



Overview

Test Description

This test evaluates 11 genes associated with response to drugs prescribed to treat cardiovascular disease, including anticoagulants, antiarrhythmics, antihypertensives, antiplatelets, beta blockers, and HMG-CoA Reductase Inhibitors (statins). Results from this test may help in predicting treatment efficacy and risk of side effects for these drugs. Any information provided for drugs listed under "Limited Evidence Drug-Gene Associations" is provided for informational use only. For sections titled "Limited Evidence Drug-Gene Associations," no interpretation of expected drug response is provided due to a lack of sufficient evidence and/or available guidelines.

Genetics Information

This test utilizes next-generation sequencing to determine results for *ABCB1*, *ABCG2*, *CYP2C cluster*, *CYP2C9*, *CYP2C19*, *CYP2D6*, *CYP3A4*, *CYP4F2*, *GRK4*, *SLCO1B1*, and *VKORC1*.

Indications For Testing

Patients for whom medication from the following list are being considered, have been ineffective, or caused side effects:

Atorvastatin, Carvedilol, Clopidogrel, Fluvastatin, Lovastatin, Mavacamten, Metoprolol, Pitavastatin, Pravastatin, Propafenone, Rosuvastatin, Simvastatin, and Warfarin.

For the following drugs, pharmacogenomic status is reported without drug response interpretation due to a lack of sufficient evidence and/or available guidelines:

Atenolol, Digoxin, Flecainide, Losartan, Nebivolol, Propranolol, Quinidine, and Timolol.

Clinical Descriptions

Many medications used to treat cardiovascular conditions are impacted by specific variations in known genes. These genetic variations can contribute to medication efficacy and risk for side effects.

Pharmacogenomic testing to guide prescribing, paired with clinical monitoring may impact outcomes for patients by reducing the time to therapeutic effect and reducing the risk of side effects.



Test Details

Genes Tested

ABCB1, ABCG2, CYP2C cluster, CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP4F2, GRK4, SLCO1B1, VKORC1

Methods & Limitations

Data is generated from extracted DNA using the validated Helix Exome+ assay by the Helix clinical laboratory. The Exome+ assay is based on target enrichment followed by next generation sequencing using paired end reads on an Illumina DNA sequencing system. Star alleles are determined using a proprietary algorithm which performs variant calling and then determines star allele solutions based on a combination of defining SNPs and exon-level copy number.

Metabolizer status is determined based on star allele solutions according to CPIC guidelines, with the following exceptions: (Metabolizer status is set as Indeterminate if (1) a novel nonsense or truncating novel mutation was observed within the gene, (2) the combination of defining SNPs and copy number suggested a novel star allele solution, and (3) if more than two copies of a gene are detected. In the absence of CPIC guidelines, metabolizer status for *CYP3A4* was determined based on the Dutch Pharmacogenetics Working Group (DPWG). Drug/gene considerations are limited to guidelines published by FDA and CPIC.

Phasing is not performed for genotypes, and therefore in some cases the star allele solution may not be disambiguated between two or more equally likely possibilities. In these cases, if the metabolizer status is the same regardless of possible star allele solutions, the more common star allele solution is provided along with the metabolizer status. If the metabolizer status is different for the equally-likely star allele solutions, the star alleles are reported as Unknown and the metabolizer status is considered Indeterminate.

All samples are sequenced and interpreted in Helix's CLIA-certified (#05D2117342) and CAP-accredited (#9382893) laboratory in San Diego, California. These tests have not been cleared or approved by the U.S. Food and Drug Administration.

The reportable range includes the following results:

*ABCB1: rs2032582, rs1128503, rs1045642; ABCG2: rs2231142; CYP2C cluster: rs12777823; CYP2C9: *1-*61; CYP2C19: *1-*19, *22-*26, *28-*39; CYP2D6: *1-*15, *4N, *17-*65, *68-*75, *81, *83-*114; CYP3A4: *1-*24, *26, *28-*38; CYP4F2: *1,*3; GRK4: rs1024323; SLCO1B1: *1-*16, *19, *20, *23-*34, *36-*44, *47-*49; VKORC1: rs9923231. Accuracy may be reduced for complex alleles in non-diploid states as well as for CYP2D6*13 (CYP2D7::CYP2D6 hybrid alleles).*

