

C2N Diagnostics Revolutionizes Alzheimer's Disease Diagnosis

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Alzheimer's disease remains difficult to diagnose and monitor, and without an easy way to test for biomarkers related to the disease, doctors rely on clinical signs like memory loss or confusion, which could lead to a misdiagnosis. To address this global health concern, C2N Diagnostics developed the Precivity™ biomarker blood tests to diagnose Alzheimer's disease more accurately and at earlier clinical stages. This is important because the sooner Alzheimer's is detected, the sooner newly approved drugs can be used to remove amyloid plaques in the brain, a hallmark of Alzheimer's.

At 95% accuracy, Precivity blood tests rival more costly PET scans and more uncomfortable spinal taps. The company's diagnostic technology uses high-resolution mass spectrometry to quantify specific plasma concentrations into proprietary algorithms. This advancement in the diagnosis of Alzheimer's disease improves accuracy, accessibility, and patient experience.

NIH small business funding has been integral to C2N Diagnostics' success. Nearly \$2 million in Small Business Innovation Research (SBIR) awards from the National Institute on Aging (NIA) helped move the company's PrecivityAD™ test from research to validation and commercialization.

Today, the PrecivityAD tests are available in 49 states, Washington, D.C., and Puerto Rico for people who are age 55 and up with signs or symptoms of mild cognitive impairment undergoing an evaluation for Alzheimer's or dementia. The patient's doctor orders the test, schedules the blood draw, and sends the blood sample to the C2N Diagnostics' lab for analysis. After they receive the report, the physician discusses the findings with their patient.

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C2N Diagnostics' story is a testament to the power of innovative science, a passionate and driven team, ongoing public-private collaboration, and the



C2N Diagnostics

4340 Duncan Ave, St. Louis, MO
63110

State-District

MO-1

Technology

Diagnostic

Primary Institute

Aging
(NIA)

Secondary Institute

N/A

Project Details from NIH RePORTER

C2N Diagnostics

Contact

Joel Braunstein
info@C2N.com

<https://c2n.com/>

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invaluable support of NIH in addressing a major unmet medical need. The company's commitment to collaboration with NIH proved instrumental. "At every key moment in the history of C2N, the NIH has been an important collaborator," notes Dr. Joel Braunstein, Co-Founder and CEO. NIH grants to Washington University School of Medicine provided the scientific foundational infrastructure for C2N's endeavors. SBIR grants from NIA funded the groundwork for C2N's pioneering work and company infrastructure. Regular discussions over the years allowed NIH to stay involved and support key developments, including an animal safety study requested by FDA, throughout the growth of the company.

The company's effort culminated in the most recent human clinical trial supported by an NIH grant that ultimately led to FDA marketing approval of the PrecivityAD® and PrecivityAD2™ tests. Collaboration with the Alzheimer's Therapeutic Research Institute (ATRI) in a landmark prevention study known as AHEAD underscores the company's dedication to public health. This prevention study, targeting high-risk people with no symptoms, uses Precivity™ diagnostic tools to facilitate enrollment, which highlights the notable impact this technology could have on patient outcomes. Recently, the investigators leading AHEAD published a large dataset from that study demonstrating the high success rates of C2N's blood tests in identifying amyloid pathology as part of the study's baseline evaluation process.

C2N Diagnostics remains focused on addressing the challenges of Alzheimer's disease but ultimately has plans for addressing the unmet diagnostic needs of other serious neurodegenerative disorders affecting cognition, movement, and function. With worldwide studies focused on improving clinical decision-making and patient care pathways, C2N Diagnostics is poised to make a lasting impact on public health by offering more efficient and cost-effective ways to diagnose and monitor brain diseases. In the coming years, C2N expects blood biomarkers to become the new standard, refining diagnostic tools for Alzheimer's and other neurodegenerative diseases and improving patient outcomes.

