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ARUP Test Code: 3001508

Collection Date: 01/23/2025

Received in lab: 01/25/2025

Completion Date: 01/31/2025

2C19GENO Specimen Whole Blood

Patient Results

| Gene | Genotype | Flag | Phenotype | Flag |
|----------------|----------|------|------------|------|
| <i>CYP2C19</i> | *17/*17 | | Ultrarapid | |

2C19GENO Interpretation

See Note

The following CYP2C19 allele(s) were detected: *17/*17. This result predicts the ultrarapid metabolizer phenotype.

Recommendation: Guidelines for genotype-based dosing are published by the Clinical Pharmacogenetics Implementation Consortium(CPIC) and can be found at: <https://cpicpgx.org/> and <https://www.pharmgkb.org/>.

This result has been reviewed and approved by [REDACTED]

Interpretive Comments

BACKGROUND INFORMATION: CYP2C19

Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that code for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.

Inheritance: Autosomal codominant.

Cause: CYP2C19 gene variants affect enzyme function.

Variants Tested:

(Variants are numbered according to NM_000769 transcript).

*1: Indicative of no detected targeted variants and an assumption of functional allele. No variants detected is predictive of the *1 functional allele.

CYP2C19*2: rs4244285, c.681G>A; rs12769205, c.332-23A>G

CYP2C19*3: rs4986893, c.636G>A

CYP2C19*4A: rs28399504, c.1A>G

CYP2C19*4B: rs28399504, c.1A>G; rs12248560, c.-806C>T

CYP2C19*5: rs56337013, c.1297C>T

CYP2C19*6: rs72552267, c.395G>A

CYP2C19*7: rs72558186, c.819+2T>A



CYP2C19*8: rs41291556, c.358T>C
CYP2C19*9: rs17884712, c.431G>A
CYP2C19*17: rs12248560, c.-806C>T
CYP2C19*35: rs12769205, c.332-23A>G

Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.

Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted CYP2C19 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publicly available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 substrates 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.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.



Test Information

The following tables list the available gene-drug pairs and genotype-based dosing published by the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the FDA table of pharmacogenomic biomarkers in drug labeling.

Published CPIC guidelines

| GUIDELINES | DRUGS | GENES |
|--|-----------------|------------------------|
| CYP2B6 and efavirenz | efavirenz | CYP2B6 |
| CYP2C19 and Clopidogrel | clopidogrel | CYP2C19 |
| CYP2C19 and Proton Pump Inhibitors | dexlansoprazole | CYP2C19 |
| | esomeprazole | |
| | lansoprazole | |
| | omeprazole | |
| | pantoprazole | |
| | rabeprazole | |
| CYP2C19 and Voriconazole | voriconazole | CYP2C19 |
| CYP2C9 and NSAIDs | aceclofenac | CYP2C9 |
| | celecoxib | |
| | diclofenac | |
| | flurbiprofen | |
| | ibuprofen | |
| | indomethacin | |
| | lornoxicam | |
| | lumiracoxib | |
| | meloxicam | |
| | metamizole | |
| | nabumetone | |
| | naproxen | |
| | piroxicam | |
| tenoxicam | | |
| CYP2C9, VKORC1, CYP4F2 and Warfarin | warfarin | CYP2C9, CYP4F2, VKORC1 |
| CYP2D6 and Atomoxetine | atomoxetine | CYP2D6 |
| CYP2D6 and Ondansetron and Tropisetron | ondansetron | CYP2D6 |
| | tropisetron | |
| CYP2D6 and Tamoxifen | tamoxifen | CYP2D6 |
| | citalopram | |
| | escitalopram | |



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|---|---|------------------------|
| CYP2D6, CYP2C19 and Selective Serotonin Reuptake Inhibitors | fluvoxamine paroxetine sertraline | CYP2C19, CYP2D6 |
| CYP2D6, CYP2C19 and Tricyclic Antidepressants | amitriptyline clomipramine desipramine doxepin imipramine nortriptyline trimipramine | CYP2C19, CYP2D6 |
| CYP2D6, OPRM1, COMT, and Opioids | alfentanil buprenorphine codeine fentanyl hydrocodone hydromorphone levomethadone methadone morphine naltrexone oxycodone remifentanil sufentanil tramadol | COMT, CYP2D6, OPRM1 |
| CYP3A5 and Tacrolimus | tacrolimus | CYP3A5 |
| DPYD and Fluoropyrimidines | capecitabine fluorouracil tegafur | DPYD |
| SLCO1B1, ABCG2, CYP2C9, and Statins | atorvastatin fluvastatin lovastatin pitavastatin pravastatin rosuvastatin simvastatin | ABCG2, CYP2C9, SLCO1B1 |
| | azathioprine | |





