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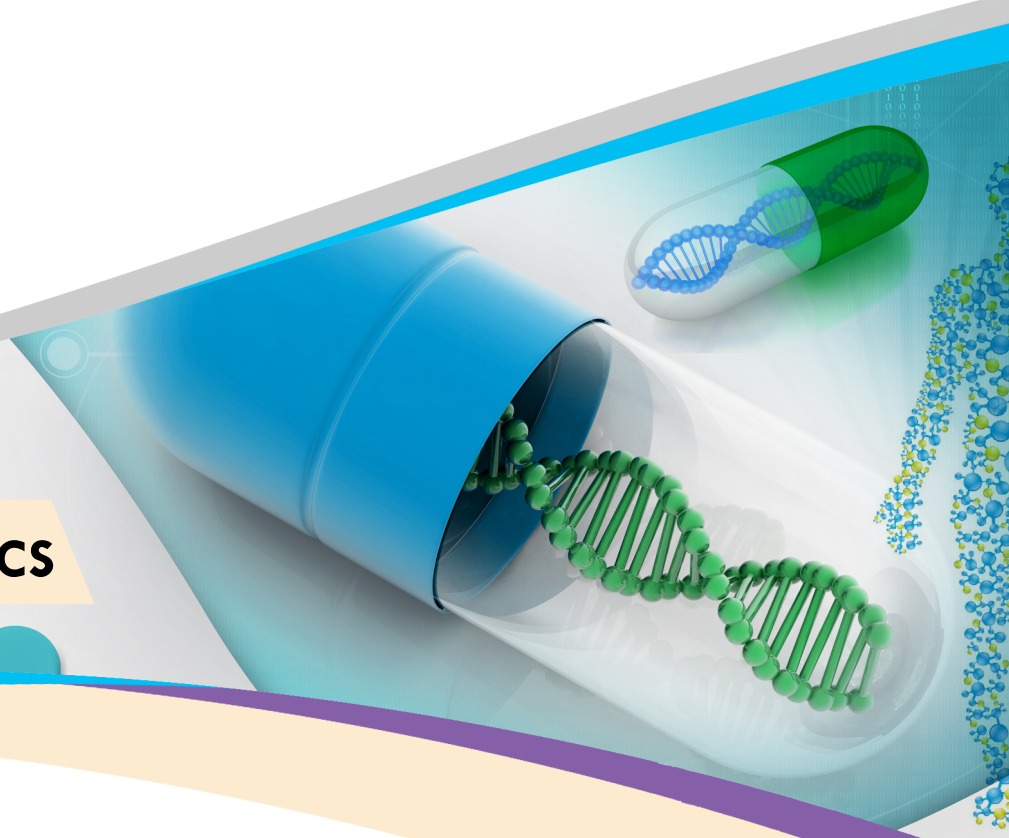


