

Patient Name: John Doe	Patient ID: 98765	Collection Date: 2024-09-11
Date of Birth: 1975-12-02	Helix ID: TST12345	Order Date: 2024-09-11
Sex Assigned at Birth: Male	Provider Name: Client Client	Report Date: 2024-10-06
Specimen Type: BLOOD	Provider Address: -	

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

Drug Summary

Anticonvulsants	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Brivaracetam (Briviact®)	✓			
Carbamazepine (Focalin®)	✓			
Lamotrigine (Lamictal®)	✓			
Oxcarbazepine (Trileptal®)	✓			

Antidepressants	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Amitriptyline (Elavil®)		⚠		
Citalopram (Celexa®)	✓			
Clomipramine (Anaranil®)		⚠		
Desipramine (Norpramine®)		⚠		
Doxepin (Sinequan®)		⚠		
Escitalopram (Lexapro®)	✓			
Fluvoxamine (Luvox®)	✓			
Imipramine (Tofranil®)		⚠		
Nortriptyline (Pamelor®)		⚠		
Paroxetine (Paxil®)		⚠		
Sertraline (Zoloft®)	✓			
Trimipramine (Surmontil®)		⚠		
Venlafaxine (Effexor®)				?
Vortioxetine (Trintellix®)	✓			

Antipsychotics	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Aripiprazole (Abilify®)	✓			
Clozapine (Clozaril®)	✓			
Haloperidol (Haldol®)	✓			
Iloperidone (Fanapt®)	✓			
Pimozide (Orap®)		⚠		
Quetiapine (Seroquel®)	✓			
Risperidone (Risperdal®)	✓			
Thioridazine (Mellaril®)	✓			

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Anxiolytics	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Clobazam (Onfi®)	✓			

CNS Stimulants	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Amphetamine	✓			
Atomoxetine (Seroquel®)		⚠		

Other	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Deutetrabenazine (Austedo®)	✓			
Flibanserin (Addyi®)	✓			
Valbenazine (Ingrezza®)	✓			

Substance use disorder treatments	Normal Interaction	Use with Caution	Consider Alternatives	Impact Undetermined
Lofexidine (Lucemyra®)	✓			

Legend

SYMBOL	IMPLICATION
⚠	Major gene-drug interaction, consider different drug
⚠	Major gene-drug interaction, consider reduced or increased dose
✓	No recommended action
?	Impact not determined, consider standard dose and alter as needed

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Gene Summary

GENE	RESULT	STATUS
ABCB1,rs2032582	G/G	rs2032582 G homozygote
COMT,rs4680	G/G	Variant absent
CYP2C19	*1/*1	Normal Metabolizer
CYP2C9	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer
CYP3A4	*1/*1	Normal Metabolizer
CYP3A5	*1/*1	Normal Metabolizer
HLA-B*15:02	ABSENT	HLA-B*15:02 Negative
MTHFR, c.1286A>C (p.Glu429Ala)	A/A	Variant absent
OPRM1,rs1799971	A/G	rs1799971 G carrier

Drug Details

Anticonvulsants

<p> Brivaracetam (Briviact®) Normal Interaction</p> <table border="1"> <thead> <tr> <th>Gene</th> <th>Result</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>CYP2C19</td> <td>*1/*1</td> <td>Normal Metabolizer</td> </tr> </tbody> </table>	Gene	Result	Status	CYP2C19	*1/*1	Normal Metabolizer
Gene	Result	Status				
CYP2C19	*1/*1	Normal Metabolizer				
<p> Carbamazepine (Focalin®) Normal Interaction</p> <table border="1"> <thead> <tr> <th>Gene</th> <th>Result</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>HLA-B*15:02</td> <td>ABSENT</td> <td>HLA-B*15:02 Negative</td> </tr> </tbody> </table>	Gene	Result	Status	HLA-B*15:02	ABSENT	HLA-B*15:02 Negative
Gene	Result	Status				
HLA-B*15:02	ABSENT	HLA-B*15:02 Negative				
<p> Lamotrigine (Lamictal®) Normal Interaction</p> <table border="1"> <thead> <tr> <th>Gene</th> <th>Result</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>HLA-B*15:02</td> <td>ABSENT</td> <td>HLA-B*15:02 Negative</td> </tr> </tbody> </table>	Gene	Result	Status	HLA-B*15:02	ABSENT	HLA-B*15:02 Negative
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HLA-B*15:02	ABSENT	HLA-B*15:02 Negative				
<p> Oxcarbazepine (Trileptal®) Normal Interaction</p> <table border="1"> <thead> <tr> <th>Gene</th> <th>Result</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>HLA-B*15:02</td> <td>ABSENT</td> <td>HLA-B*15:02 Negative</td> </tr> </tbody> </table>	Gene	Result	Status	HLA-B*15:02	ABSENT	HLA-B*15:02 Negative
Gene	Result	Status				
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Antidepressants

Amitriptyline (Elavil®) Use With Caution

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Citalopram (Celexa®) Normal Interaction

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer

Clomipramine (Anarantil®) Use With Caution

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Desipramine (Norpramine®) Use With Caution

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Doxepin (Sinequan®) Use With Caution

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Escitalopram (Lexapro®) Normal Interaction

