

**Specific Test(s) Ordered and Information** Refer to test requisition for tests ordered:

Specific Test(s) Ordered (refer to test requisition)	What is the purpose of this test and what are its limitations?
<p><b>Cytochrome P450 2D6 (includes Tamoxitest)</b> This test detects common mutations that are found in the cytochrome P450 2D6 (CYP2D6) gene.</p>	<p>The cytochrome P450 2D6 gene codes for an enzyme that metabolizes approximately one-fourth of all drugs in current clinical use, including selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), beta-blockers, opiates, neuroleptics, antiarrhythmics, tamoxifen, and a variety of toxic plant substances. The test identifies whether an individual is a CYP2D6 ultra-rapid, normal, intermediate, or poor metabolizer. If no genetic variants are detected, the individual is a normal metabolizer and can be administered drugs following the recommended dosing guidelines. If genetic variants are detected, the individual is classified as a poor, intermediate, or ultra-rapid metabolizer. These genetic variations may affect drug metabolism rates and half-life as well as the drug dose requirement. The test is not designed to identify certain rare genetic variants.</p>
<p><b>Cytochrome P450 2C9 with VKORC1</b> This test detects common mutations that are found in the cytochrome P450 2C9 (CYP2C9) gene and one common mutation in the VKORC1 gene.</p>	<p>The cytochrome P450 2C9 gene codes for an enzyme that metabolizes approximately 16% of drugs in current clinical use, including angiotensin II blockers, nonsteroidal anti-inflammatory drugs, alkylating anticancer prodrugs, sulfonyleureas, some antidepressants, tolbutamide, and phenytoin. CYP2C9 is tested with VKORC1 (-1639G&gt;A) because they both affect the metabolism of, and response to, warfarin. The CYP2C9 test identifies whether an individual is a normal, intermediate, or poor metabolizer of CYP2C9. The VKORC1 (-1639G&gt;A) test identifies how sensitive an individual is to warfarin: low sensitivity (GG), high sensitivity (AA), or intermediate sensitivity (GA). If no genetic variants are detected for CYP2C9 and VKORC1 (-1639G&gt;A) is GG, the individual is a normal metabolizer and can be administered drugs following the recommended dosing guidelines. If genetic variants are detected, the individual is classified as a poor or intermediate metabolizer with either low, intermediate or high sensitivity to warfarin. These genetic variations may affect drug metabolism rates and half-life as well as the drug dose requirement. The results from this test will help the physician select a more appropriate target dose. The test is not designed to identify certain rare genetic variants.</p>
<p><b>Cytochrome P450 2C19 (includes Plavix)</b> This test detects common mutations that are found in the cytochrome P450 2C19 (CYP2C19) gene.</p>	<p>The cytochrome P450 2C19 gene codes for an enzyme that metabolizes approximately 5-10% of all drugs in current clinical use, including antidepressants, barbiturates, proton pump inhibitors, antimalarial and antitumor drugs, and Plavix. The test identifies whether an individual is a CYP2C19 normal, intermediate, or poor metabolizer. If no genetic variants are detected, the individual is a normal metabolizer and can be administered drugs following the recommended dosing guidelines. If genetic variants are detected, the individual is classified as a poor or intermediate metabolizer. These genetic variations may affect drug metabolism rates and half-life as well as the drug dose requirement. The test is not designed to identify certain rare genetic variants.</p>

**TURN OVER FOR REQUIRED PATIENT SIGNATURE**

**Information Applying to All Tests**

**What is required to perform this test?**

Samples can be collected in one of two ways:

- **Blood:** You will be asked to provide 5-10 mL of blood, which is equal to about one to two tablespoons. 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. In the unlikely event that you should be injured in the course of having your blood drawn, 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.
- **Buccal:** Special swabs are provided that are rubbed inside your cheek. You should not eat or drink anything except water for thirty minutes prior to the collection. If you do not swab properly, there may not be enough DNA collected, in which case the specimens will be rejected and need to be recollected.

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

**What will happen to the DNA once the test is complete?** No tests other than those authorized (DNA Drug Sensitivity Tests marked) shall be performed on the biological sample. The sample shall be destroyed sixty days after the collection unless patient initials below to provide permission to store longer, should additional testing be required (sign below).

**How will I obtain results from this test?** DNA testing and the interpretation of results are complex. Results will be mailed to your healthcare provider(s). Additional copies may be requested. Your healthcare provider will contact you to review the results. Genelex includes 90-days access to GeneMedRx drug and gene interaction software with each test so healthcare providers can see the effect of genetics on medications, herbals, and over-the-counter medicines. Patients may have genetic counseling prior to signing the consent form. Additional genetic counseling, physician consults, and/or additional testing is available and may be needed. Genetic testing is complex and these tests have not been designed to identify certain rare genetic variants. These tests have been validated by Genelex Corporation. As with all laboratory testing, there is a possibility of error. Genelex Corporation is certified by the Clinical Laboratory Improvement Amendments (CLIA No. 50D0980559), and as Washington State Medical Test Site No. MTS-39190 is qualified to perform high-complexity clinical testing. 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**

**PATIENT:** My signature below indicates that I have received information about the tested specified in the table above 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. I agree that my test results can be sent to the ordering physician.

\_\_\_\_\_  
Signature of Patient or Parent/Guardian if Patient is a minor

\_\_\_\_\_  
Print Name

**Patient Initial** I agree to have my sample retained for six months should additional testing be required.

**PHYSICIAN:** Check informed consent box on test requisition