# PHARMACOGENOMICS

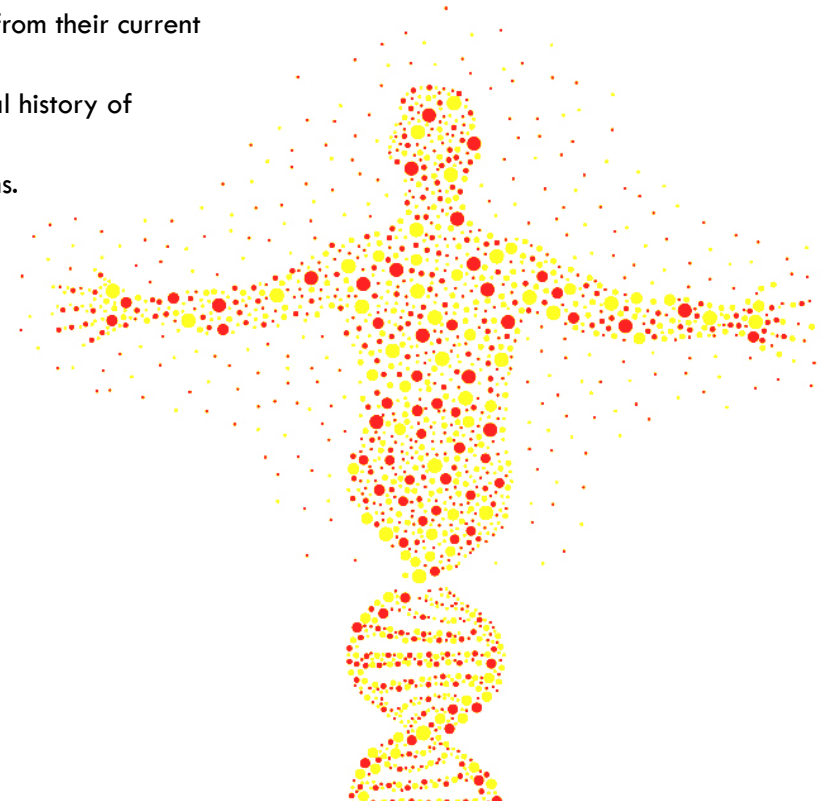
## What is pharmacogenomics?

Pharmacogenomics studies the influence of genetic variation on drug response. Knowledge of gene variants causing differences in drug response among patients has the potential to allow 'personalized' drug therapy.

Pharmacogenomics testing is recommended to aid physicians in determining the proper medication at the right dose to improve effectiveness of the drug, and to decrease the chance of negative side effects and save healthcare costs.

## What are the indications for ordering pharmacogenomics?

- To determine patients' phenotypes (drug metabolism type) prior to taking a new medication.
- To predict patients' medication outcomes (adverse effects, toxicity, inefficacy).
- To evaluate patients that have not received relief from their current medications.
- To evaluate patients who have a family or personal history of unexpected outcomes from certain medications.
- To evaluate patients who take multiple prescriptions.



## What is the economic value of pharmacogenomics?

According to the U.S. Department of Health & Human Services, more than 770,000 injuries or deaths due to drug reactions occur in the United States each year. These events may cost a hospital up to $5.6 million each year.[1]

This number does not include the adverse drug events that cause hospital admissions, malpractice and litigation costs, or the cost of injuries to the patients.

**Pharmacogenomics testing provides an opportunity to lower this number by:**

- Preventing many adverse drug events before they occur.
- Reducing pharmacy costs for clients by optimizing dosage.
- Decreasing the number of patient hospitalizations.
- Improving patient compliance with their drug therapies.
- Pharmacogenomics test results become part of a patient's medical record.
- The record can be referred to when future medications are prescribed.


**References:**

1. U.S. Department of Health & Human Services. Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs. https://archive.ahrq.gov/research/findings/factsheets/errors-safety/aderia/ade.html.


## Collection Procedure (Buccal Swab)

**IMPORTANT:** Patient should NOT drink, eat, chew gum, or smoke for at least an hour before specimen collection.

1. Verify that the patient's mouth is empty.
2. To prevent contamination, wash or sanitize hands then put on gloves.
3. Carefully remove foam swab from package. Avoid touching swab tip with gloves or against any surface.
4. Have the subject open his or her mouth and immediately bring swab tip to inside of cheek.
5. Gently rub and rotate swab along the inside of the cheek for 5-10 seconds, ensuring that the entire swab-tip has made contact with the cheek. Immediately remove swab, being careful not to touch swab tip against teeth, lips, or other surface.
6. Place swab directly into dry, sterile transport tube. Tube must be closed tightly to preserve the quality of the sample.
7. Label the tube with identification information.
8. Store swab at room temperature.