TPMT, NUDT15 and Thiopurines

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|----------------|
| mercaptopurine |
| thioguanine |

NUDT15, TPMT



FDA Table of Pharmacogenomic Biomarkers in Drug Labeling

| Drug | Therapeutic Area* | Biomarker† | Labeling Sections |
|-----------------------|-------------------|------------|---|
| Abrocitinib | Dermatology | CYP2C19 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Amitriptyline | Psychiatry | CYP2D6 | Precautions |
| Amoxapine | Psychiatry | CYP2D6 | Precautions |
| Amphetamine | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Arformoterol | Pulmonary | CYP2D6 | Clinical Pharmacology |
| Aripiprazole | Psychiatry | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Aripiprazole Lauroxil | Psychiatry | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Atomoxetine | Psychiatry | CYP2D6 | Dosage and Administration, Warnings and Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, Clinical Pharmacology |
| Avatrombopag | Hematology | CYP2C9 | Clinical Pharmacology |
| Azathioprine | Rheumatology | TPMT | Dosage and Administration, Warnings, Precautions, Drug Interactions, Adverse Reactions, Clinical Pharmacology |
| Azathioprine | Rheumatology | NUDT15 | Dosage and Administration, Warnings, Precautions, Adverse Reactions, Clinical Pharmacology |
| Belzutifan | Oncology | CYP2C19 | Warnings and Precautions, Drug Interactions, Use in Specific Populations, Clinical Pharmacology |
| Brexpiprazole | Psychiatry | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Brivaracetam | Neurology | CYP2C19 | Clinical Pharmacology |
| Bupropion | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Capecitabine | Oncology | DPYD | Warnings and Precautions, Clinical Pharmacology, Patient Counseling Information |
| Cariprazine | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Carisoprodol | Rheumatology | CYP2C19 | Use in Specific Populations, Clinical Pharmacology |
| Carvedilol | Cardiology | CYP2D6 | Drug Interactions, Clinical Pharmacology |
| Celecoxib | Rheumatology | CYP2C9 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Cevimeline | Dental | CYP2D6 | Precautions |
| Cisplatin | Oncology | TPMT | Adverse Reactions |
| Citalopram | Psychiatry | CYP2C19 | Dosage and Administration, Warnings, Clinical Pharmacology |



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|------------------------------------|-----------------------------|---------|--|
| Citalopram | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Clobazam | Neurology | CYP2C19 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Clomipramine | Psychiatry | CYP2D6 | Precautions |
| Clopidogrel | Cardiology | CYP2C19 | Boxed Warning, Warnings and Precautions, Clinical Pharmacology |
| Clozapine | Psychiatry | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Codeine | Anesthesiology | CYP2D6 | Boxed Warning, Warnings and Precautions, Use in Specific Populations, Patient Counseling Information |
| Darifenacin | Urology | CYP2D6 | Clinical Pharmacology |
| Desipramine | Psychiatry | CYP2D6 | Precautions |
| Desvenlafaxine | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Deutetrabenazine | Neurology | CYP2D6 | Dosage and Administration, Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology |
| Dexlansoprazole | Gastroenterology | CYP2C19 | Drug Interactions, Clinical Pharmacology |
| Dextromethorphan and Quinidine | Neurology | CYP2D6 | Warnings and Precautions, Clinical Pharmacology |
| Diazepam | Neurology | CYP2C19 | Clinical Pharmacology |
| Donepezil | Neurology | CYP2D6 | Clinical Pharmacology |
| Doxepin | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Doxepin | Psychiatry | CYP2C19 | Clinical Pharmacology |
| Dronabinol | Gastroenterology | CYP2C9 | Use in Specific Populations, Clinical Pharmacology |
| Drospirenone and Ethinyl Estradiol | Gynecology | CYP2C19 | Clinical Pharmacology |
| Duloxetine | Psychiatry | CYP2D6 | Drug Interactions |
| Efavirenz | Infectious Diseases | CYP2B6 | Clinical Pharmacology |
| Elagolix | Gynecology | SLCO1B1 | Clinical Pharmacology |
| Eliglustat | Inborn Errors of Metabolism | CYP2D6 | Indications and Usage, Dosage and Administration, Contraindications, Warnings and Precautions, Drug Interactions, Use in Specific Populations, Clinical Pharmacology, Clinical Studies |
| Erdafitinib | Oncology | CYP2C9 | Use in Specific Populations, Clinical Pharmacology |
| Escitalopram | Psychiatry | CYP2D6 | Drug Interactions |
| Escitalopram | Psychiatry | CYP2C19 | Adverse Reactions |
| Esomeprazole | Gastroenterology | CYP2C19 | Drug Interactions, Clinical Pharmacology |



