

## WHAT YOU NEED TO KNOW:

The U.S. Food and Drug Administration has issued a black box warning against clopidogrel (Plavix®) alerting patients and healthcare professionals that the drug can be less effective in people who cannot metabolize the drug to convert it to its active form.

Plavix® reduces the risk of heart attack, unstable angina, stroke, and cardiovascular death in patients with cardiovascular disease by making platelets less likely to form blood clots.

Plavix® does not have its anti-platelet effects until it is metabolized into its active form by the liver enzyme, CYP2C19.

People who have reduced functioning of their CYP2C19 liver enzyme cannot effectively convert Plavix® to its active form. As a result, Plavix® may be less effective in altering platelet activity in those people. These "poor metabolizers" may not receive the full benefit of Plavix® treatment and may remain at risk for heart attack, stroke, and cardiovascular death.

A genetic test can identify poor metabolizers of CYP2C19.



## WHAT IS PHARMACOGENETICS?

Pharmacogenetics is the study of how genes affect a person's response to drugs. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that are tailored to a person's genetic makeup.

Many drugs that are currently available are prescribed as a one dose suits all patients. In reality, drugs do not work the same way for everyone. Often clinicians can have difficulty in predicting who will benefit from a medication, who will not respond at all, and who will experience negative side effects (called Adverse Drug Reactions).

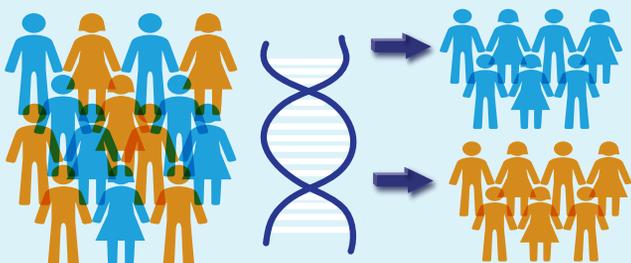
Adverse Drug Reactions are a significant cause of hospitalization and death in the United States. The knowledge obtained from the Human Genome Project and the latest advances in cost effective sequencing has brought researchers and clinicians to the leading edge of drug therapy. Researchers are learning how inherited differences in genes affect the body's response to medications. These genetic differences are used to predict whether a given medication will be effective for a particular person and prevent Adverse Drug Reactions.

The decision about which drug to prescribe may also be influenced by other drugs that the patient is taking. Pharmacogenetics can not only provide precision guidance on the best therapy for a given patient, but can also inform on how to best avoid drug to drug interactions.

### Traditional "One Size Fits All" Approach

All patients with the same diagnosis receive the same treatment

Treatment strategy based on patient's unique genetic profile



The RIGHT Dose. The FIRST Time.

# FAQ'S

## 1. What is a CYP2C19 clopidogrel gene test?

It is a genetic test ordered by your provider which identifies your personal DNA response to the effectiveness of clopidogrel (Plavix®).

## 2. Is this test different than a platelet function test?

Yes. This test is a genetic test that determines which form of the *CYP2C19* gene you have, which may help predict how you will respond to clopidogrel.

## 3. Can platelet function assays be used to assess CYP2C19 response?

There are several platelet function assays that have been used for detecting nonresponse (termed “clopidogrel resistance”) (e.g., platelet aggregometry with ADP, with collagen epinephrene); however, their clinical utility has not been widely accepted due to poor agreement between the assays.

## 4. Should everyone be treated for CYP2C19 gene variations?

Testing is not recommended to screen the general population. It is currently only indicated for those taking a drug that may be influenced by the activity of the CYP2C19-related enzymes. In some cases, a doctor may recommend that family members of a poor metabolizer consider testing so that this information is on record.

## 5. Should I tell my other doctors about my CYP2C19 test results?

Yes, this would be good information for them to have, regardless of whether you are currently taking Plavix®.

## 6. Should I tell my doctors that I am taking Plavix®?

Yes, it is important for you to tell all of your doctors or any provider that you are taking Plavix®, aspirin, or another antiplatelet agent. They will need to incorporate this information into any other treatments or procedures.

## 7. How long will it take for me to receive my results?

You should have your results in about a week after the laboratory receives the specimen.

## 8. Does my insurance or Medicare cover the cost of testing for CYP2C19?

Your provider completes a medical necessity form and a pre-authorization so that coverage is determined prior to testing.



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