

Helix Pharmacogenomics (PGx) Tacrolimus CYP3A5 Test

Patient Name: Jane Doe Date of Birth: 01/01/1990 Sex Assigned at Birth: Female

Helix ID: Test12345 Provider Name: Client Client Collection Date: 2025-01-23

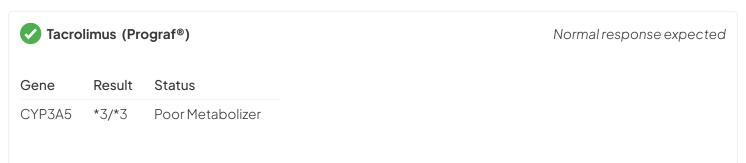
Patient ID: 0123456

Order Date: 2025-04-29 Report Date: 2025-04-29

Specimen Type: WHOLE BLOOD

Note: This report is intended for use by a medical professional. Please discuss any adjustments to your medication with your treating provider.

Results & Interpretations



Legend

onsider different drug
onsider reduced or increased dose
ler standard dose and alter as needed
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Methods and Limitations

Data were 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 were 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. Star allele definitions came from PharmVar v5.2.22 for CYP3A5.

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

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

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

The reportable range includes the following star alleles: CYP3A5: *1, *3, *6-*9.

Results are based on: Tacrolimus, CYP3A5 (FDA Section 1).

PFI#9396



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Provider Name: Client Client Collection Date: 2025-01-23

Patient ID: 0123456

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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.

Result Notations

https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations https://cpicpgx.org/guidelines https://www.pharmgkb.org/guidelineAnnotations

Report Signed By

Kenneth David Becker, PhD, HCLD, CQ, CGMBS

Helix's Sequence Once, Query Often® Model

When your provider orders a genetic test through Helix, we use our proprietary Sequence Once, Query Often® model to perform whole exome sequencing and analyze the specific genes related to the test. Helix securely stores your whole exome for future clinical use. With your permission, this allows your health care providers to order future medically necessary genetic tests from Helix without needing another sample. Instead, these tests are conducted through digital analysis of your stored genetic information.

To learn more about how Helix protects the privacy and security of your genetic information and learn more about your rights, please visit https://www.helix.com/privacy-and-policy-highlights.

San Diego, CA 92121

CAP #9382893 PFI#9396

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