NeuroABC

ACCESS Biomarker Collection

Beckman Coulter:

We utilize IVD compliant level process controls and reproducibility into RUO assay development

Start Exploring

NeuroABC

ACCESS Biomarker Collection

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Analyzers

NeuroABC

ACCESS Biomarker Collection

Changing how neurodegenerative diseases are researched, investigated, diagnosed, and monitored.

The promising pipeline of blood-based biomarkers in the Neuro ACCESS Biomarker Collection meets a full range of neurodegenerative research needs from early translation research to full scale test commercialization.

Partnering with Beckman Coulter provides ACCESS to a breadth of assays across a wide spectrum of diseases coupled with a focused disease-area initiative using a scalable, global platform.

Biomarker Research Pipeline Areas of Focus

- **AMYLOID PATHOLOGY LANDSCAPE**
- **EARLY TAU PATHOLOGY DETECTION**
- **CO-PATHOLOGIES FOR A RANGE OF NEURODEGNERATIVE DISEASES**
- **PROTOTYPIC ASSAYS FOR GENETIC RISK STRATIFICATION**

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Value for Pharma and CROs

Advantages of Using the Future IVD Platform in Clinical Trials

Why is making a strategic decision regarding the diagnostic platform used for clinical trials increasingly critical for pharmaceutical companies on the front lines of developing novel Alzheimer's disease (AD) therapeutics?

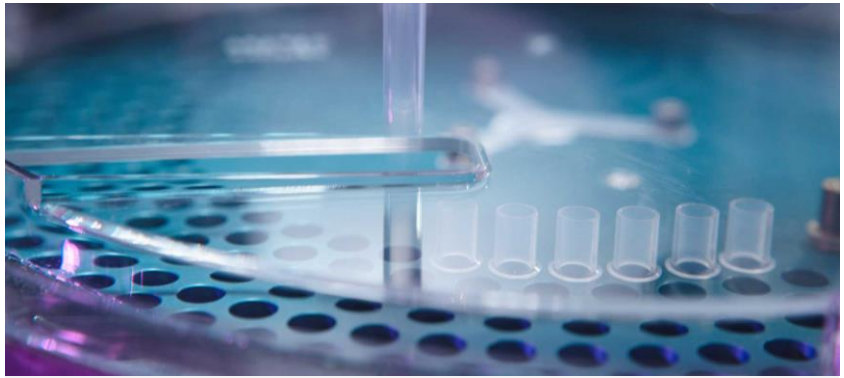
- Regulatory compliance, quality assurance, training and accreditation.[1]
- Technology transfer — moving the test from the research laboratory to the clinical laboratory

What exists today as a pipeline of blood-based biomarkers and RUO assays points toward a possible future of groundbreaking diagnostics. Core labs with in-house access to the right neurodegenerative pipeline on a high-throughput, highly precise, and reproducible platform will be positioned to lead the way.

1. Clinical Laboratory Technology Transfer Navigating the Challenges of Clinical Laboratory Technology Transfer — FasterCapital.

The advent of highly sensitive and specific blood-based biomarkers for neurodegenerative disease (NDD) pathology is revolutionizing the research and development of potential simpler, less invasive, and more cost-effective methods to investigate and understand disease progression, and treatment response. These biomarkers hold promise for future clinical applications, including screening, diagnosis, prognosis, and monitoring.

Choose a Partner Who's Rapidly Changing the Research and Diagnostics Landscape



Incorporation of blood-based biomarkers as a research screening tool prior to clinical trial enrollment can provide up to **58% screening cost savings,** more convenient patient recruiting, and reduced volunteer time[2]

Data from screening on the IVD platform provides **deeper insight into assay performance** characteristics within the target clinical population, even before the IVD test is commercialized

2. Karikari TK, Ashton NJ, Brinkmalm G, Brum WS, Benedet AL, Montoliu-Gaya L, Lantero-Rodriguez J, Pascoal TA, Suárez-Calvet M, Rosa-Neto P, Blennow K, Zetterberg H. Blood phospho-tau in Alzheimer disease: analysis, interpretation, and clinical utility. Nat Rev Neurol. 2022;18(7):400-18.

Can Prescreening for p-Tau217 Turn into Huge Recruitment Cost Savings?

Accelerate Regulatory Approval and Facilitate Research Collaboration

Regulatory agencies, including the FDA, are increasingly focused on the performance and clinical utility of diagnostics, particularly when they are intended to guide the use of a therapeutic (e.g., companion diagnostics). Leveraging the same platform across all phases of trials[3]:

- Streamlines data management
- Increases data integrity and consistency
- Enhances regulatory compliance
- Reduces rework (and subsequently costs)

3. Pharmaceutical Technology. The benefits of using a nimble platform from phase to phase. 2024, https://www.pharmaceutical-technology.com/sponsored/the-benefits-of-using-a-nimble-platform-from-phase-to-phase/

A Valuable Partner in Pre-Clinical NDD Research

An ACCESS Biomarker Collection collaboration with Beckman Coulter establishes a partnership that can span from early clinical feasibility to widespread commercial availability and scalability.

