ADNI Alzheimer's Disease Neuroimaging Initiative

Lumipulse *G* β-Amyloid 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 validate the Lumipulse ***G*** β-Amyloid Ratio (1-42/1-40) cutoff for inclusion in the Lumipulse ***G*** β-Amyloid Ratio (1-42/1-40) package insert. To support the proposed intended use, the results obtained from CSF sample testing will be compared to the Amyloid Positron Emission Tomography (PET) results within the LONI database.
The secondary objective of testing the samples was to acquire pTau and tTau results using he Lumipulse G pTau and tTau reagents on the Lumipulse G System. No additional analysis is to be performed on these samples at this time. In order to preserve potential bias by issuing the results in a public database, these results at Fujirebio have been blinded and locked. A proposed analysis of the sample results will be provided for approval and the test results will be provided at a later date. This submission is focused on the acquisition of the Amyloid PET results and provision of the Lumipulse G Amyloid results.

Method

Samples were stored at Fujirebio Diagnostics, Inc. at 201 Great Valley Pkwy, Malvern PA at a storage temperature of ≤ -60˚C upon receipt from ADNI. Prior to testing, the samples were thawed for ≥ 45 mins at room temperature, mixed on a horizontal roller mixer for approximately 20 mins, and then tested in single replicate within 3 hours of thaw using the LUMIPULSE G System in combination with the Lumipulse ***G*** β-Amyloid 1-42 and 1-40 reagents.

The 422 samples were split into 10 run sets and tested in combination with the quality control samples provided by ADNI (ADNI Pool 59 Normal and ADNI Pool 56 AD). One aliquot of each control sample pair was tested in single replicate during each run.

The description of the calibrators and reagents are below:

Lumipulse ***G*** β-Amyloid 1-42 Immunoreaction Cartridges
For use with the LUMIPULSE G System for the quantitative measurement of β-Amyloid$_{1-42}$ in human cerebrospinal fluid (CSF).

Lumipulse ***G*** β-Amyloid 1-42 Calibrators
For use in the calibration of the LUMIPULSE G System for the quantitative determination of β-Amyloid$_{1-42}$ in human cerebrospinal fluid (CSF).

Lumipulse ***G*** β-Amyloid 1-40 Immunoreaction Cartridges
For use with the LUMIPULSE G System for the quantitative measurement of β-Amyloid$_{1-40}$ in human cerebrospinal fluid (CSF).

Lumipulse ***G*** β-Amyloid 1-40 Calibrators
For use in the calibration of the LUMIPULSE G System for the quantitative determination of β-Amyloid$_{1-40}$ in human cerebrospinal fluid (CSF).

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
FUJIREBIOABETA.csv	07 January 2020
FUJIREBIOABETA_DICT.csv	07 January 2020

Attachments

PPSB Response for Residual Samples – Fujirebio.pdf – August 3, 2017

About the Authors

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