ADNI Alzheimer's Disease Neuroimaging Initiative

Janssen Plasma p217+tau Simoa assay

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Background:

Objective diagnosis and staging of Alzheimer's Disease using biomarkers has become a reality in the last decade, using CSF or PET imaging. Less invasive methods for collecting this data, such as from plasma, can greatly improve access to these biomarkers. To address this need Janssen R&D has developed a highly sensitive assay for measuring p217+tau in human plasma which accurately predicts brain amyloid and tau status[1-6]. This assay has now been licensed to Quanterix for global use, and will be offered as an LDT in their CLIA lab by end of 2023[7].

ADNI has collected plasma, PET imaging, and cognition on a large cohort of subjects with longitudinal data, with one aim being to support validation of promising Alzheimer's Disease biomarkers. Here we evaluate the Janssen plasma p217+tau Simoa assay in a pilot cohort of ADNI2/3 plasma samples, with comparison to existing Amyloid and Tau status and cognition data.

Methods and Procedures

A set of n=130 plasma samples from ADNI2/3 was sent from University of Pennsylvania to Quanterix (Billerica, MA), acting as subcontractor for Janssen R&D. 3 aliquots each of 2 control samples was included, to be included on each Simoa plate. Plasma p217+tau data was generated at Quanterix per SOP established with Janssen, then shared with Janssen for technical QC. Data was then sent to University of Pennsylvania for analysis.

Technical specifications for Janssen plasma p217+tau Simoa assay:

- Platform = Simoa HD-X
- Program format = 3-step
- Capture Ab = pT3 (epitope = aa 210-220, with required phosphorylation of aa 212 and 217)
- Detector Ab = hT43 (epitope = aa 7-20)
- Calibrator = synthetic peptide comprised of 20mer peptide covering hT43 epitope – PEG4 linker - 20mer peptide covering pT3 epitope
- Calibrator range: 0.002 – 10 pg/ml
- LLOD = 0.0007 pg/ml
- LLOQ = 0.0187 pg/ml
- ULOQ = 10 pg/ml
- Sample type: K^2-EDTA plasma

- Suggested dilution of samples: 1:2 (as in ADNI pilot)
- Dilution linearity: 1:2 to 1:16 dilution
- Intra-test precision: 5.06 +/- 4.09% (avg +/- SD of n=147 plasma samples in ADNI pilot, duplicate measures)
- Inter-test precision: 6.98, 4.48, 4.16% (CV% of n=5 plates measurements for peptide-based controls at 0.08, 0.36, and 1.47 pg/ml in the ADNI pilot)
- Demonstrated sample stability: 8 hrs RT, 72 hrs 4°C, 3 FTs

Version Information

Version 2

-Updates = adding technical performance specs in "Methods and Procedures" section

Data Description

Briefly describe the purpose of the study and the research question(s) the data addresses: the *purpose of the study is to provide clinical validation of the Janssen plasma p217+tau data, regarding its ability to predict Amyloid and Tau status and burden (derived from PET or CSF) and change in these metrics.*

There are no missing data or incomplete measures.

References

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7. https://www.quanterix.com/press-releases/quanterix-announces-new-agreement-to-advance-blood-based-alzheimers-disease-detection/

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