- ACCESS to a growing portfolio of blood-based biomarkers, assays and support services aligns to your business objectives
- ACCESS to global deployment on the high-throughput instruments already in field

Generate Enhanced Real-World Evidence

Conducting clinical trial research using an RUO assay on an IVD platform enables a head-to-head data comparison between the data collected during clinical trials and the data generated from routine clinical testing once the diagnostic and drug are on the market.

Platform consistency facilitates the collection and analysis of real-world data, which is increasingly important for understanding long-term treatment effectiveness, safety, and healthcare applications in diverse patient populations outside the controlled clinical trial setting.

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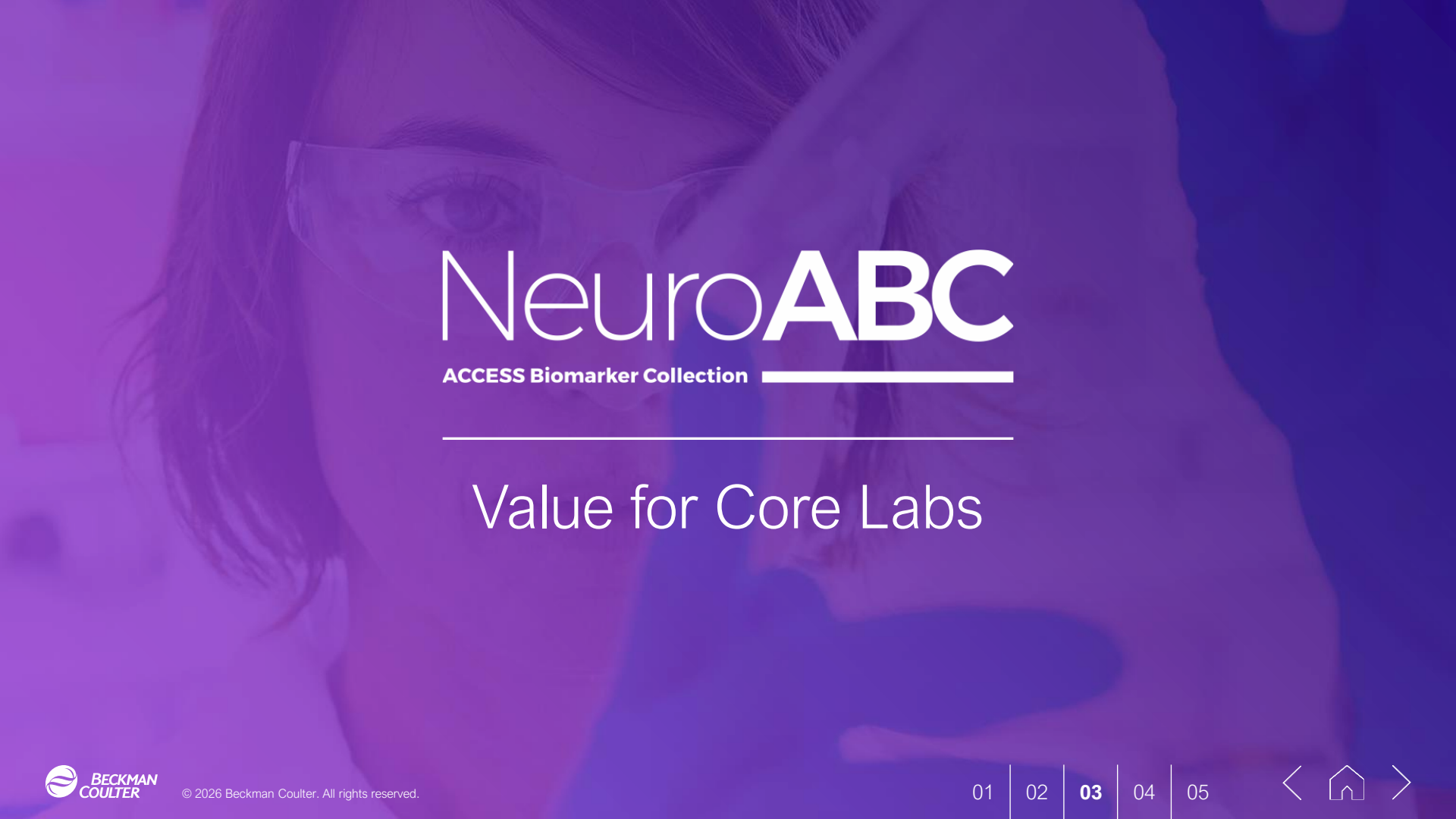


NeuroABC

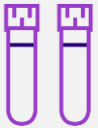
ACCESS Biomarker Collection

Value for Core Labs

ACCESS Biomarker Collection

An ACCESS Biomarker Collection collaboration with Beckman Coulter provides you with a neurodegenerative disease research roadmap that centers on three key areas spanning our portfolio of diagnostic solutions:

Reliable, streamlined laboratory workflows



Increased testing sensitivity

Our pipeline of innovative biomarkers

8. WHO. Dementia. World Health Organization. 2025, https://www.who.int/news-room/fact-sheets/detail/dementia
9. Gauthier S, Rosa-Neto P, Morais J, Webster C. World Alzheimer Report 2021: Journey through the Diagnosis of Dementia. London, England: Alzheimer's Disease International; 2021.

