



# Laboratory Dimensions

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## **SANFORD LABORATORIES PARTNERS WITH SANFORD IMAGENETICS TO OFFER PHARMACOGENETIC TESTING**

### **Disease Overview**

The manner in which a patient processes and responds to medications is influenced by the individual's genetic variation. Pharmacogenetics (PGx) is the study of these gene variants related to a body's response to and interaction with many common prescription and over-the-counter medications. These gene variants are associated with a predicted drug response or drug disposition which may predispose a patient to risk of drug-related toxicity or lack of therapeutic benefit.

Genotyping identifies known gene changes (variants) that affect an individual's metabolism. This information can help to determine the optimal therapy and dosing in order to avoid ineffectiveness or intolerance for drugs in some individuals.

The goal of the PGx panel is to reduce the number of adverse drug reactions and identify non-responders who may benefit from a different medication or dosage, thus providing prophylactic guidance for drug and dose selection.

### **Uses for Test**





- To estimate the risk of abnormal drug metabolism due to specific gene variants involving multiple drug classes; such as statins, specific psychologic and pain medications, and anti-coagulants.
- To attempt to identify the cause of personal or family history of an adverse drug reaction or therapeutic failure for a large group of drugs and thereby guide drug and dose selection.



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## PHARMACOGENETIC TESTING CAN IDENTIFY AN INDIVIDUAL'S DRUG METABOLISM.

Drug metabolism is categorized in the following manner:			
<b>Ultra Rapid Metabolizer (UM)</b> 	<b>Extensive Normal Metabolizer (EM)</b> 	<b>Intermediate Metabolizer (IM)</b> 	<b>Poor Metabolizer (PM)</b> 

The definition of metabolizer can vary for different drug types. For example, for some antidepressants, the following is true.

**UM** = Lack of therapeutic response, responds to increased dose

**EM** = Expected therapeutic response, responds to normal dosage

**IM** = Exaggerated therapeutic response, responds to reduced dosage

**PM** = Adverse effects, responds to alternative medication, however, for a different drug class, the response by metabolizer can vary.

### Related Tests

- Genotyping tests are available for each gene included in this panel: *CYP2C19*, *CYP2D6*, *CYP2C9/VKORC1*, *SLCO1B1*, *TPMT*, *CYP3A5* and *DPYD* as individual tests. (see table on page 3)
- Therapeutic drug monitoring and/or metabolic ratios may be useful for evaluating the pharmacokinetics of a particular drug for a particular patient.
- Analytical sensitivity/specificity: > 99%.

### Results

A detailed report is provided. This report is reviewed and signed out by the Laboratory Director.

The major *CYP2C9*, *VKORC1*, *SLCO1B1*, *TPMT*, *DPYD*, *CYP2C19*, *CYP3A5*, *CYP2D6* genotypes will be identified and classified.

### Test Limitations

- The panel includes a comprehensive medication report based on the genotypes detected.
- Only the targeted genes and variants of the genes tested will be detected.

- Diagnostic errors can occur due to rare sequence variations.
- Risk of therapeutic failure or adverse reactions may be affected by genetic and non-genetic factors that are not detected by this test.
- This result does not replace the need for therapeutic drug or clinical monitoring.

## HOW TO ORDER TESTING

### Sample Requirements

- **Collection**
  - Lavender-top tube (EDTA)
- **Specimen**
  - Whole blood, preferred volume: 2mL to 4mL (1mL minimum).
  - Send in original tube, do not aliquot.
- **Stability**
  - Room temp – 72 hours
  - Refrigerated – 28 days
  - Frozen – 28 days
  - Not affected by hemolysis
  - Not affected by lipemia
- **Methodology**
  - Polymerase chain reaction (PCR)/allele-specific primer extension.
- **Test Schedule**
  - Monday to Friday.
  - Turn Around Time: 10-14 days.
- **Test Interpretation**
  - Clinical sensitivity: drug dependent.