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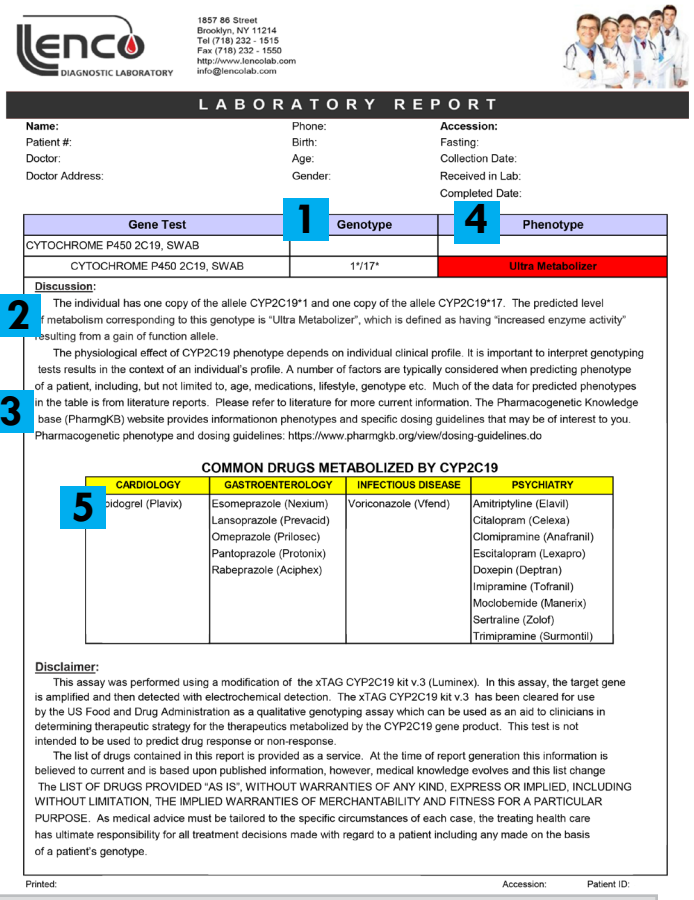
## UNDERSTANDING PHARMACOGENOMICS RESULTS

1. **Genotype:** Shows patient's genotype for the tested gene. The genotype is presented as two numbers (e.g. *1 / *4) which represent the two variations of the gene. The combination of these gene variants determines patient's phenotype for this gene.

2. **Discussion:** Looks at each gene separately and explains how patient's particular genotype and phenotype may impact drug response.

3. **Treatment guidelines:** The Clinical Pharmacogenetics Implementation Consortium (CPIC) provides information on phenotypes and specific dosing guidelines for CYP2C19 genotypes and CYP2D6 genotypes: https://www.pharmgkb.org/view/dosing-guidelines.do

4. **Phenotype:** Shows patient's phenotype for the tested gene.



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LABORATORY REPORT

Name:
Patient #:
Doctor:
Doctor Address:

Phone:
Birth:
Age:
Gender:

Accession:
Fasting:
Collection Date:
Received in Lab:
Completed Date:

| Gene Test | 1 Genotype | 4 Phenotype |
|---|---|---|
| CYTOCHROME P450 2C19, SWAB | | |
| CYTOCHROME P450 2C19, SWAB | 1*/17* | Ultra Metabolizer |

Discussion:

2 The individual has one copy of the allele CYP2C19*1 and one copy of the allele CYP2C19*17. The predicted level of metabolism corresponding to this genotype is "Ultra Metabolizer", which is defined as having "increased enzyme activity" resulting from a gain of function allele.

The physiological effect of CYP2C19 phenotype depends on individual clinical profile. It is important to interpret genotyping tests results in the context of an individual's profile. A number of factors are typically considered when predicting phenotype of a patient, including, but not limited to, age, medications, lifestyle, genotype etc. Much of the data for predicted phenotypes in the table is from literature reports. Please refer to literature for more current information. The Pharmacogenetic Knowledge 3 base (PharmgKB) website provides informationon phenotypes and specific dosing guidelines that may be of interest to you. Pharmacogenetic phenotype and dosing guidelines: https://www.pharmgkb.org/view/dosing-guidelines.do