The Challenge:
Current Standard of Care Diagnostics are not Scalable

The current methods of testing to accurately detect elevated levels of amyloid plaque are inherently limited in their ability to scale.

Positron Emission Topography (PET) scanning

- Expensive
- Patient access limited by PET scanner installation

Cerebral Spinal Fluid (CSF) testing with mass spectrometry

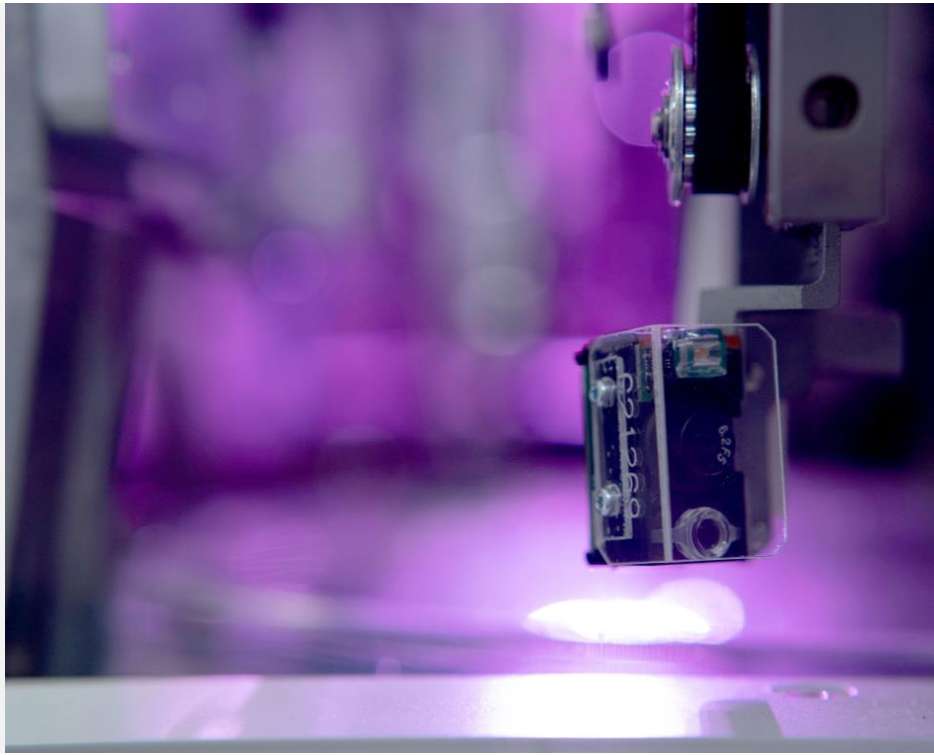
- Expensive
- Time consuming
- Requires lumbar puncture expertise

The Solution:
A More Accessible Standard of Care

Blood-based biomarker testing offers the patient accessibility and cost efficiency benefits necessary to accelerate the move from diagnostic to therapeutic availability.

Blood-based biomarker immunoassay testing

- Inexpensive
- Low-risk
- Potentially scalable on existing diagnostic platforms



How Pharma Investment is Opening the Floodgates

Over the past 30 years, the pharma industry has invested more than $42.6 billion in Alzheimer's disease therapeutic clinical trials.

187 Alzheimer's therapeutic clinical trials ongoing in 2024[10]

The leading indicators of diagnostic demand indicate an immense potential need

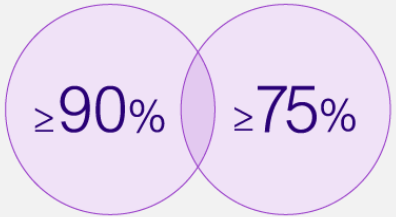
90 Phase 2 trials
48 Phase 3 trials[10]

10. Alzheimer's Disease Drug Development Pipeline: 2024

“Alzheimer’s Association Releases Its First Clinical Practice Guideline (CPG) for Blood-Based Biomarker Tests”

At the 2025 Alzheimer’s Association International Conference (AAIC), the Alzheimer’s Association unveiled Clinical Practice Guidelines (CPG) focused on the role of blood-based biomarker tests in assessing levels of Alzheimer’s disease pathology in people with cognitive impairment.

The following CPG recommendations apply to patients with cognitive impairment being seen in specialized care for memory disorders:



At BBM tests with ≥90% sensitivity and ≥75% specificity can be used as a triaging test, in which a negative result rules out Alzheimer’s pathology with high probability. A positive result should also be confirmed with another method, such as a cerebral spinal fluid (CSF) or amyloid positron emission tomography (PET) test.

Blood-Based Biomarker (BBM) tests with ≥90% for both sensitivity and specificity can serve as a substitute for PET amyloid imaging or CSF Alzheimer’s biomarker testing.

Alzheimer’s Association. Alzheimer’s Association Releases Its First Clinical Practice Guideline for Blood-Based Biomarker Tests. Alzheimer’s Association.

Why p-Tau217?

Plasma p-Tau217 levels have shown correlation with amyloid pathology, which has implications for identifying neurodegenerative diseases such as Alzheimer's disease. Measuring p-Tau217 may help to further research into AD pathology, flag samples from those with early-stage AD pathology, and help distinguish AD from other forms of dementia.