### Test Code, CPT, price and required form information:

**Price: \$199 for 1-6 Single Genes ordered together**

**\$199 for Basic PharmGx Panel**

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**Important Note:** *These tests are rarely covered by insurance and require a signed patient acknowledgement form (Medicare ABN) to accompany the specimen. A link to the appropriate form is listed within each of the test records in the on-line catalog at [www.sanfordlaboratories.org](http://www.sanfordlaboratories.org). In the absence of the signed patient acknowledgement form, the ordering provider/facility will be billed.*

CODE	TEST	CPT	REQUIRED FORM
LBOR0140	CYP2C19 Genotyping for: Plavix and antidepressants, where applicable	81225	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0141	CYP2D6 Genotyping for: Opioids or antidepressants, where applicable	81226	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0139	CYP2C9 Genotyping & VKORC1 for: Warfarin	81355 81227  No additional charge for VKORC1 which is included with CYP2C9	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0148	"SLC01B1 Genotyping for: Statins	81400	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0150	TPMT Genotyping for: Thiopurine drugs	81401	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0149	DPYD Genotyping for: Fluoropyrimidine drugs	81400	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0154	CYP3A5 for: Tacrolimus	81401	Requires Patient Acknowledgement Form for Pharmacogenomics Services
LBOR0142	Basic Pharm GX- Panel: Includes all 8 genotypes	81479	Requires Patient Agreement form for Self- Pay Pharmacogenomics Services

**References:**

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- Implementation Consortium Guidelines for CYP2C19 Genotype and Clopidogrel Therapy: 2013 Update. • Mega, J.L. et al. Cytochrome p-450 polymorphisms and response to clopidogrel. *N. Engl. J. Med.* 360, 354–362 (2009). • Amstutz U, Carleton BC. Pharmacogenetic testing: time for clinical practice guidelines. *Clin Pharmacol Ther.* 2011; 89(6): 924-7. PubMed. • Charles M. Strom MD, PhD, Dana Goos BS, Beryl Crossley MD, Ke Zhang PhD, Arlene Buller-Burkle PhD, Michael Jarvis PhD, Franklin Quan PhD, Mei Peng PhD & Weimin Sun PhD : Testing for variants in CYP2C19: population frequencies and testing experience in a clinical laboratory. • Becquemont L, Alfrevic A, Amstutz U, Brauch H, Jacqz-Aigrain E, Laurent-Puig P, Molina MA, Niemi M, Schwab M, Somogyi AA, Thervet E, van der Zee AM, van Kuilenburg AB, van Schaik RH, Verstuyft C, Wadelius M, Daly AK. Practical recommendations for pharmacogenomics-based prescription: 2010 ESF-UB Conference on Pharmacogenetics and Pharmacogenomics. *Pharmacogenomics.* 2011; 12(1): 113-24. PubMed. • Clinical Pharmacogenetics Implementation Consortium, Dutch Pharmacogenetics Working Group. Dosing Guidelines. • Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2C19, CYP2D6, CYP2C9, VKORC1, SLC01B1, TPMT, CYP3A5 and DPYD genotypes. • The human cytochrome P450 (CYP) allele nomenclature database, available at [www.cypalleles.ki.se/](http://www.cypalleles.ki.se/)

Address Service Requested

## Specimen Handling Key to Optimal Test Results

Sanford Transportation Services offers temperature - controlled conditions (including monitored MicroXpress™ incubators) when transporting specimens. Our conscientious drivers take great care in ensuring specimens are maintained at the proper temperature during transportation to and from the laboratory. When the temperature on the specimen bag is not marked or marked incorrectly, testing may be delayed or cancelled because the specimen integrity has been compromised. Sanford Laboratories relies on assistance from our valued clients in making sure specimens are stored at the correct temperature and that the temperature on the specimen transport bag is marked appropriately.

Together, we can ensure the highest quality of laboratory testing for all patients.

