

AmpliChip CYP450 Test INFORMED CONSENT

1. What is AmpliChip CYP450 Genotyping? CYP450 is an abbreviation for Cytochrome P450. "Cytochromes" are enzymatic proteins produced by a group of CYP450 genes in liver cells that are responsible for most drug metabolism in your body. Two of the major CYP450 genes are CYP2D6 and CYP 2C19. The AmpliChip™ is an FDA-approved, proprietary method used to look for multiple common gene variations or 'mutations' that are found in CYP2D6 and CYP 2C19 genes.

2. What is the purpose of this test and what are its limitations? The CYP2D6 enzyme is responsible for metabolizing about 20% of therapeutic drugs including anti-arrhythmics, anti-depressants, anti-psychotics, beta-blockers, neuroleptic, and opioid agents. The CYP2C19 enzyme is responsible for metabolizing other classes of therapeutic drugs such as anticonvulsants, proton pump inhibitors, benzodiazepines and antimalarial medications. The AmpliChip™ CYP450 test indicates the relative ability of individuals to metabolize about 25% of all prescribed medications. The test identifies those patients considered 'intermediate metabolizers' or 'poor metabolizers' who might experience toxic effects of overmedication while taking a standard dose. These patients are likely to benefit from smaller doses of therapeutic medication. The test also identifies those patients who would be considered 'ultrarapid metabolizers' who might not respond to a standard dose of medication. These patients metabolize certain drugs so quickly that the blood concentration of the medication never reaches optimum therapeutic levels needed to achieve the desired effect. Hence, these patients are likely to benefit from increased doses of therapeutic medication. Patients identified as 'extensive metabolizers' are considered able to properly metabolize certain therapeutic drugs given within a standard dosing schedule. They would have an expected response to medication similar to that of the majority of people within a give population. Due to the impact of these genetic variations or 'polymorphisms' upon the patient's response to a variety of medications, distinct CYP2D6 and CYP2C19 genotype-based dose recommendations have been proposed to improve patient outcomes. The AmpliChip™ CYP450 test identifies the most common variants of the two genes, but is not designed to identify some rare mutations which may also affect therapeutic drug metabolism.

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. 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, **AmpliChip CYP450 Test** 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