

Physician/Health Care Provider: Please ask your patient or his/her legal guardian to read and complete this consent form for genetic testing.

Patient Information Regarding the *COMT* Genetic Test

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

Reason for Medical Referral—The *COMT* Genetic Test assesses the genotype for six variants that are associated with reduced activity of the encoded enzyme catechol-*O*-methyltransferase. *COMT* catalyzes the *O*-methylation and inactivation of catecholamine neurotransmitters (epinephrine, norepinephrine, and dopamine), catechol hormones (hydroxylated estradiol), and neuroactive drugs (eg, L-DOPA). These *COMT* variants are associated with disease risk or drug responsiveness for improved pharmaceutical treatment (eg, early vs. late Parkinson's disease, schizophrenia, chronic pain conditions). The test can provide information related to *COMT*'s role in cognition and behavioral modification (eg, smoking cessation, modafinil responsiveness in sleep deprivation). Literature sources suggest other potential roles for *COMT* genotyping (eg, to characterize susceptibility alleles for breast cancer risk when taking hormone replacement therapy).

Description of the test—A blood sample is taken from you. This may cause you some pain and discomfort. Alternatively you may submit a saliva or buccal specimen. The sample is sent to the laboratory where DNA is purified. Your DNA is analyzed to look for variants in selected regions of the *COMT* gene.

Limitations of the test—This test analyzes selected regions of the *COMT* gene. Because all regions are not tested, the possibility cannot be ruled out that you have a *COMT* gene mutation in a region not analyzed. You could also have a rare variant that may interfere with the assay. Donor DNA from transplants and recent transfusions can lead to inaccurate results. Some of the variants produce their effect when they occur on the same gene copy. The arrangement of the variants on the two gene copies is inferred based on our validation studies.

Meaning of a positive test result—A positive test result indicates the presence of at least one clinically important variation in your *COMT* gene. *COMT* plays many roles in the body, and variants with low or normal activity can have opposite effects on different systems. They can be beneficial or detrimental depending on the clinical indication for testing.

Meaning of a negative test result—A negative test result indicates that no clinically important variation was detected in the targeted regions of the *COMT* gene. This will be reported as normal *COMT* metabolic activity. A negative test result does not rule out the possibility of an undetected variant in a region of the *COMT* gene not analyzed by this test. A negative result does not guarantee that you will not develop any toxic effects associated with *COMT*-metabolized drugs, as other genes and non-genetic factors are not evaluated by this test.

Confidentiality and distribution of your test result—Stringent laboratory processes are in place to keep your personal information and your *COMT* Genetic Test results strictly confidential. Only the *COMT* Genetic Test will be performed on your specimen. The *COMT* Genetic 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 and/or DNA specimens for up to 60 days after completion of testing. At the end of this time, the specimens will be destroyed unless you specify that we may store the DNA specimen for a defined period of time to be used for research, development, and/or quality control purposes. All means of identifying the DNA specimen will be removed so that it will not be possible to identify the source of the DNA. If you want us to store your DNA specimen beyond 60 days after completion of ordered testing and agree to having your leftover specimen used for research, development, and/or quality control purposes, please indicate so by checking the box below. There will be no compensation if any invention results from this research and development.

I agree to allow my DNA specimen to be used for research, development, and/or quality control purposes. I understand that all means of identifying the specimen as belonging to me will be removed before it is used for such purposes. The sample will be discarded after 10 years.

Patient Signature—I have read the information provided above and I have discussed the *COMT* Genetic 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 legal guardian: _____ Date: _____

Signature of health care provider: _____ Date: _____