Provider

Date



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