

# Optimization and Validation of an Indicator Cell Assay for Blood-Based Diagnosis of Alzheimers Disease

<https://www.neurodegenerationresearch.eu/survey/optimization-and-validation-of-an-indicator-cell-assay-for-blood-based-diagnosis-of-alzheimers-disease/>

## Principal Investigators

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## Institution

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## Contact information of lead PI

### Country

USA

## Title of project or programme

Optimization and Validation of an Indicator Cell Assay for Blood-Based Diagnosis of Alzheimers Disease

## Source of funding information

NIH (NIA)

## Total sum awarded (Euro)

€ 1,827,753.21

## Start date of award

01/09/2015

## Total duration of award in years

2

## The project/programme is most relevant to:

Alzheimer's disease & other dementias

## Keywords

Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Brain Disorders... Dementia...

### **Research Abstract**

? DESCRIPTION (provided by applicant): We are developing the Indicator Cell Assay Platform (iCAP), a broadly applicable and inexpensive platform for blood-based diagnostics that can be used for early detection of disease, and as a companion diagnostic for drug development. The iCAP uses cultured cells as biosensors, capitalizing on the ability of cells to respond differently to signals present in the serum (or other biofluid) from normal or diseased subjects with exquisite sensitivity, as opposed to traditional assays that rely on direct detection of molecules in blood. Developing the iCAP involves exposing cultured cells to serum from normal or diseased subjects, measuring a global differential response pattern, and using it to build a reliable disease classifier comprised of a small number of features. Deploying the iCAP involves measuring only expression genes that are features of the disease classifier using cost-effective tools. Indicator cells are chosen based on the disease application, and those typically selected have known relationships to the disease pathology. The iCAP can overcome barriers to blood-based diagnostics like broad dynamic range of blood components, low abundance of specific markers, and high levels of noise. We have demonstrated proof of concept for an iCAP for the early detection of Alzheimer's disease (AD) that can identify AD from plasma at two stages of progression, presymptomatic AD (no clinical symptoms but markers of AD pathophysiology present) and early stage AD, with 77-82% accuracy compared to normal controls. The focus of this proposal is to optimize the assay to generate a robust and accurate classifier of AD that can distinguish three sample classes (presymptomatic AD, early stage AD and normal controls), and rigorously validate the assay with extended cohorts. To do this, we will 1) Identify optimal indicator cells and experimental conditions for the AD iCAP. 2) Generate new data with the optimized assay conditions and use them to train and test an optimized classifier of presymptomatic and early AD that can also distinguish AD from non-AD dementia. 3) Rigorously validate the robustness and accuracy of the classifier by training and testing on extended cohorts from two different clinical sources. Our goal is to generate a robust final classifier based on expression levels of = 100 genes that can distinguish two stages of AD progression with blind predictive accuracy of 90% with 90% sensitivity and specificity (over normal samples and those with non-AD dementia) that can be used for early detection of AD and for clinical trials.

### **Lay Summary**

**PUBLIC HEALTH RELEVANCE:** We are developing a non-invasive diagnostic tool to detect Alzheimer's disease (AD) from blood samples called the indicator cell assay platform (iCAP). In the assay, patient serum is applied to specifically selected standardized indicator cells and the multicomponent response of the cell provides the readout. The iCAP will succeed where other methods have failed by exploiting cells' natural capability to amplify and integrate multi-analyte signals. We aim to experimentally optimize and rigorously validate the AD iCAP to generate a robust and accurate assay for early detection of AD and for use in clinical trials.

### **Further information available at:**

#### **Types:**

Investments > €500k

#### **Member States:**

United States of America

#### **Diseases:**

Alzheimer's disease & other dementias

**Years:**

2016

**Database Categories:**

N/A

**Database Tags:**

N/A