Helix Pharmacogenomics (PGx) Tacrolimus Test

Patient Name: John Doe

Date of Birth: 11/22/1950

Sex Assigned at Birth: Male

Specimen Type: WHOLE BLOOD

Provider Name: Client Client

Address: 123, One Ave, Test City, CA 67890

Collection Date: 04/25/2024

Order Date: 04/24/2024

Report Date: 05/28/2024

Helix ID: TST12345

Patient ID: 98765

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

Results & Interpretation

Tacrolimus (Prograf®)

Gene: CYP3A5 Status: Intermediate Metabolizer

Result: *1/*3

The CYP3A5 intermediate metabolizer status results in increased metabolism leading to lower plasma concentrations of tacrolimus, and may result in higher rejection risk. The Clinical Pharmacogenetics Implementation Consortium (CPIC) recommends increasing starting dose 1.5 to 2 times of the recommended starting dose, with total starting dose not exceeding 0.3 mg/kg/day. The FDA recommends measuring drug concentrations and adjusting dosage based on trough whole blood tacrolimus concentration for CYP3A5 intermediate metabolizers.

Legend

SYMBOL	IMPLICATION
	Major gene-drug interaction identified, affecting medication metabolism. Consider prescribing a different drug.
	Moderate gene-drug interaction identified, affecting medication metabolism. Consider prescribing an alternate dose or use caution.
	Minimal gene-drug interaction identified, with no known effect on medication metabolism. No drug considerations identified.
	Limited scientific evidence on the effect on drug metabolism identified. Consider prescribing the standard dose and alter the dose as needed.
	The metabolizer status cannot be determined.

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Methods & 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 PharmGKB.

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, 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.

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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 determined star alleles and 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.

Notes

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

Philip D Cotter, PhD, FACMG, FFSC (RCPA)

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Helix's Sequence Once, Query Often® Model

When your provider first orders a genetic test through Helix, Helix leverages its proprietary Sequence Once, Query Often® model to perform whole exome sequencing and interpret the specific genes related to the test being ordered. Helix will then continue to store your genetic information for future clinical use. This means that, with your permission, your health care providers can order future medically necessary genetic tests from Helix without the need for you to submit another sample in most cases. Instead, future tests will be performed through digital analysis of your genetic information that is stored by Helix.

When you receive a genetic test performed by Helix, you are in control of how and when your genetic information is used. To manage your genetic information and understand your rights, please visit https://www.helix.com/privacy-and-policy-highlights.