

NCRAD Biomarker Assay Lab

An Update to the Alzheimer's Disease Research Centers

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Keeping the End in Mind – Biomarker Assay Lab Goal

- Advance neurodegenerative disease research where standardization of processes and delivery of reliable and consistent research biomarker results can be achieved

Currently Available Assays

- Quanterix Simoa HD-X
 - Nf-Light Advantage Kit
 - pTau 181 v2 Advantage Kit
 - Neurology 2 Plex B Advantage Kit (NfL, GFAP)
 - Neurology 4 Plex E Advantage Kit (NfL, GFAP, Abeta 40, Abeta 42)
- Fujirebio Lumipulse
 - Lumipulse G β -Amyloid 1-42 Plasma Assay (January 2023)
 - Lumipulse G β -Amyloid 1-40 Plasma Assay (January 2023)
 - Lumipulse G pTau 181 Plasma Assay (January 2023)
- AlzPATH (Simoa HD-X)
 - pTau217 (July 2023)



ADCFB Initiative

- Participation
 - 24 ADRCs are providing samples prospectively
 - ~80 samples received per week
- Data Returns
 - Assays: N4PE (NfL, GFAP, Abeta 40, Abeta 42) and pTau 181
 - October 2022
 - 1846 samples
 - 16 Centers
 - April 2023 (just occurred)
 - 1023 samples
 - 19 Centers
- Data is returned via NACC
 - Working with NACC and the ADRC Biomarker Steering Committee to develop data return template compatible with the NACC “Data Front Door”
 - This will enable broader sharing of plasma biomarker data in the future and integrated with other data streams

ADRC_Site	PT_ID	Specimen_Barcode	Specimen_Quantity	Unit_of_Measure	LAB_ID	Lab_Study_ID	Analysis_Date	INST_ID	Assay_Platform	Assay_Name	Assay_Lot_No.	Avg_NFL_Conc	Avg_GFAP_Conc	Avg_Abeta_40_Conc	Avg_Abeta_42_Conc	Unit_of_Measure	Notes
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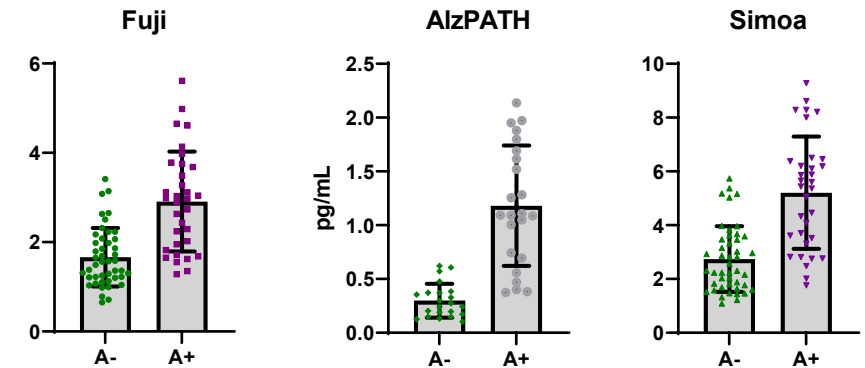
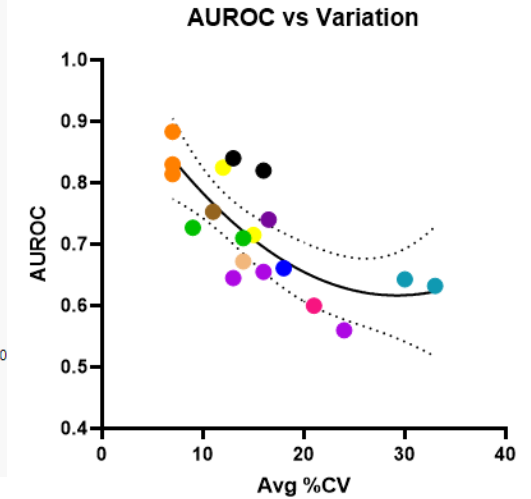
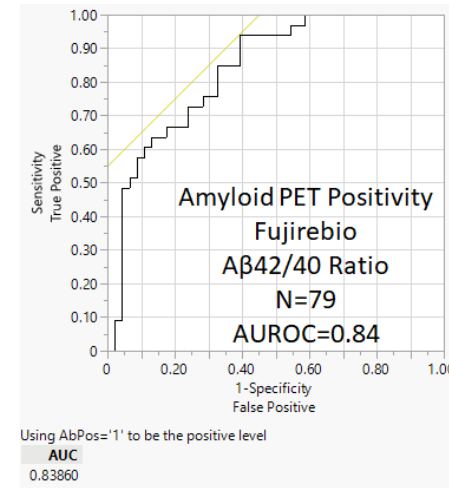


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Changing Assays in ADCFB Initiative

Process of changing Assays for ADCFB

- First Example: Changing from A β 42/40 in N4PE with A β 42/40 on Lumipulse
 - Reason: improved analytical precision, improved AUROC
 - Bridge (analysis of some samples ≥ 200 on both platforms)
 - Share harmonization methods within data description files
- Second Example: Changing from pTau181 to pTau217
 - Reason: Improved fold change and AUROC for amyloid
 - Bridge (analysis of some samples ≥ 200 on both platforms)
 - Share harmonization methods within data description files



Assay	Fold Change	AUROC A+
Fujirebio pTau181	1.7	0.92
AlzPATH pTau217	4.0	0.96
Simoa pTau181	1.9	0.91

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