An ACCESS Biomarker Collection collaboration with Beckman Coulter is a giant step towards blood-based Alzheimer's disease testing that:

Is sensitive, accurate and reliable in detecting targeted NDD biomarkers in blood

Is easily accessible to patients and clinicians through a widespread installed base

Requires no special labor skills compared to other routine diagnostic tests

Is high-throughput

Leverages workflow automation

Is affordable relative to alternate testing methods

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- **APOE ε4**
- **BD-Tau**

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BD p-Tau217

MTBR-Tau (CSF)

TDP-43

p-Tau205

IVD ASSAYS IN DEVELOPMENT

P-Tau217*

p-Tau217/ß-Amyloid 1–42 Plasma Ratio*

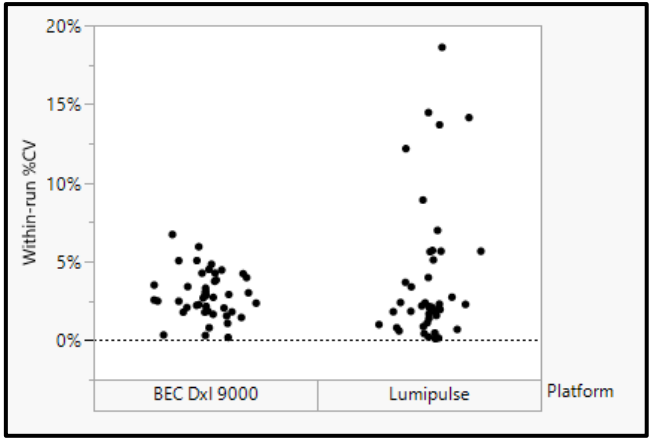
APOE ε4*

*IVD Assay in Development. Not currently for use in diagnostic procedures.

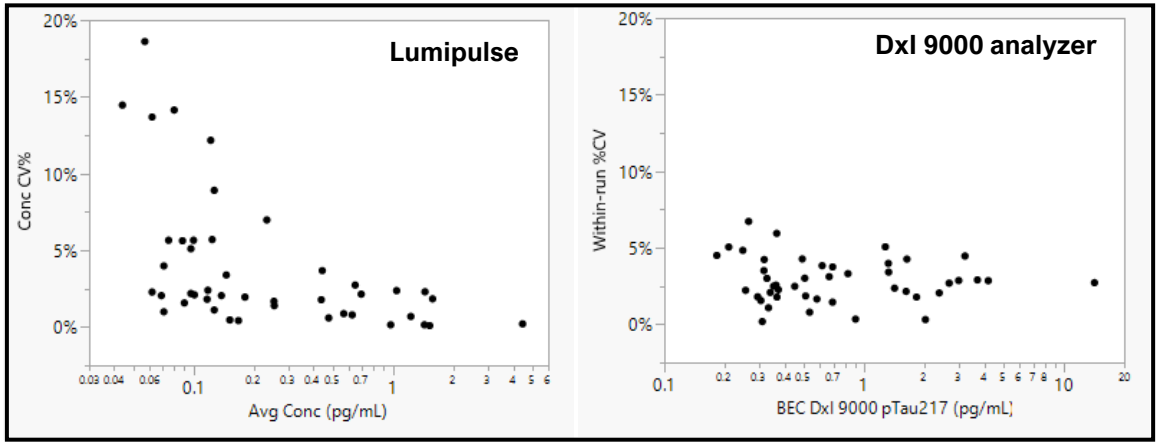
p-Tau217

Precision Profile Comparison

Study: N=45 samples were tested in duplicate using the Beckman Coulter Access and Fujirebio Lumipulse RUO p-Tau217 assays.



Within-run Precision Profile



- Access p-Tau 217 (RUO) on the **DxI 9000 Immunoassay Analyzer** maintained within-run **%CV ≤ 10% across all tested concentrations**.
- **Lumipulse** p-Tau217 (RUO) exhibited higher within-run precision, and **at low biomarker concentrations (<1 pg/mL) %CV increased to >15%**

At low concentrations, the DxI 9000 Immunoassay Analyzer showed significantly better reproducibility, with tighter imprecision and less variability in measurement.

Reference: Data on File

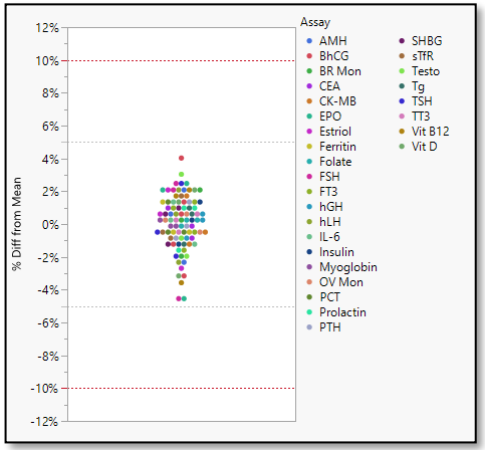
Lot-to-Lot Reproducibility

Study: Another good aspect of the Access p-Tau217 (RUO) assay is we are controlling lot-to-lot reproducibility. We ran 12 samples across 3 instruments on 3 reagents across 3 days with 2 runs per day and 2-3 replicates per run. The Access p-Tau217 (RUO) assay demonstrated reproducibility aligned with DxI 9000 Immunoassay Analyzer menu.