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|----------------|------------------|---------|---|
| Fesoterodine | Urology | CYP2D6 | Drug Interactions, Clinical Pharmacology |
| Fosphenytoin | Neurology | CYP2C9 | Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology |
| Flibanserin | Gynecology | CYP2C9 | Clinical Pharmacology |
| Flibanserin | Gynecology | CYP2C19 | Adverse Reactions, Use in Specific Populations, Clinical Pharmacology |
| Flibanserin | Gynecology | CYP2D6 | Clinical Pharmacology |
| Fluorouracil | Dermatology | DPYD | Contraindications, Warnings |
| Fluorouracil | Oncology | DPYD | Warnings and Precautions, Patient Counseling Information |
| Fluoxetine | Psychiatry | CYP2D6 | Precautions, Clinical Pharmacology |
| Flurbiprofen | Rheumatology | CYP2C9 | Clinical Pharmacology |
| Fluvoxamine | Psychiatry | CYP2D6 | Drug Interactions |
| Formoterol | Pulmonary | CYP2D6 | Clinical Pharmacology |
| Formoterol | Pulmonary | CYP2C19 | Clinical Pharmacology |
| Galantamine | Neurology | CYP2D6 | Clinical Pharmacology |
| Gefitinib | Oncology | CYP2D6 | Clinical Pharmacology |
| Iloperidone | Psychiatry | CYP2D6 | Dosage and Administration, Warnings and Precautions, Drug Interactions, Clinical Pharmacology |
| Imipramine | Psychiatry | CYP2D6 | Precautions |
| Lacosamide | Neurology | CYP2C19 | Clinical Pharmacology |
| Lansoprazole | Gastroenterology | CYP2C19 | Drug Interactions, Clinical Pharmacology |
| Lesinurad | Rheumatology | CYP2C9 | Drug Interactions, Clinical Pharmacology |
| Lofexidine | Anesthesiology | CYP2D6 | Use in Specific Populations |
| Mavacamten | Cardiology | CYP2C19 | Dosage and Administration, Clinical Pharmacology |
| Meclizine | Neurology | CYP2D6 | Warnings and Precautions |
| Meloxicam | Anesthesiology | CYP2C9 | Use in Specific Populations, Clinical Pharmacology |
| Mercaptopurine | Oncology | TPMT | Dosage and Administration, Warnings and Precautions, Adverse Reactions, Clinical Pharmacology |
| Mercaptopurine | Oncology | NUDT15 | Dosage and Administration, Warnings and Precautions, Clinical Pharmacology |
| Metoclopramide | Gastroenterology | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Metoprolol | Cardiology | CYP2D6 | Clinical Pharmacology |
| Mirabegron | Urology | CYP2D6 | Clinical Pharmacology |
| Modafinil | Psychiatry | CYP2D6 | Clinical Pharmacology |



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|-----------------|---------------------|---------|---|
| Nateglinide | Endocrinology | CYP2C9 | Drug Interactions |
| Nebivolol | Cardiology | CYP2D6 | Dosage and Administration, Clinical Pharmacology |
| Nefazodone | Psychiatry | CYP2D6 | Precautions |
| Nortriptyline | Psychiatry | CYP2D6 | Precautions |
| Oliceridine | Anesthesiology | CYP2D6 | Warnings and Precautions, Drug Interactions, Use in Specific Populations, Clinical Pharmacology |
| Omeprazole | Gastroenterology | CYP2C19 | Drug Interactions, Clinical Pharmacology |
| Ondansetron | Gastroenterology | CYP2D6 | Clinical Pharmacology |
| Ospemifene | Gynecology | CYP2C9 | Clinical Pharmacology |
| Ospemifene | Gynecology | CYP2B6 | Clinical Pharmacology |
| Paliperidone | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Palonosetron | Gastroenterology | CYP2D6 | Clinical Pharmacology |
| Pantoprazole | Gastroenterology | CYP2C19 | Clinical Pharmacology |
| Paroxetine | Psychiatry | CYP2D6 | Drug Interactions, Clinical Pharmacology |
| Perphenazine | Psychiatry | CYP2D6 | Precautions, Clinical Pharmacology |
| Phenytoin | Neurology | CYP2C9 | Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology |
| Phenytoin | Neurology | CYP2C19 | Clinical Pharmacology |
| Pimozide | Psychiatry | CYP2D6 | Dosage and Administration, Precautions |
| Piroxicam | Rheumatology | CYP2C9 | Clinical Pharmacology |
| Pitolisant | Psychiatry | CYP2D6 | Dosage and Administration, Use in Specific Populations, Clinical Pharmacology |
| Prasugrel | Cardiology | CYP2C19 | Use in Specific Populations, Clinical Pharmacology, Clinical Studies |
| Prasugrel | Cardiology | CYP2C9 | Use in Specific Populations, Clinical Pharmacology, Clinical Studies |
| Prasugrel | Cardiology | CYP3A5 | Use in Specific Populations, Clinical Pharmacology, Clinical Studies |
| Prasugrel | Cardiology | CYP2B6 | Use in Specific Populations, Clinical Pharmacology, Clinical Studies |
| Propafenone | Cardiology | CYP2D6 | Dosage and Administration, Warnings and Precautions, Drug Interactions, Clinical Pharmacology |
| Propranolol | Cardiology | CYP2D6 | Clinical Pharmacology |
| Protriptyline | Psychiatry | CYP2D6 | Precautions |
| Quinidine | Cardiology | CYP2D6 | Precautions |
| Quinine Sulfate | Infectious Diseases | CYP2D6 | Drug Interactions |



