ADNI Alzheimer's Disease Neuroimaging Initiative

Lumipulse *G* β-Amyloid Plasma 1-42, 1-40 and Ratio Results

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Summary

The primary objective of testing the samples provided from the Alzheimer's Disease Neuroimaging Initiative (ADNI) sample bank was to evaluate the performance of Fujirebio's Lumipulse® G β-Amyloid 1-42 plasma and Lumipulse® G β-Amyloid 1-40 plasma when used as the β-Amyloid (1-42/1-40) ratio in plasma in increasing the prediction of whether an individual is amyloid PET positive beyond the level of prediction possible using age and apolipoprotein E (APOE) genotype.

Plasma samples were provided by the Alzheimer's Disease Neuroimaging Initiative (ADNI) repository of biofluids from participants who had been characterized in terms of ATN status. A balanced sample size of those that were amyloid PET positive and amyloid PET negative was prospectively identified as well as a prespecified analytic plan of the type typically required in industry to support decisions about whether to rely on a method. The results of this first study will be used to prioritize assays for inclusion in a larger, more extensive study and as a pilot study to determine appropriate cutoffs for future testing.

Method

Plasma samples were collected in 10 mL K2-EDTA (purple top) tubes and centrifuged within 1 hour of collection at room temperature in a clinical centrifuge at 1300 g for 10 minutes. Plasma samples were transferred to 13 mL Sarstedt polypropylene transfer tubes and then frozen on dry ice at each ADNI center followed by overnight shipment on dry ice to the ADNI Biobank at the University of Pennsylvania.

Aliquoting was performed, after thawing at room temperature, into 0.5 mL polypropylene tubes, and samples were frozen and stored at –80°C. Samples were tested at the University of Pennsylvania. Prior to testing samples were thawed at room temperature for a minimum of 30 minutes. 0.5 mL plasma samples were vortexed for 10 sec. and centrifuged according to instructions in Fujirebio IRC insert. Samples were then transferred to Lumipulse system recommended sample cups for testing.

The description of the calibrators and reagents are below:

Lumipulse® G β-Amyloid 1-42 plasma Immunoreaction Cartridges
For use with the LUMIPULSE G System for the quantitative measurement of β-Amyloid$_{1-42}$ in human plasma.

Lumipulse® G β-Amyloid 1-42 plasma Calibrators

For use in the calibration of the LUMIPULSE G System for the quantitative determination of β-Amyloid$_{1-42}$ in human plasma.

Lumipulse® ***G*** β-Amyloid 1-40 plasma Immunoreaction Cartridges
For use with the LUMIPULSE G System for the quantitative measurement of β-Amyloid$_{1-40}$ in human plasma.

Lumipulse® ***G*** β-Amyloid 1-40 plasma Calibrators
For use in the calibration of the LUMIPULSE G System for the quantitative determination of β-Amyloid$_{1-40}$ in human plasma.

The validity of test results was ensured through using Lumipulse ***G*** B-Amyloid Controls.

The results from the testing were obtained and combined with the de-identified sample IDs and were uploaded into the LONI database per the named files named in the dataset information section.

Version Information

This is the first version of this document.

Dataset Information

This methods document applies to the following results provided uploaded into the LONI database:

Dataset Name	Date Submitted
FUJIREBIOABETAPLASMA	05 January 2023

About the Authors

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