Sample ID	Mean (fg/mL)	N	Variance Component (CV%)						Within Lab Precision	Total Reproducibility
			W/in Run	Bet. Run	Day	Calib.	Inst.	Reagent Pack Lot		
AD1	439.8	648	4.2%	1.5%	1.4%	2.1%	0.0%	1.9%	4.7%	5.5%
AD2	561.5	684	3.6%	2.2%	0.0%	2.0%	0.0%	1.7%	4.3%	5.0%
C4QCpt01	354.3	864	3.8%	0.5%	1.2%	2.6%	0.0%	1.2%	4.1%	5.0%
Normal1	204.7	648	4.5%	0.0%	1.9%	3.1%	0.6%	1.6%	4.9%	6.0%
Normal2	301.7	648	3.6%	1.1%	0.0%	2.8%	0.0%	1.8%	3.8%	5.1%
Normal3	489.9	648	3.1%	0.7%	0.0%	2.4%	1.6%	1.7%	3.1%	4.6%
Normal4	261.0	648	4.4%	0.0%	0.7%	2.9%	0.9%	1.1%	4.5%	5.5%
QC001	70.3	870	7.4%	4.1%	0.0%	4.9%	2.3%	0.0%	8.5%	10.0%
QC002	207.3	816	5.9%	3.6%	0.0%	2.7%	0.0%	1.7%	6.9%	7.6%
QC003	653.8	864	3.7%	1.5%	1.1%	2.0%	0.0%	0.7%	4.1%	4.6%
RecAgQCpt01	228.7	840	3.7%	0.4%	1.9%	3.0%	0.0%	1.0%	4.2%	5.3%

DxI 9000 Immunoassay Analyzer Menu

% Difference from mean by reagent pack lot



Access p-Tau217 (RUO) assay demonstrates reproducibility aligned with DxI 9000 Immunoassay Analyzer assay menu performance

Reference: Data on File

Method Comparison

Purpose: Evaluate assay performance of the Beckman Coulter prototype Access p-Tau217 assay v1 on the DxI 9000 Immunoassay Analyzer in characterized samples.

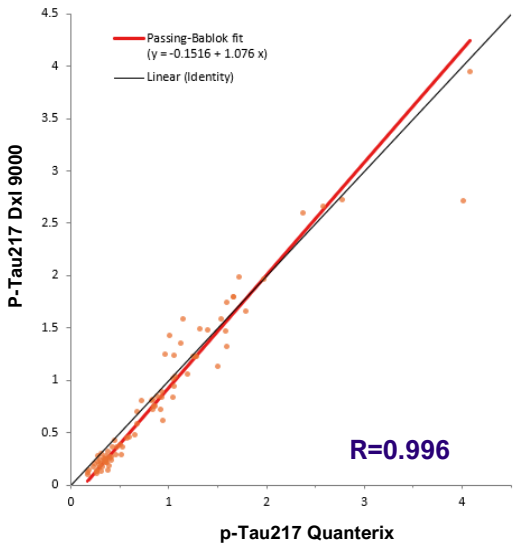
Reference Methods:

- Quanterix Simoa
- Fujirebio Lumipulse

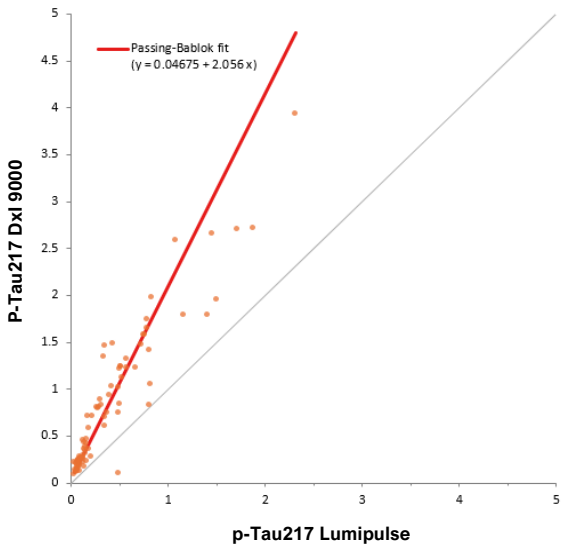
Study cohort:

- Cohort of 90 subject/samples
  - 45 with AD diagnosis (characterized with CSF Aβ 42 / Aβ 40)
  - 20 with other neurodegenerative disease diagnoses
  - 25 aged match controls

DxI 9000 Immunoassay Analyzer vs. Quanterix Simoa



DxI 9000 Immunoassay Analyzer vs. Fujirebio Lumipulse



Excellent correlation of Beckman Coulter and Quanterix p-Tau217 RUOs with limited bias
Excellent correlation of Beckman Coulter and Lumipulse p-Tau217 RUOs with proportional positive bias

Mondesert E, Dupuy AM, Cherif D, Wynveen P, Carlson C, Szabo M, Ley K, Knutson C, Blanchet JS , Delaby C, Busto G, Hirtz C (1), Gabelle A, Cristol JP, Lehmann S. Novel plasma assay for p-Tau217: Evaluation in a cohort of individuals with cerebral amyloidosis and Alzheimer's disease. CTAD 2024

Assays Available & In Development

ASSAYS FOR RESEARCH USE ONLY

- **P-Tau217***
- **ß-Amyloid 1–42**
- **APOE ε4**
- **BD-Tau**

GFAP

NfL

RESEARCH USE ONLY ASSAYS IN DEVELOPMENT

BD p-Tau217

MTBR-Tau (CSF)

TDP-43

p-Tau205

IVD ASSAYS IN DEVELOPMENT

P-Tau217*

p-Tau217/ß-Amyloid 1–42 Plasma Ratio*

APOE ε4*

*IVD Assay in Development. Not currently for use in diagnostic procedures.