COMMON DRUGS METABOLIZED BY CYP2C19

| CARDIOLOGY | GASTROENTEROLOGY | INFECTIOUS DISEASE | PSYCHIATRY |
|---|---|---|---|
| 5 idogrel (Plavix) | Esomeprazole (Nexium) | Voriconazole (Vfend) | Amitriptyline (Elavil) |
| | Lansoprazole (Prevacid) | | Citalopram (Celexa) |
| | Omeprazole (Prilosec) | | Clomipramine (Anafranil) |
| | Pantoprazole (Protonix) | | Escitalopram (Lexapro) |
| | Rabeprazole (Aciphex) | | Doxepin (Deptran) |
| | | | Imipramine (Tofranil) |
| | | | Moclobemide (Manerix) |
| | | | Sertraline (Zolof) |
| | | | Trimipramine (Surmontil) |

Disclaimer:

This assay was performed using a modification of the xTAG CYP2C19 kit v.3 (Luminex). In this assay, the target gene is amplified and then detected with electrochemical detection. The xTAG CYP2C19 kit v.3 has been cleared for use by the US Food and Drug Administration as a qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy for the therapeutics metabolized by the CYP2C19 gene product. This test is not intended to be used to predict drug response or non-response.

The list of drugs contained in this report is provided as a service. At the time of report generation this information is believed to current and is based upon published information, however, medical knowledge evolves and this list change

The LIST OF DRUGS PROVIDED "AS IS", WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. As medical advice must be tailored to the specific circumstances of each case, the treating health care has ultimate responsibility for all treatment decisions made with regard to a patient including any made on the basis of a patient's genotype.

Printed: Accession: Patient ID:

| Phenotype | Definition |
|---|---|
| ◆ Ultra-rapid Metabolizer | Increased enzyme activity compared to rapid metabolizers. |
| ◆ Rapid Metabolizer | Increased enzyme activity compared to normal metabolizers but less than ultra-rapid metabolizers. |
| ◆ Normal Metabolizer | Fully functional enzyme activity |
| ◆ Intermediate Metabolizer | Decreased enzyme activity (activity between normal and poor metabolizer) |
| ◆ Poor Metabolizer | Little to no enzyme activity |

5. **Drugs pharmacogenomics testing applies to:**

| Common drugs metabolized by CYP2C19 | | Common drugs metabolized by CYP2D6 | |
|---|---|---|---|
| Amitriptyline (Elavil) | Moclobemide (Manerix) | Amitriptyline (Elavil) | Metoprolol (Lopressor) |
| Citalopram (Celexa) | Omeprazole (Prilosec) | Atomoxetine (Strattera) | Mirtazapine (Remeron) |
| Clomipramine (Anafranil) | Pantoprazole (Protonix) | Carvedilol (Coreg) | Nortriptyline (Pamelor) |
| Clopidogrel (Plavix) | Rabeprazole (Aciphex) | Clomipramine (Anafranil) | Olanzapine (Zyprexa) |
| Doxepin (Deptran) | Sertraline (Zolof) | Clozapine (Clozaril) | Oxycodone (Oxycontin) |
| Escitalopram (Lexapro) | Trimipramine (Surmontil) | Codeine (Codeine) | Paroxetine (Paxil) |
| Esomeprazole (Nexium) | Voriconazole (Vfend) | Desipramine (Norpramin) | Propafenone (Rythmol) |
| Imipramine (Tofranil) | | Doxepin (Deptran) | Risperidone (Risperdal) |
| Lansoprazole (Prevacid) | | Duloxetine (Cymbalta) | Tamoxifen (Soltamox) |
| | | Flecainide (Tambocor) | Tramadol (ConZip, Ultram) |
| | | Flupenthixol (Depixol) | Trimipramine (Surmontil) |
| | | Fluvoxamine (Luvox) | Venlafaxine (Effexor) |
| | | Haloperidol (Haldol) | Zuclopenthixol (Clopixol) |
| | | Imipramine (Tofranil) | |