Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 34 Y

Referral Testing

Collected: 04/22/2020 18:10 Received: 04/22/2020 18:10

Test Name	Result	Flag	Ref-Ranges	Units	Site

ADmark ApoE Genotype Analysis and Interpretation (Sympto)

Interpretation — See Note — QCRL

This individual does not possess an ApoE 4 allele.

Technical Results — See Note — QCRL

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Interpretive Result Table
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INTERPRETIVE RESULT: Negative
TEST: APOE
TECHNICAL RESULT: Alleles: 2 and 3
CLINICAL RELEVANCE: See Limitations of Analysis
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Comments — See Note — QCRL

Comments: While this analysis did not identify an APOE allele associated with AD, a diagnosis of AD cannot be ruled out.

Clinical limitations: The frequency of the E4 allele in the APOE gene is reported to occur in 40-50% of individuals with Alzheimer's disease (1,2). This ApoE analysis is only appropriate for symptomatic individuals. Results cannot be interpreted for asymptomatic individuals and should not be used for predictive testing.

Background information: Alzheimer's disease (AD) is a heterogeneous disorder and is the most common cause of dementia. Memory failure is often the initial presenting sign in affected individuals. As the disease progresses, additional deficits develop including those in judgment and language. Psychiatric changes may also occur. In the late stages of the disease, physical functioning is impacted which leads to incapacitation. Diagnosis relies on the clinical picture as well as findings of amyloid plaques and neurofibrillary tangles in the brain (1) .
There are different types of AD based on the age of onset of symptoms and the presence of family history. The more common 'sporadic' late-onset AD (LOAD) is characterized with symptoms usually starting after 60 years old and lacking a clear mode of transmission. Alternatively, a smaller portion of AD cases have an onset prior to 60 years old with a strong family history. These are familial early-onset AD (EOAD) (1) .
The ApoE gene has been associated with AD. There are three major isoforms of ApoE, E2, E3 and E4, that are differentiated by either cysteine or arginine residues at positions 112 and 158. Specifically,

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the E4 allele is considered to be the risk factor for AD. These amino acid differences impact binding capabilities of ApoE protein with other cellular products including amyloid-beta peptides. An accumulation of amyloid-beta is observed in the brains of individuals with AD who carry the E4 allele (1). Although this allele appears to increase an individual's risk of AD, it is considered to be a reduced penetrant allele because it is not required to cause disease and it cannot predict one's risk to develop AD (3).
APOE gene information: MIM ID: +107741; Chromosome Location: 19q13.32
Phenotype information: MIM ID: #104310 for Alzheimer's disease

Methods — See Note — QCRL

ApoE genotyping was performed by restriction endonuclease digestion of PCR amplified genomic DNA.

Limitations of analysis: Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

References — See Note — QCRL

1. Liu, CC, et al. (2013) Nat Rev Neurol 9: 106-18. (PMID: 23296339)
2. Chouraki, V, et al. (2014) Adv Genet 87: 245-94. (PMID: 25311924)
3. Roberts, JS, et al. (2013) Prog Neurobiol 110: 89-101. (PMID: 23583530)

This test was developed and its analytical performance characteristics have been determined by Athena Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Laboratory oversight provided by Vivekananda Datta, M.D., Ph.D., CLIA license holder, Athena Diagnostics (CLIA# 22D0069726)

Testing performed at:
Athena Diagnostics 200 Forest Street Marlborough, MA 01752

Test Performed at:
Athena Diagnostics, Inc.
200 Forest Street, 2nd Floor
Marlborough, MA 01752 V Datta MD, PhD

Reported Date: 04/22/2020 18:16 APOE

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675