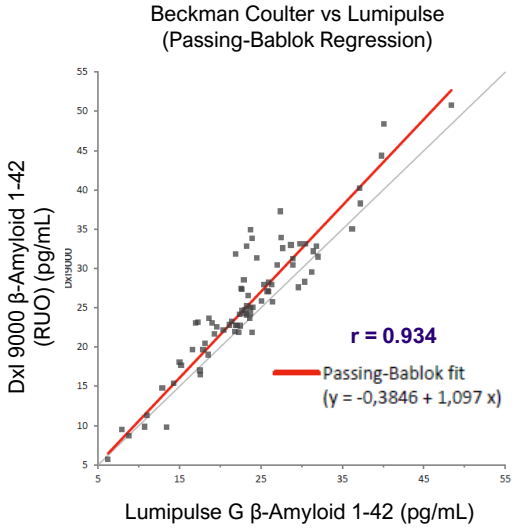
β-Amyloid 1-42

Method Comparison

Study: Evaluate the Access β-Amyloid 1-42 (RUO) assay on DxI 9000 Immunoassay Analyzers compared to the Lumipulse G β-Amyloid 1-42 assay.

- The Beckman Coulter Access β-Amyloid 1-42 (RUO) assay showed a positive bias on the DxI 9000 Immunoassay Analyzer with a slope of 1.097.
- The Beckman Coulter Access β-Amyloid 1-42 (RUO) assay had an excellent correlation, r=0.934.

Beckman Coulter DxI 9000 Immunoassay Analyzer vs. Fujirebio Lumipulse



Strong correlation was observed between Fujirebio Lumipulse G β-Amyloid 1-42 and Beckman Coulter Access β-Amyloid 1-42 (RUO) assays on DxI 9000 Immunoassay Analyzer.

Reference: EDMS Abeta 42 Plasma Feasibility Readiness Review RUO

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P-Tau217*

p-Tau217/ß-Amyloid 1–42 Plasma Ratio*

APOE ε4*

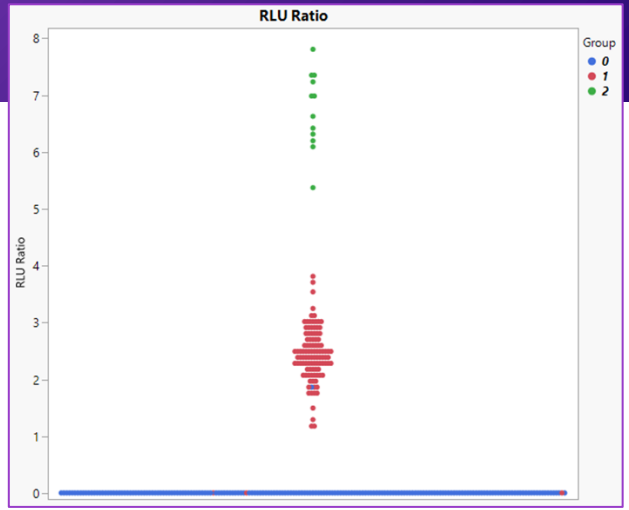
*IVD Assay in Development. Not currently for use in diagnostic procedures.

APOE ε4

Concordance with PCR Genotyping — Study 1

Study: Concordance of Access APOE ε4 (RUO) assay on the DxI 9000 Immunoassay Analyzer in a cohort of 300 clinically characterized and ε4 zygosity status assessed, compared to PCR genotyped samples:

- 300 subjects (68% female, 32% male)
- 54–93 years (median 77)
- Cognitively normal (35.3%), or presenting with variable stages of cognitive decline (33% early MCI, 22% late MCI, 8% dementia) and non-AD dementia (1.3%) were evaluated
- Single replicates, single reagent lot, single DxI 9000 Immunoassay Analyzer
- Amyloid status was determined by amyloid PET imaging



Sample Count			PCR Test: APOE ε4 Zygosity -/-	PCR Test: APOE ε4 Zygosity +/-	PCR Test: APOE ε4 Zygosity +/+	PCR Test: Total	Concordance (%)
DxI 9000 Immuno-assay Analyzer	APOE ε4 Zygosity	Negative (-/-)	181	0	0	181	100.00
		Heterozygous (+/-)	2	105	0	107	98.10
		Homozygous (+/+)	0	0	12	12	100.00
	Total		183	105	12	300	99.30

	Predicted Group (-/-)	Predicted Group (+/-)	Predicted Group (+/+)
Minimum Ratio	0.003	1.156	5.372
Max Ratio	0.007	3.786	7.806
Mean Ratio	0.004	2.404	6.726
SD Ratio	0.001	0.462	0.684
SD Separation G1/G0	5.2		
SD Separation G2/G1	5.2		

Access APOE ε4 plasma immunoassay displays 99.3% overall concordance with a PCR genetic test with 100% concordance in APOE ε4-/- and APOE ε4+/+ groups.

