Specimen ID: 033-127-9509-0
Control ID:

SAMPLE REPORT, 511710

Acct #: 90000999 **Phone:** (336) 436-8645 **Rte:** 00
LabCorp Test Master
Test Account
3060 South Church Street
Burlington NC 27215

Patient Details
DOB: 01/01/1990
Age(y/m/d): 027/01/01
Gender: F **SSN:**
Patient ID:

Specimen Details
Date collected: 02/02/2017 0000 Local
Date entered: 02/02/2017
Date reported: 00/00/0000 0000 ET

Physician Details
Ordering:
Referring:
ID:
NPI:

General Comments & Additional Information
Clinical Info: NORMAL REPORT

Ordered Items
Clopidogrel P450 2C19

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
Clopidogrel P450 2C19					
2C19 Genotype:	*1/*1				01
2C19 Metabolic Activity:	Normal				01
Interpretation:					01

The phenotype assigned is based on an FDA-cleared algorithm introduced in 2005 using the highest functioning allele to predict the enzyme activity for that individual. Emerging data suggests that, at least for some drugs such as clopidogrel, gene dosage drug response differences can be clinically significant.

Clopidogrel is a pro-drug which is metabolized to its active component by several cytochrome P450 proteins of which CYP2C19 plays a key role. Among clopidogrel treated patients, intermediate (IM) or poor (PM) metabolizers are associated with reduced platelet inhibition and an increased risk of cardiovascular complications such as myocardial infarction, stroke, stent thrombosis, and/or death, as compared with extensive metabolizers (EM). Intermediate to extensive metabolizers (IM-EM) are anticipated to have a range of reduced to normal enzyme activity. Extensive metabolizers (EM) are anticipated to have normal enzyme activity. Individuals who are carriers of the *17 allele are ultrarapid metabolizers (UM) and may have an enhanced response to clopidogrel. Ultrarapid metabolizers may be at increased risk of bleeding. Other common drugs metabolized by the 2C19 pathway include proton pump inhibitors (Omeprazole), anticonvulsants (Phenytoin and Diazepam), and Tricyclic antidepressants (Amitriptyline and Nortriptyline).

Limitations: This assay detects poor metabolizer CYP2C19 alleles *2 and *3 (loss-of-function alleles) as well as the ultrarapid metabolizer allele, *17. Other, rare alleles are not detected by this assay. Metabolism of drugs including clopidogrel may also be influenced by race, ethnicity, diet, and/or other medications. Results must be interpreted in the context of other test results and clinical findings. This

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Date collected: 02/02/2017 0000 Local

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB

test result does not rule out the possibility of variant alleles in other drug metabolism pathways that may impact drug efficacy and/or toxicity.

CYP2C19 Information: 01

Methodology:
DNA analysis of the Cytochrome P450 2C19 gene (OMIM 124020, 10q24.1-10q24.3) is performed using primer extension chemistry. Multiplex PCR amplifies DNA fragments containing the variants below. Primer extension then generates a biotin-labeled product to permit flow-sorted detection of both normal and variant sequences. Molecular-based testing is highly accurate, but as in any laboratory test, rare diagnostic errors may occur.

Alleles Detected:
*1,*2,*3,*17

*1 represents detection of the normal sequence for the variant sites tested. This assay does not detect other variants in the CYP2C19 gene that may affect metabolic activity.

Buccal cells for CYP2C19: This test was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

References:
1. Scott SA, et al. Clinical Pharmacogenetics Implementation Consortium guidelines for CYP2C19 genotype and clopidogrel therapy: 2013 Update. Clin Pharmacol Ther. 2013:94(3):317-323. PubMed 23698643
2. Sibbing D, et al. Cytochrome 2C19*17 allelic variant, platelet aggregation, bleeding events, and stent thrombosis in clopidogrel-treated patients with coronary stent placement. Circulation. 2010;121:512-518. PubMed 20083681
3. Simon T, et al. Genetic determinants of response to clopidogrel and cardiovascular events. N Engl J Med. 2009;360:363-75. PubMed 19106083

Director Review:
Annette K. Taylor, M.S., Ph.D., FACMG
Toni R. Prezant, Ph.D.
Samuel H. Pepkowitz, M.D., FAAP
Joseph B. Kearney, Ph.D., FACMG

01	UY	Esoterix Coagulation Lab 8490 Upland Drive Ste 100, Englewood, CO 80112-7116	Dir: Dorothy Adcock, MD

For inquiries, the physician may contact **Branch: 800-222-7566 Lab: 800-282-7300**

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Gender: F **SSN:**
Patient ID:

Specimen Details
Date collected: 02/02/2017 0000 Local
Date entered: 02/02/2017
Date reported: 00/00/0000 0000 ET

Physician Details
Ordering:
Referring:
ID:
NPI:

General Comments & Additional Information
Clinical Info: ABNORMAL REPORT

Ordered Items
Clopidogrel P450 2C19

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
Clopidogrel P450 2C19					
2C19 Genotype:	*1/*17				01
2C19 Metabolic Activity:	Ultrarapid				01
Interpretation:					01

The phenotype assigned is based on an FDA-cleared algorithm introduced in 2005 using the highest functioning allele to predict the enzyme activity for that individual. Emerging data suggests that, at least for some drugs such as clopidogrel, gene dosage drug response differences can be clinically significant.

Clopidogrel is a pro-drug which is metabolized to its active component by several cytochrome P450 proteins of which CYP2C19 plays a key role. Among clopidogrel treated patients, intermediate (IM) or poor (PM) metabolizers are associated with reduced platelet inhibition and an increased risk of cardiovascular complications such as myocardial infarction, stroke, stent thrombosis, and/or death, as compared with extensive metabolizers (EM). Intermediate to extensive metabolizers (IM-EM) are anticipated to have a range of reduced to normal enzyme activity. Extensive metabolizers (EM) are anticipated to have normal enzyme activity. Individuals who are carriers of the *17 allele are ultrarapid metabolizers (UM) and may have an enhanced response to clopidogrel. Ultrarapid metabolizers may be at increased risk of bleeding. Other common drugs metabolized by the 2C19 pathway include proton pump inhibitors (Omeprazole), anticonvulsants (Phenytoin and Diazepam), and Tricyclic antidepressants (Amitriptyline and Nortriptyline).

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TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB

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