Doubts abound about a new Alzheimer's blood test

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For the first time, people worried about their risk of Alzheimer's disease can go online, order a blood test, and receive results in the privacy of their homes.

This might seem appealing on the surface, but the development has Alzheimer's researchers and clinicians up in arms.

The Quest Diagnostics blood test, AD-Detect, measures elevated levels of amyloid-beta proteins, a signature characteristic of Alzheimer's. Introduced in late July, the test is targeted primarily at people 50 and older who suspect their memory and thinking might be impaired and people with a family history of Alzheimer's or genetic risks for the condition.

Given Alzheimer's is among the most feared of all medical conditions, along with cancer, this could be a sizable market indeed. Nearly 7 million older adults in the U.S. have Alzheimer's, and that number is expected to double by 2060 if medical breakthroughs don't occur.

But Alzheimer's researchers and clinicians aren't convinced the Quest test is backed by sound scientific research. The possibility of false-positive results is high, as is the likelihood that older adults won't understand the significance of their results, they say. The test should be taken only under a physician's supervision, if at all, they advise. And, priced originally at $399 (recently discounted to $299) and not covered by insurance, it isn't cheap.

Though blood tests for Alzheimer's are likely to become common in the years ahead, the Alzheimer's Association said it's premature to offer a test of this kind directly to consumers.

For its part, Quest, which also sells direct-to-consumer tests for sexually transmitted diseases and various other conditions, suggests older adults can be trusted to respond responsibly to AD-Detect results. The test is not meant to diagnose Alzheimer's, the company stressed; instead, it's meant to help assess an individual's risk of developing the condition. But under a new proposed biological definition of Alzheimer's, excess

amyloid could automatically trigger a diagnosis of "preclinical" Alzheimer's.

Michael Racke, Quest's medical director of neurology, said individuals who test positive might be inspired to talk to their physicians about cognitive symptoms and seek comprehensive evaluations from dementia specialists. Others may just want to adopt behaviors associated with brain health, such as exercising more and maintaining healthy blood pressure, blood sugar and cholesterol levels.

"People who do consumer-initiated testing are often very motivated to figure out what they can do to help reduce the risk of disease," he said.

To get the test, a person first needs to go to the AD-Detect test's website and report that they're experiencing mild cognitive decline and have at least one other risk factor. (Self-reported complaints of this kind are often unreliable, experts note.) The order then goes automatically to a doctor paid by Quest, who will order a blood test to be drawn at a Quest laboratory.

Results classifying a person as low, medium or high risk will be provided on a secure patient portal. Post-test counseling isn't mandatory, but individuals can speak to a physician paid by Quest, if they like. (There is a separate $13 "physician service fee.")

A new poll from the University of Michigan confirms that older adults will take results seriously: 97% of seniors said they would take steps to improve brain health upon receiving a positive result from a blood test, while 77% said they would consider changes to financial or end-of-life plans.

But research scientists and clinicians worry that Quest hasn't published any peer-reviewed studies documenting the test's validity. The

company's preliminary data released at the 2022 Alzheimer's Association International Conference in San Diego suggests there's a relatively high chance of false-positive results, said Suzanne Schindler, an associate professor of neurology at Washington University School of Medicine in St. Louis.

That's a significant problem because telling someone they have biological changes associated with Alzheimer's disease is a "big deal and you want to be as accurate as possible," Schindler noted.

Racke said at least three scientific studies giving more details about the AD-Detect test have been submitted to medical journals and might be published by the end of this year.

Experts also question the usefulness of the test since a positive result (indicating abnormal levels of amyloid in the blood) doesn't mean an individual will definitely develop Alzheimer's disease. Amyloid in the brain accumulates slowly over the course of decades, typically beginning in middle age, and becomes more common as people age.

"This test gives you a fuzzy answer. We don't know whether you're going to get dementia, or when symptoms might begin or, really, how high the risk is for any individual," said Meera Sheffrin, medical director of the Senior Care clinic at Stanford Healthcare.

Also, cognitive symptoms that prompt someone to take the test might be due to a wide variety of other causes, including mini-strokes, sleep apnea, thyroid problems, vitamin B12 deficiency, or medication interactions. If an older adult becomes anxious, depressed or hopeless upon learning they're at risk for Alzheimer's—another source of concern—"they may not go for further evaluation and seek appropriate care," said Rebecca Edelmayer, senior director of scientific engagement at the Alzheimer's Association.

The University of Michigan poll confirms the potential for misunderstanding. Upon receiving a positive result from a blood test, 74% of seniors said they would believe they were likely to develop Alzheimer's and 64% said they would be likely to experience significant distress.

Because the science behind blood tests for Alzheimer's is still developing and because "patients may not really understand the uncertainty of test results," Edelmayer said, the Alzheimer's Association "does not endorse the use of the AD-Detect test by consumers."

Quest's blood test is one of several developments altering the landscape of Alzheimer's care in the United States. In early July, the FDA granted full approval to Leqembi, an anti-amyloid therapy that slightly slows cognitive decline in people with mild cognitive impairment and early-stage Alzheimer's. Early detection of cognitive symptoms and diagnosis of cognitive dysfunction have assumed greater importance now that this disease-modifying drug is available.

Also in July, a work group convened by the National Institute on Aging and the Alzheimer's Association proposed a new definition of Alzheimer's disease to be used in clinical practice.

Previously, Alzheimer's could be diagnosed only when there was evidence of underlying brain pathology (amyloid plaques and tau tangles) as well as cognitive symptoms (memory loss, poor judgment, disorientation, among others) and accompanying impairments (difficulty with managing finances, wandering, problems with self-care and more).

Under the new definition, Alzheimer's would be defined purely on a biological basis, as a "continuum that is first evident with the appearance of brain pathologic changes" including amyloid accumulation, according to a draft of the work group's report.

That would mean "you can get a positive result from the Quest test and be diagnosed with Alzheimer's disease if these guidelines are adopted, even if you're cognitively normal," cautioned Eric Widera, a professor of medicine at the University of California-San Francisco.

Demand for follow-up evaluations by dementia specialists is likely to be high and contribute to already-long waits for care, he suggested.

Additional concerns about the test relate to safeguarding privacy and the potential for discrimination. No federal laws protect people who receive Alzheimer's biomarker results from discriminatory practices, such as employment discrimination or the denial of life, disability or long-term care insurance. (The Genetic Information Nondiscrimination Act applies only to genetic tests.) And "laws that normally protect the privacy of health information do not apply in this space," said Emily Largent, an assistant professor of medical ethics and health policy at the University of Pennsylvania's Perelman School of Medicine.

Notably, HIPAA, the Health Insurance Portability and Accountability Act, doesn't extend to laboratory tests marketed directly to consumers.

The bottom line: Before taking a test, "older adults need to ask themselves, "Why do I want to know this? What will I do with the information? How will I react? What would I change in the future?'" said C. Munro Cullum, a neuropsychologist and distinguished professor of clinical psychology at the University of Texas Southwestern Medical Center. "This test needs to be used very cautiously and with great forethought."