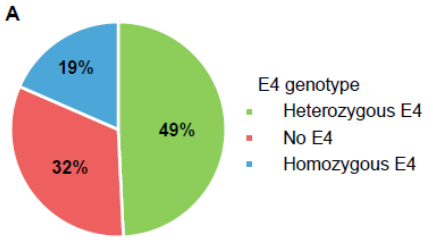
Szabo M et al. High-throughput, fully automated immunoassay for detecting zygosity of apolipoprotein ε4 (APOE ε4) in plasma EDTA. 17th Clinical Trials on Alzheimer's Disease (CTAD), Madrid, Spain, October 29 – November 1, 2025.
20250726-BE294-0064-ID9032-APOE Genotyped Sample Testing

Concordance with PCR Genotyping — Study 2

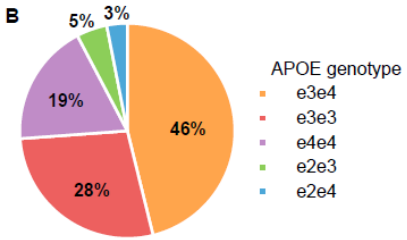
Study: The Access APOE ε4 (RUO) assay on the Access 2 and DxI 9000 Immunoassay Analyzers and Lumipulse G ApoE4 & Pan-ApoE RUO Assay on the Lumipulse G1200 analyzer were evaluated for concordance to an established APOE genotyping method.

- Utilized 65 EDTA samples which underwent ApoE PCR-based genotyping for clinical purposes to evaluate.

DISTRIBUTION OF APOE GENOTYPE RESULTS

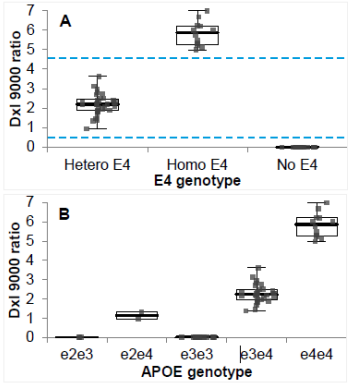


Distribution of APOE E4 zygosity based on genotype results (n=65).



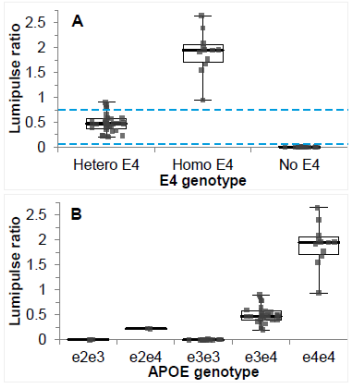
Distribution of APOE genotype (n=65).

BECKMAN COULTER — DxI 9000 APOE ε4 RESULTS



Distribution of results of the Beckman Coulter assay on the DxI 9000 platform by: A. heterozygous or homozygous E4 genotype, and B. APOE genotype. Using the manufacturer's calculated cut-points, shown by blue dashed lines, concordance was 100% with PCR-based genotyping; 100% concordance was also shown with the Access 2 platform.

FUJIREBIO — LUMIPULSE G1200 ApoE4/Pan-ApoE RESULTS



Distribution of results of the Fujirebio Lumipulse assay on the Lumipulse G1200 platform by: A. heterozygous or homozygous E4 genotype, and B. APOE genotype. Using the manufacturer's cut-points provided in the IFU, shown as blue dashed lines, 94% concordance was shown with the PCR-based genotype assay.

The Access APOE ε4 (RUO) assay achieved 100% concordance with PCR-based genotyping across both Access 2 and DxI 9000 Immunoassay Analyzer platforms, outperforming the Fujirebio Lumipulse assay, which demonstrated 94% concordance.

Daniel J. Figdore, Susan Ashrafzadeh-Kian, Joshua A. Bornhorst, Ph.D., Alicia Algeciras-Schimnich, Ph.D. Comparison of Two Automated ApoE4 Proteotype Immunoassays. AAIC 2025. Poster

Method Comparison

Study: Method correlation study to compare the Beckman Coulter Access APOE ε4 RUO assay on the Access 2 and DxI 9000 Immunoassay Analyzers with the Lumipulse G APOE ε4 RUO assay (Item #81453) on the Lumipulse G1200 analyzer.

- K2 EDTA plasma samples with variable APOE ε4 status were tested (n=20).
- All samples were tested on one reagent lot in replicates of two for the Access 2 and DxI 9000 Immunoassay Analyzers and in a single replicate for the Lumipulse G1200 analyzer. Correlation between the methods was determined using Passing-Bablok linear regression.