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| Rabeprazole | Gastroenterology | CYP2C19 | Drug Interactions, Clinical Pharmacology |
| Rimegepant | Neurology | CYP2C9 | Clinical Pharmacology |
| Risperidone | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Rosuvastatin | Endocrinology | SLCO1B1 | Clinical Pharmacology |
| Rucaparib (2) | Oncology | CYP2D6 | Clinical Pharmacology |
| Siponimod | Neurology | CYP2C9 | Dosage and Administration, Contraindications, Drug Interactions, Use in Specific Populations, Clinical Pharmacology |
| Tamoxifen | Oncology | CYP2D6 | Clinical Pharmacology |
| Tamsulosin | Urology | CYP2D6 | Warnings and Precautions, Adverse Interactions, Clinical Pharmacology |
| Tetrabenazine | Neurology | CYP2D6 | Dosage and Administration, Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology |
| Thioguanine | Oncology | TPMT | Dosage and Administration, Warnings, Precautions, Clinical Pharmacology |
| Thioguanine | Oncology | NUDT15 | Dosage and Administration, Warnings, Precautions, Clinical Pharmacology |
| Thioridazine | Psychiatry | CYP2D6 | Contraindications, Warnings, Precautions |
| Ticagrelor | Cardiology | CYP2C19 | Clinical Pharmacology |
| Tolterodine | Urology | CYP2D6 | Warnings and Precautions, Drug Interactions, Clinical Pharmacology |
| Tramadol | Anesthesiology | CYP2D6 | Boxed Warning, Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology, Patient Counseling Information |
| Trimipramine | Psychiatry | CYP2D6 | Precautions |
| Umeclidinium | Pulmonary | CYP2D6 | Clinical Pharmacology |
| Upadacitinib | Rheumatology | CYP2D6 | Clinical Pharmacology |
| Valbenazine | Neurology | CYP2D6 | Dosage and Administration, Warnings and Precautions, Use in Specific Populations, Clinical Pharmacology |
| Venlafaxine | Psychiatry | CYP2D6 | Drug Interactions, Use in Specific Populations, Clinical Pharmacology |
| Viloxazine | Psychiatry | CYP2D6 | Clinical Pharmacology |
| Viloxazine | Psychiatry | SLCO1B1 | Clinical Pharmacology |
| Voriconazole | Infectious Diseases | CYP2C19 | Clinical Pharmacology |
| Vortioxetine | Psychiatry | CYP2D6 | Dosage and Administration, Clinical Pharmacology |
| Warfarin | Hematology | CYP2C9 | Dosage and Administration, Drug Interactions, Clinical Pharmacology |





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| Warfarin | Hematology | VKORC1 | Dosage and Administration, Clinical Pharmacology |
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* Therapeutic areas do not necessarily reflect the CDER review division.

† Representative biomarkers are listed based on standard nomenclature as per the Human Genome Organization (HUGO) symbol and/or simplified descriptors using other common conventions. Listed biomarkers do not necessarily reflect the terminology used in labeling. The term “Nonspecific” is provided when labeling does not explicitly identify the specific biomarker(s) or when the biomarker is represented by a molecular phenotype or gene signature, and in some cases the biomarker was inferred based on the labeling language.

