



# Helix Pharmacogenomics (PGx) Mental Health Panel

Item	Description
<b>Test Name</b>	Helix Pharmacogenomics (PGx) Mental Health Panel
<b>Test Type</b>	Pharmacogenomics
<b>Catalog Number</b>	PMNH1
<b>Procedure Code</b>	H00123-1
<b>Test Description</b>	This panel evaluates 7 genes associated with Mental Health. Results from this test may help in predicting treatment efficacy and risk of side effects for drugs used to treat various mental health disorders.
<b>Genes Tested</b>	<i>CYP2C9, CYP2C19, CYP3A4, CYP3A5, CYP2D6, HLA-B*15:02, SLCO1B1</i>
<b>Genetics Information</b>	<p>This test utilizes next-generation sequencing to determine star alleles and metabolizer status for <i>CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, HLA-B*15:02, and SLCO1B1</i>. These results are used to determine drug considerations for the following drugs amitriptyline, amphetamine, aripiprazole, atomoxetine, carbamazepine, citalopram, clomipramine, desipramine, doxepin, escitalopram, fluvoxamine, haloperidol, imipramine, lamotrigine, nortriptyline, oxcabazepine, paroxetine, pimozide, quetiapine, risperidone, sertraline, trimipramine, venlafaxine, and vortioxetine.</p> <p>See Method Description for additional details.</p>
<b>Clinical Indication</b>	Providing a genetic evaluation to determine optimal prescription based on risk of side effects and drug efficacy for mental health disorders.
<b>Clinical Descriptions</b>	<p>Psychiatric disorders such as depression, anxiety, schizophrenia, bipolar disorder, and others impact 1 in 8 adults. 5.5% of all U.S. adults suffer from mental illness, which is defined as disorders that result in serious functional impairment and interfere substantially with activities of daily living.</p> <p>Many drugs for psychiatric disorders are impacted in efficacy as well as risk of side effects by specific variations in known genes. Pharmacogenomic testing to guide prescribing, paired with clinical monitoring, can significantly improve outcomes for patients by reducing the burden of failing multiple medications and optimizing chances of efficacious treatment while reducing risk of side effects.</p>
<b>Disease States</b>	Psychiatric disorders such as depression, anxiety, schizophrenia, bipolar disorder, and others
<b>Genes &amp; Methodology</b>	See Record-0088-S1 Targeted Genes & Methodology Details for Helix Pharmacogenomics (PGx) Mental Health Panel
<b>Methods &amp; Limitations</b>	<p>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 3.4 for <i>CYP2D6</i>, PharmVar v4.1.3 for <i>CYP2C9</i> and <i>CYP4F2</i>, PharmVar v5.2.13 for <i>CYP2C19</i>, PharmVar v5.2.22 for <i>CYP3A4</i> and <i>CYP3A5</i>, and PharmVar 6.0.2 for <i>SLCO1B1</i>. HLA-B*15:02 detection is based on rs144012689.</p> <p>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 <i>CYP2D6</i> where activity scores were summed across all star alleles to determine metabolizer status. In the absence of CPIC guidelines, metabolizer status for <i>CYP3A4</i> 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.</p> <p>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.</p> <p>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.</p>



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<b>Methods &amp; Limitations</b>	<p>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.</p> <p>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.</p>
<b>Interpretation</b>	All detected variants are evaluated according to the Clinical Pharmacogenetics Implementation Consortium (CPIC). Variants are classified based on known, predicted, or possible impact on drug metabolism.
<b>Reclassification of Variants</b>	Helix does not systematically review variants evaluated and reported for this test looking for guideline updates or classification changes. Helix will review the classification of previously reported variants upon request of the ordering physician/provider. Ordering physicians/providers may contact Helix Customer Support to request a review of updates to CPIC guidelines and/or variant classification in terms of impact on drug metabolism. At the discretion of the laboratory director, the frequency of reclassification requests may be limited to once per year, no earlier than 12 months after initial evaluation has been performed.
<b>Variant Evaluation</b>	<p>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.</p> <p>Recommendations and interpretation for dosage and prescription are based on guidelines set forth by CPIC, the Food and Drug Administration (FDA), and the Pharmacogenomics Knowledgebase (PharmGKB). Variants are classified as having impact on drug metabolism with the following tiers: poor metabolizer, intermediate metabolizer, normal metabolizer, and ultrarapid metabolizer. These 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.</p>
<b>Turnaround Time</b>	7 to 10 days
<b>Available in NY State</b>	No
<b>Test Classification</b>	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.
<b>Performing Laboratory Information</b>	CLIA Laboratory Number: 05D2117342 Laboratory Hours of Operation: Monday-Sunday (6AM-10PM PST) Address: 10170 Sorrento Valley Road, Suite 100, San Diego, CA 92121 Helix Customer Service: (844) 211-2070 Email: support@helix.com
<b>Regulatory Information</b>	CLIA Complexity: High Test Classification: Non-Waived/ Laboratory Developed Test
<b>CLIA Category</b>	Chemistry / Routine Chemistry