

See Note

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OPRM1 Variant Interpretation

OPRM1

Indication for testing: predict opioid sensitivity.

GG

Interpretation: Two copies of the OPRM1 G allele (rs1799971) were detected in this sample. Decreased sensitivity to opioid receptor agonists and increased sensitivity to opioid receptor antagonists are predicted. This patient may require higher or more frequent doses of opioid receptor agonists (e.g., morphine) to achieve adequate pain control. He/she may also be more likely to respond to opioid antagonists (e.g., naltrexone) in the treatment of alcohol and/or opioid dependency. This association of OPRM1 and drug sensitivity is not definitive and may be different for individual opioids.

Recommendation: Annotations for clinical application of this OPRM1 allele are available through the Pharmacogenomics Knowledge Base at: https://www.pharmgkb.org/gene/PA31945

This result has been reviewed and approved by



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Interpretive Comments

BACKGROUND INFORMATION: Opioid Receptor, Mu OPRM1, 1 Variant

CHARACTERISTICS: The mu opioid receptor is involved in mediating the clinical response to opioids (agonists and antagonists). OPRM1 c.118A>G has been associated with lower sensitivity to opioid receptor agonists prescribed for pain control (e.g., morphine) and higher sensitivity to opioid receptor antagonists used in the treatment of alcohol and drug dependency (e.g., naltrexone). Risk of side effects to opioids is also associated with this genetic variant. INHERITANCE: Autosomal codominant. CAUSE: SNP rs1799971; OPRM1 c.118A>G (p.Asn40Asp), also known as G allele, alters response to opioids. CLINICAL SENSITIVITY: Drug dependent. METHODOLOGY: Polymerase Chain Reaction (PCR) and Fluorescence Monitorina ANALYTICAL SENSITIVITY and SPECIFICITY: Greater than 99 percent. LIMITATIONS: Only the targeted OPRM1 mutation, c.118A>G, will be detected. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with opioids may be affected by genetic and nongenetic factors that are not detected by this test. This result does not replace the need for therapeutic or clinical monitoring.

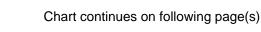
Please note the information contained in this report does not contain medication recommendations and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

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.



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Test Information

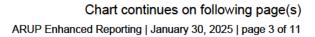
The following tables list the available gene-drug pairs and genotype-based dosing published by the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the FDA table of pharmacogenomic biomarkers in drug labeling.

Published CPIC guidelines

GUIDELINES	DRUGS	GENES
CYP2B6 and efavirenz	efavirenz	CYP2B6
CYP2C19 and Clopidogrel	clopidogrel	CYP2C19
	dexlansoprazole	
	esomeprazole	
CYP2C19 and Proton Pump Inhibitors	lansoprazole	CYP2C19
	omeprazole	
	pantoprazole	
	rabeprazole	
CYP2C19 and Voriconazole	voriconazole	CYP2C19
	aceclofenac	
	celecoxib	
	diclofenac	
	flurbiprofen	
	ibuprofen	
	indomethacin	
CYP2C9 and NSAIDs	lornoxicam	CYP2C9
	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	CYP2C19, CYP2D6
	paroxetine	
	sertraline	
	amitriptyline	
	clomipramine	
	desipramine	
CYP2D6, CYP2C19 and Tricyclic Antidepressants	doxepin	CYP2C19, CYP2D6
	imipramine	
	nortriptyline	
	trimipramine	
	alfentanil	
	buprenorphine	
	codeine	
	fentanyl	
	hydrocodone	
CYP2D6, OPRM1, COMT, and Opioids	hydromorphone	COMT, CYP2D6, OPRM1
	levomethadone	
	methadone	
	morphine	
	naltrexone	
	oxycodone	
	remifentanil	
	sufentanil	
	tramadol	
CYP3A5 and Tacrolimus	tacrolimus	CYP3A5
	capecitabine	
DPYD and Fluoropyrimidines	fluorouracil	DPYD
	tegafur	
	atorvastatin	
	fluvastatin	
	lovastatin	
SLCO1B1, ABCG2, CYP2C9, and Statins	pitavastatin	ABCG2, CYP2C9, SLCO1E
	pravastatin	
	rosuvastatin	
	simvastatin	
	azathioprine	

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TPMT, NUDT15 and Thiopurines	mercaptopurine	NUDT15, TPMT	
	thioguanine		



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Chart continues on following page(s) ARUP Enhanced Reporting | January 30, 2025 | page 5 of 11

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	ТРМТ	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	ТРМТ	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
lloperidone	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	ТРМТ	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	ТРМТ	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

Warfarin	Hematology	VKORC1	Dosage and Administration, Clinical Pharmacology

* 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.



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