# **Helix**

# **Helix Pharmacogenomics** (PGx) APOE Panel

Patient Name: Jane Doe Date of Birth: 01/01/1990 Sex Assigned at Birth: Female Specimen Type: WHOLE BLOOD

Patient ID: 0123456 Helix ID: Test12345 Provider Name: Client Client Collection Date: 2025-01-23

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

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

#### **Results & Interpretations**

✓ Donanemab-Azbt (Kisunla™)			
Gene	Result	Status	
APOE	E3/E3	Typicalrisk	

Lecanemab-Irmb (Leqembi			
Gene	Result	Status	
APOE	E3/E3	Typical risk	

## 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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#### **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. Data was then aligned to a modified version of GRCh38 and small variant calling was completed using a customized version of Sentieon's DNAseg 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 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<sup>®</sup> 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.

CAP #9382893 PFI #9396