SANFORD LABORATORIES PARTNERS WITH SANFORD IMAGENETICS TO OFFER PHARMACOGENETIC TESTING

Disease Overview

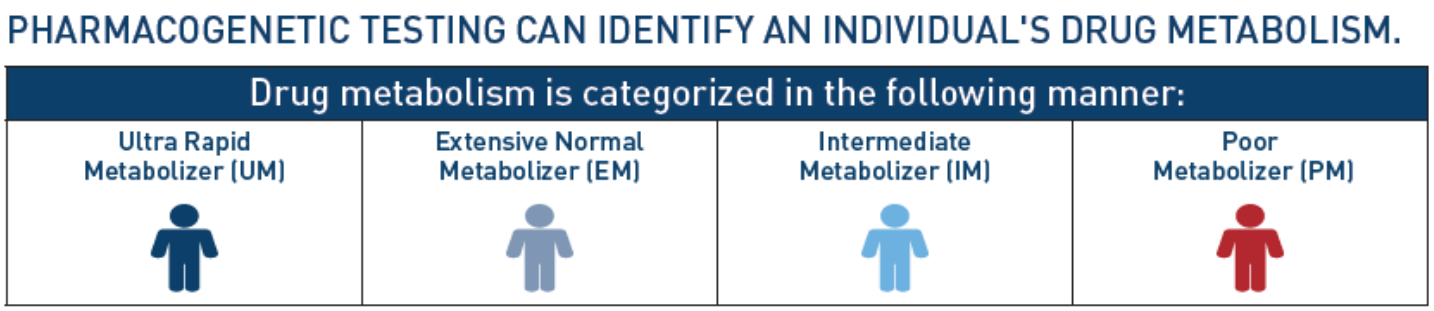
The manner in which a patient processes and responds to medications is influenced by the individual's genetic variation. Pharmacogenetics (PGx) is the study of these gene variants related to a body's response to and interaction with many common prescription and over-the-counter medications. These gene 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.



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.
- 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.

Please see the attached letter for specific pricing and additional information. Completed patient acknowledgement forms should be faxed directly to 605-333-5222.