Lab Dept:	**Anatomic Pathology**
Test Name:	**CYTOCHROME P450 2C19 GENOTYPE SEQUENCING**

General Information

Lab Order Codes:	2C19S
Synonyms:	P450 Genotyping
CPT Codes:	81225 – CYP2C19 gene analysis, common variants
Test Includes:	An interpretive report detailing the patient's 2C19 phenotype and ability to metabolize drugs affected by CYP2C19.

Logistics

Test Indications:	Identifying patients who may be at risk for altered metabolism of drugs that are modified by CYP2C19.
Lab Testing Section:	Anatomic Pathology - Sendouts
Referred to:	Mayo Medical Laboratories (MML Test: 2C19V)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 - 5 days, performed Monday - Friday
Special Instructions:	N/A

Specimen

Specimen Type:	Whole blood
Container:	Lavender top tube
Draw Volume:	3 mL (minimum: 0.4 mL) blood
Processed Volume:	Same as Draw Volume
Collection:	Routine venipuncture

Special Processing:	Lab Staff: **Do Not** centrifuge. **Do Not** freeze. Submit specimen in original collection container. Store and ship at room temperature.
Patient Preparation:	Transfusions will interfere with testing. Wait 4-6 weeks post-transfusion to draw. Bone marrow and liver transplants will also interfere with testing.
Sample Rejection:	Mislabeled or unlabeled specimens

Interpretive

Reference Range:	An interpretive report will be provided. The genotype, with associated star alleles, is assigned using standard allelic nomenclature as published by the Human Cytochrome P450 (CYP) Allele Nomenclature Database Committee. Drug-drug interactions and drug/metabolite inhibition must be considered when treating immediate metabolizers. It is important to interpret the results of testing and dose adjustments in the context of hepatic and renal fuction and patient age.
Limitations:	Rare variants may be present that could lead to false-negative or false-positive results. If results obtained do not match the clinical findings (phenotype), additional testing should be considered. Samples may contain donor DNA if obtained from patients who received heterologous blood transfusions or allogenic blood or marrow transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. For individuals whod have received allogeneic blood or marrow transplantation, a pretransplant DNA specimen is recommended for testing. CYP2C19 genetic test results in patients who have undergone live transplantation may not accurately reflect the patient's CYP2C19 status. This method may not detect all variants that result in altered CYP2C19 activity. Therefore, absence of a detectable variant does not rule out the possibility that a patient has altered CYP2C19 metabolism due to other CYP2C19 variants that cannot be detected with this method. Furthermore, when 2 or more variants are identified, the cis/trans-status (whether the variants are on the same of opposite chromosomes) is not always known. This testing is designed to detect only the variants specified. Other variants in the primer binding regions can affect testing and ultimately, the genotype and phenotype predictions made.
Methodology:	Real-Time Polymerase Chain Reaction (PCR) with Allelic Discrimination Analysis

References:	Mayo Medical Laboratories November 2017
Updates:	10/23/2017: Updated method.