TITLE: METHOD AND KIT FOR THE DIAGNOSIS OF ALZHEIMER'S DISEASE BASED ON THE DETECTION OF APOLIPOPROTEIN E

TECNOLOGY DESCRIPTION

This system is an *in vitro* method for diagnosing Alzheimer's Disease that consists in the determination of apoE-based biomarkers, specifically: the presence, quantity or concentration of 34 kDa apoE (immature glycoform) in apoE aggregates 100 kDa in size (which also reflect abnormal aggregates/dimers identified only in AD patients); apoE dimer/monomer ratio detected in a native electrophoresis assay; and the presence of apoE dimers detected in a native electrophoresis assay. This Alzheimer's Disease diagnostic kit includes the reagents necessary to carry out the method.

BUSINESS APLICATION SECTORS

Sectors that develop research into neurodegenerative diseases, whose main objective is the prevention, diagnosis or treatment of said diseases. In addition, sectors that seek to promote scientific advances in the health system.

TECNICAL ADVANTAGES AND BUSINESS BENEFITS

In the current state of affairs, various methods have been described to determine the type of APOE variant, as well as methods for sub-grouping patients with Alzheimer's Disease by APOE genotype to estimate other biomarkers. However, no diagnostic methods or kits have yet been described for this disease based on alterations of the apoE protein itself associated with the development of Alzheimer's Disease.

The invention presented here provides an *in vitro* method and a kit for diagnosing Alzheimer's Disease, providing a solution to the technical problem stated.

TECHNOLOGY DEVELOPMENT LEVEL

TRL 6-7. Alterations in the balance of immature apoE species have been demonstrated in brain extracts from Alzheimer's Disease patients, and more relevantly also in the cerebrospinal fluid (CSF), where an aberrant/abnormal dimer or complex is also characterized, which is only detected in subjects with Alzheimer's Disease.

INTELLECTUAL PROPERTY RIGHTS

The rights correspond to the Miguel Hernández University of Elche (UMH), the Spanish National Research Council (CSIC) and the Network Centre for Biomedical Research in Neurodegenerative Diseases (CIBERNED).

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COLABORATION SEARCHED

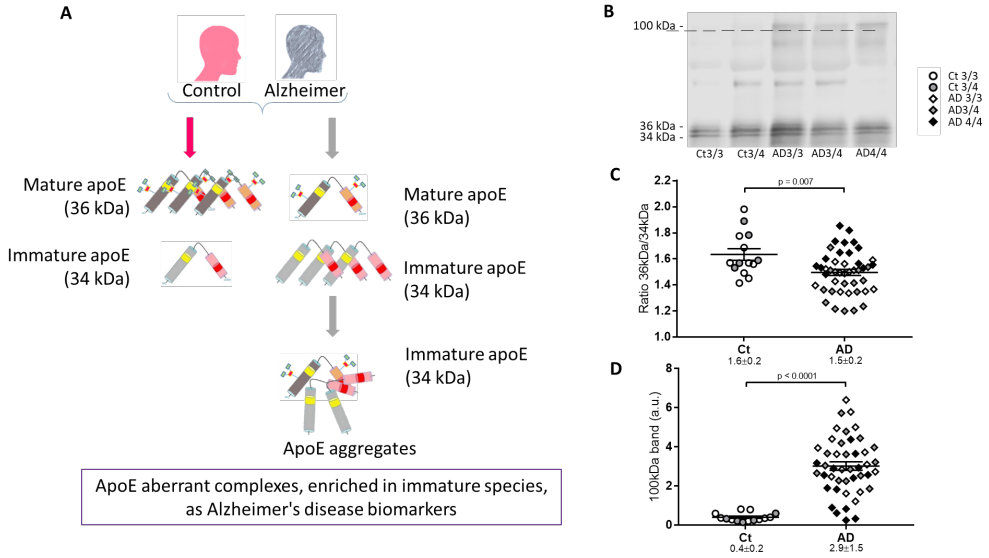
We are looking for a company interested in the development of the patent, and particularly in the design of a kit that is easy to apply in clinical areas, through:

i) Financing the employment of personnel dedicated exclusively to the development of the aforementioned kit.

ii) Development by the company itself with our advice and assistance.

The development period of the aforementioned kit (in electrophoresis or ELISA format) is estimated to be between 6 and 12 months.

RELATED IMAGES



A) Scheme illustrating the imbalance between immature and mature forms, and aberrant complexes, of apoE between Alzheimer's Disease patients (AD) and controls. **B)** Representative immunoblot of the electrophoretic separation of apoE in CSF from Alzheimer's Disease patients and controls (with different APOE genotypes; there are no APOE ε4/ε4 controls given that this genotype increases the possibility of suffering Alzheimer's Disease by 8-12 times) resolved with an anti-apoE antibody that recognizes all the variants of apoE. **C)** Densitometric quantification and quotient between the immature forms of apoE (34 kDa, see **B**) and the mature forms (36 kDa, see B). **D)** Densitometric quantification of the 100 kDa dimers/complexes considered to be aberrant, due to their appearance exclusively in Alzheimer's Disease cases (the electrophoretic conditions are denaturing, thus the natural/non-pathological dimers would not be resolved as such, and instead appear as apoE monomers.

CONTACT DETAILS

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