Results are based on:

All outcomes are informed by one or more of the following:

1. U.S. Food and Drug Administration (FDA) Table of Pharmacogenetic Associations, Sections 1 and 2 (U.S. FDA, Center for Drug Evaluation and Research; available at <https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations>; accessed March 17, 2026)
2. Clinical Pharmacogenetics Implementation Consortium (CPIC) gene-drug pairs list, levels A and B-Final (available at <https://www.clinpgx.org/cpic/pairs>; accessed March 17, 2026)

3. U.S. Food and Drug Administration (FDA) Table of Pharmacogenomic Biomarkers in Drug Labeling, filtered to entries with Boxed Warning designations (U.S. FDA, Center for Drug Evaluation and Research; available at <https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling>; accessed March 17, 2026)

Disclaimer

The interpretations and drug considerations provided by Helix are intended solely for use by a medical professional and do not constitute medical advice by Helix. All treatment decisions and diagnoses remain the full responsibility of the treating provider. Results included in this report are based on the guidelines published by the FDA and CPIC, and do not account for other factors that may impact drug response, such as environment, medical conditions, drug-drug interactions, or additional genetic variants. Helix is not responsible or liable for any errors, omissions, or ambiguities in the interpretation or use of the results of this report. Administration of any medication listed in this report requires careful therapeutic monitoring regardless of the drug considerations outlined in this report. All dates and times displayed are Pacific Time and may vary from the dates and times for Collection, Order and Report for the providers/patients.

Interpretation

All detected variants are evaluated according to CPIC and the FDA. Variants are classified based on known, predicted, or possible impact on drug metabolism.

Reclassification

Helix reviews relevant pharmacogenomic guidelines as published by the FDA and CPIC at least annually.

Variant Evaluation

Variant classification is performed using data provided by CPIC whenever available. When CPIC data is not available, a thorough literature search is performed to evaluate whether specific alleles have known and established impact on drug metabolism.

Recommendations and interpretation for dosage and prescription are based on guidelines set forth by CPIC and the FDA. Classifications are based on the combination of alleles found in the given individual and data set forth by CPIC and the other entities mentioned above. Variants of unknown significance on drug metabolism are not reported.



Laboratory Details			
Turnaround Time - Standard	Typically 6 to 9 days	Turnaround Time - Requery (SOQO [®])	Typically ≤ 5 minutes
Available in NY State	Yes	Procedure Code	H00825-1
Test Classification	This test was developed, and its performance characteristics determined, by Helix, Inc. in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.		
Regulatory Information	- CLIA Complexity: High - Test Classification: Non-Waived/ Laboratory Developed Test		
CLIA Category	Chemistry / Routine Chemistry		
Performing Laboratory Information	- CLIA Laboratory Number: 05D2117342 - Laboratory Hours of Operation: Monday-Saturday (7AM-10:30PM PST) - Address: 10170 Sorrento Valley Road, Suite 100, San Diego, CA 92121 - Helix Customer Support: (844) 211-2070 - Email: support@helix.com		



The following applies to the Helix Pharmacogenomics (PGx) Cardiovascular Panel. Next-generation sequencing is performed to test for the presence of star allele solutions in the genes analyzed, according to the reportable range listed.

This list is current from July 2026 to the present. For questions regarding genes, reference transcripts, or specific regions covered, contact Helix Customer Support at (844) 211-2070.

Gene	Reportable Range
<i>ABCB1</i>	rs2032582, rs1128503, rs1045642
<i>ABCG2</i>	rs2231142
<i>CYP2C cluster</i>	rs12777823
<i>CYP2C9</i>	*1-*61
<i>CYP2C19</i>	*1-*19, *22-*26, *28-*39
<i>CYP2D6</i>	*1-*15, *4N, *17-*65, *68-*75, *81, *83-*114
<i>CYP3A4</i>	*1-*24, *26, *28-*38
<i>CYP4F2</i>	*1,*3
<i>GRK4</i>	rs1024323
<i>SLCO1B1</i>	*1-*16, *19, *20, *23-*34, *36-*44, *47-*49
<i>VKORC1</i>	rs9923231