Helix

Helix Pharmacogenomics (PGx) APOE Test

Patient Name: Jane Doe	**Patient ID:** 555100001	**Provider Name:** Client Client	**Order Date:** 2025-12-17
Date of Birth: 1990-01-01	**Helix ID:** TSTSAP72RK	**Collection Date:** 2025-12-17	**Report Date:** 2025-12-17

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™)

Normal response expected

Gene	Result	Status
APOE	E3/E3	Typical risk

Lecanemab-Irmb (Leqembi®)

Normal response expected

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

The APOE gene has three common isoforms, commonly known as alleles: APOE2, APOE3, and APOE4. Each person has a combination of two of these types. APOE3 is the most common version and is linked to an average risk of Alzheimer's disease, about 10–15% over a lifetime. APOE2 may lower the risk of developing Alzheimer's, while APOE4 is linked to a higher risk. People with one APOE4 allele have a 20–25% chance of developing Alzheimer's, and those with two APOE4 alleles have a 31–40% chance (1). It's important to know that having one or two APOE4 alleles does not mean a person will definitely get Alzheimer's. Other factors, like genetics, lifestyle, and the environment also affect the risk. These results might matter for family members too, as genes are passed down through generations. Speaking with a healthcare provider or genetic counselor can clarify what this test result means for a patient's personal risk of developing Alzheimer's as well as the risk of disease for their family members.

1. Qian J, et al. APOE-related risk of mild cognitive impairment and dementia for prevention trials: An analysis of four cohorts. PLoS Med. 2017;14(3):e1002254. PMID: 28323826

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

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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 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

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Helix's Sequence Once, Query Often® 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.

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