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer

Fluvoxamine (Luvox®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

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Imipramine (Tofranil®)

Use With Caution

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Nortriptyline (Pamelor®)

Use With Caution

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Paroxetine (Paxil®)

Use With Caution

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Sertraline (Zoloft®)

Normal Interaction

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer

Trimipramine (Surmontil®)

Use With Caution

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Venlafaxine (Effexor®)

Impact Undetermined

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Vortioxetine (Trintellix®)

Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

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Limited Evidence Drug-Gene Associations

Desvenlafaxine (Pristiq®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Amoxapine (Asendin®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Duloxetine (Cymbalta®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Fluoxetine (Prozac®) Limited Evidence

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Levomilnacipran (Fetzima®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Mirtazapine (Remeron®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Protriptyline (Vivactil®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

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Trazodone (Desyrel®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Vilazodone (Viibryd®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Bupropion (Wellbutrin®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Antipsychotics

Aripiprazole (Abilify®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Haloperidol (Haldol®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Pimozide (Orap®) Use With Caution

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Quetiapine (Seroquel®) Normal Interaction

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

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Risperidone (Risperdal®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Clozapine (Clozaril®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Iloperidone (Fanapt®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Thioridazine (Mellaril®) Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Limited Evidence Drug-Gene Associations

Paliperidone (Invega®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Olanzapine (Abilify®) Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer
MTHFR, c.1286A>C (p.Glu429Ala)	A/A	Variant absent

Aripiprazole (Abilify®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

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Brexpiprazole (Rexulti®)

Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer
CYP3A4	*1/*1	Normal Metabolizer

Cariprazine (Vraylar®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Clozapine (Clozaril®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer
MTHFR, c.1286A>C (p.Glu429Ala)	A/A	Variant absent

Iloperidone (Fanapt®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Lurasidone (Latuda®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Perphenazine (Tilafon®)

Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Pimozide (Orap®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

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Quetiapine (Seroquel®) Limited Evidence

Gene	Result	Status
CYP3A5	*1/*1	Normal Metabolizer

Ziprasidone (Geodon®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Anxiolytics

Clobazam (Onfi®) Normal Interaction

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer

Limited Evidence Drug-Gene Associations

Alprazolam (Xanax®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Buspirone (BuSpar®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Clonazepam (Klonopin®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Diazepam (Valium®) Limited Evidence

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer
CYP3A4	*1/*1	Normal Metabolizer

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Triazolam (Halcion®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

CNS Stimulants

Atomoxetine (Seroquel®)

Use With Caution

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Amphetamine

Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Limited Evidence Drug-Gene Associations

Methylphenidate (Ritalin, Concerta)

Limited Evidence

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Other

Deutetrabenazine (Austedo®)

Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

Valbenazine (Ingrezza®)

Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

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Flibanserin (Addyi®)

Normal Interaction

Gene	Result	Status
CYP2C19	*1/*1	Normal Metabolizer

Limited Evidence Drug-Gene Associations

Lithium (Lithobid®)

Limited Evidence

Gene	Result	Status
ABCB1,rs2032582	G/G	rs2032582 G homozygote

Eszopiclone (Lunesta®)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Flibanserin (Addyi®)

Limited Evidence

Gene	Result	Status
CYP2C9	*1/*1	Normal Metabolizer
CYP2D6	*9/*10	Intermediate Metabolizer

Zolpidem (Ambien)

Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Substance use disorder treatments

Lofexidine (Lucemyra®)

Normal Interaction

Gene	Result	Status
CYP2D6	*9/*10	Intermediate Metabolizer

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Limited Evidence Drug-Gene Associations

Buprenorphine (Buprenex®, Butrans®, Probuphine®) Limited Evidence

Gene	Result	Status
CYP3A4	*1/*1	Normal Metabolizer

Naloxone (Evzio®, Narcan®) Limited Evidence

Gene	Result	Status
COMT, rs4680	G/G	Variant absent
OPRM1, rs1799971	A/G	rs1799971 G carrier

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 Pharm Var 3.4 for CYP2D6, Pharm Var v4.1.3 for CYP2C9 and CYP4F2, Pharm Var v5.2.13 for CYP2C19, Pharm Var v5.2.22 for CYP3A4 and CYP3A5, and Pharm Var 6.0.2 for SLCO1B1. HLA-B*15:02 detection is based on rs144012689.

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 except for CYP2D6 where activity scores were summed across all star alleles to determine metabolizer status. In the absence of CPIC guidelines, metabolizer status for CYP3A4 was determined based on Zhou, Y., Lauschke, V.M. Pharmacogenomics J 22, 284-293 (2022). 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:

CYP2C9: *1-*61; CYP2C19: *1-*19, *22-*26, *28-*39; CYP3A4: *1-*24, *26, *28-*38; CYP3A5: *1, *3, *6-*9; CYP2D6: *1-*15, *4N, *17-*65, +68-*75, *81, *83-*114, HLA-B*15:02, SLCO1B1: *1-*16, *19, *20, *23-*34, *36-*44, *47-*49. Sensitivity may be reduced for CYP2D6*13 alleles and SLCO1B1*49.

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.



Helix Pharmacogenomics (PGx) Mental Health Panel

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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)

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>.