Helix Pharmacogenomics (PGx) APOE Panel

Item	Description
Test Name	Helix Pharmacogenomics (PGx) APOE Panel
Test Type	Pharmacogenomics
Catalog Number	PAPO1
Procedure Code	H00324-1 (Helix)
Test Description	This test evaluates a patient's *APOE* status, which can aid in appropriate prescription of lecanemab-irmb and donanemab-azbt.
Genes Tested	*APOE*
Genetics Information	This test utilizes next-generation sequencing to determine *APOE* status.
Indications For Testing	Patients for whom lecanemab-irmb or donanemab-azbt treatments are being considered.
Clinical Descriptions	Lecanemab-irmb and donanemab-azbt are prescribed for patients with mild cognitive impairment (MCI) or mild dementia stage of Alzheimer's disease (AD) in order to slow the progression of MCI due to AD and mild AD dementia. APOE ε4 homozygotes have an increased risk for adverse events.
Disease States	Mild cognitive impairment (MCI) or mild dementia stage of Alzheimer's disease.
Interpretation	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.
Reclassification Of Variants	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.
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, 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.
Turnaround Time	7 to 10 days
Available In NY State	No

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Item	Description
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.
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 Service: (844) 211-2070 Email: support@helix.com
Regulatory Information	CLIA Complexity: High Test Classification: Non-Waived/ Laboratory Developed Test
CLIA Category	Chemistry / Routine Chemistry

Methods & Limitations for Helix Pharmacogenomics (PGx) APOE Panel

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. Data was then aligned to a modified version of GRCh38 and small variant calling was completed using a customized version of Sentieon's DNAseq software.

E2/E4 and E1/E3 genotypes cannot be distinguished by this assay and are reported as E2/E4. E1 genotypes are reported as 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 rs429358 and rs7412.

Results are based on:
Donanemab-azbt, APOE (FDA Boxed Warning); Lecanemab-irmb, APOE (FDA Boxed Warning).

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.

Targeted Genes & Methodology for Helix Pharmacogenomics (PGx) APOE Panel

The following applies to the Helix Pharmacogenomics (PGx) APOE 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 January 2025 to the present. For questions regarding genes, reference transcripts, or specific regions covered, contact Helix Customer Service at (844) 211-2070.

Catalog Number: PAPO1

Gene	Reportable Range
APOE	rs429358 and rs7412 (e2, e3, e4)