Sample	Dose Ratio	Calculated Result	
	Lumipulse	Access 2*	DxI 9000*
Sample 1	3.33	7.64	7.69
Sample 2	1.02	4.48	3.73
Sample 3	1.18	4.13	4.10
Sample 4	0.73	3.98	2.81
Sample 5	0.85	3.58	3.02
Sample 6	0.52	3.57	2.01
Sample 7	0.66	3.48	2.81
Sample 8	0.46	3.15	2.73
Sample 9	0.32	2.98	2.59
Sample 10	0.54	2.93	2.67
Sample 11	0.31	2.63	2.13
Sample 12	0.30	2.10	2.05
Sample 13	0.37	1.84	1.47
Sample 14	0.08	0.63	0.44
Sample 15	0.04	0.26	0.14
Sample 16	0.00	0.02	0.00
Sample 17	0.00	0.02	0.00
Sample 18	0.00	0.02	0.00
Sample 19	0.01	0.02	0.00
Sample 20	0.00	0.01	0.00
Correlation with Lumipulse ®		0.89	0.94

Access APOE ε4 assay demonstrated good correlation between Access 2 and DxI 9000 Immunoassay Analyzers, and the Fujirebio Lumipulse Platform

Szabo M et al. High-throughput, fully automated immunoassay for detecting zygosity of apolipoprotein ε4 (APOE ε4) in plasma EDTA. 17th Clinical Trials on Alzheimer's Disease (CTAD), Madrid, Spain, October 29 – November 1, 2025.

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P-Tau217*

p-Tau217/ß-Amyloid 1–42 Plasma Ratio*

APOE ε4*

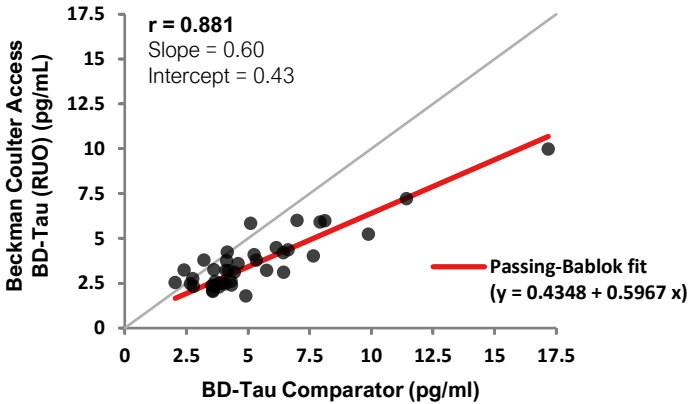
*IVD Assay in Development. Not currently for use in diagnostic procedures.

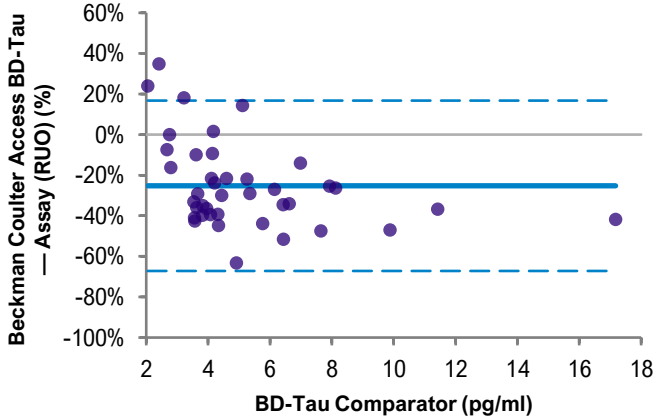
BD-Tau

Method Comparison

Study: Evaluate the Access BD-Tau (RUO) assay on a single DxI 9000 Immunoassay Analyzer compared to an academic partner's "home brew" BD-Tau assay using 40 K2 EDTA Plasma samples measured in duplicate.

- The Beckman Coulter BD-Tau (RUO) assay showed a positive bias on the DxI 9000 Immunoassay Analyzer with a slope of 0.6.
- Both the Beckman Coulter BD-Tau (RUO) and academic partner's "home brew" assays had good correlation, r=0.881.





Strong correlation and precision compared to widely studied competitive assay and advancing to large scale analytical validation.

Ben Schlichtmann, Kara Johnson, Miklos Szabo, Jeff Todtleben, Laura Mediger, Marnie Wallin, and Mikaela Nichkova-Doseva. New High-throughput, fully automated immunoassay for plasma and serum Brain-Derived Tau. AAIC 2025 Poster.

Assays Available & In Development

ASSAYS FOR RESEARCH USE ONLY

- **P-Tau217***
- **ß-Amyloid 1–42**
- **APOE ε4**
- **BD-Tau**

GFAP

NfL

RESEARCH USE ONLY ASSAYS IN DEVELOPMENT

BD p-Tau217

MTBR-Tau (CSF)

TDP-43

p-Tau205

IVD ASSAYS IN DEVELOPMENT

P-Tau217*

p-Tau217/ß-Amyloid 1–42 Plasma Ratio*

APOE ε4*

*IVD Assay in Development. Not currently for use in diagnostic procedures.

NeuroABC

ACCESS Biomarker Collection

01
What is NeuroABC?

02
Value for Pharma / CROs

03
Value for Core Labs

04
Assays Available & In Development

05
Analyzers

Analyzers

Scalable Neurology Assay Solutions to Match Your Lab

Access 2

IMMUNOASSAY ANALYZER

DxI 9000

IMMUNOASSAY ANALYZER