A Blood Test for Alzheimer's: What to Know

The test may make it easier to identify whether people with memory and thinking problems have Alzheimer's or not.

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A blood test that can help diagnose Alzheimer's disease has received clearance from the Food and Drug Administration. This is a step toward a goal of scientists and doctors to one day be able to diagnose a confounding illness with the prick of a finger. But there is still a long way to go.

Here is what to know:

What is the test, and how should it be used?

The test, manufactured by Fujirebio Diagnostics, is intended to be used only by specialists in Alzheimer's, the F.D.A. said. Its mouthful of a name — Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio — describes what the test measures: levels of two proteins, amyloid and tau, that are hallmarks of Alzheimer's disease.

In people who develop Alzheimer's, amyloid begins to accumulate and form plaques in the brain more than 20 years before any symptoms of cognitive impairment. Tau accumulates later, forming tangles in the brain, and is much more closely correlated with cognitive decline.

Can people who don't have memory problems take the blood test?

No. The F.D.A., and Alzheimer's experts, emphasized that the blood test should be given only to people who are already experiencing cognitive decline and are ages 55 and older. Moreover, it should not be used on its own to diagnose or to rule out Alzheimer's.

"Other clinical evaluations or additional tests should be used for determining treatment options," the F.D.A. said in a statement, adding that "the results must be interpreted in conjunction with other patient clinical information."

The current gold standard for diagnosing Alzheimer's still involves either imaging using PET scans, which are expensive, or spinal taps, which are invasive. The blood test can help flag the presence of the Alzheimer's-related proteins, and doctors might then order confirmatory testing with one of the other methods.

Patients interested in getting the blood test should be referred to dementia clinics or similar settings. But before getting it, experts said, a patient should undergo cognitive tests that assess memory and thinking and possibly CT scans that look for alternative causes like strokes or brain tumors.

How accurate is the test?

The test measures two forms of the proteins — pTau217 and beta-amyloid 1-42 — in plasma, a component of blood, and then compares the ratio of those two proteins with the presence or absence of amyloid plaques in a patient's brain, the F.D.A. said.

The agency said that it had evaluated a study of 499 plasma samples from patients who were cognitively impaired and compared the results of the blood test with assessments of the patients by PET scan or spinal tap.

The study found that the blood test was nearly 92 percent as accurate as a PET scan or a spinal tap in flagging people with Alzheimer's pathology. It was over 97 percent as accurate as those measures in identifying people who did not have Alzheimer's pathology.

The blood test didn't always yield a positive or negative result. It was indeterminate in less than 20 percent of the cases, the F.D.A. said.

The agency noted that because the test wasn't 100 percent accurate, there was a risk of false positive or false negative results.

"False positive results, in conjunction with other clinical information, could lead to an inappropriate diagnosis of, and unnecessary treatment for, Alzheimer's disease," the F.D.A. said. "This could lead to psychological distress, delay in receiving a correct diagnosis as well as expense and the risk for side effects from unnecessary treatment. False negative results could result in additional unnecessary diagnostic tests and potential delay in effective treatment."

What implications could this test have for people with Alzheimer's?

This is not the first blood test to be developed for Alzheimer's, but it is the first to be cleared for marketing. Specialists have been using blood tests like this for several years, often to screen participants for clinical trials and to help pinpoint if a patient's dementia is caused by Alzheimer's. But the F.D.A. clearance of the Lumipulse test is likely to make more doctors, patients and families aware of the option and such blood tests more widely available.

The test could allow more patients to receive accurate diagnoses for the causes of their cognitive impairment. Alzheimer's disease is the most common dementia, but there are other types, including vascular dementia and Lewy body dementia, that have different underlying pathologies.

Differentiating between types of dementia has become increasingly important, partly because in the last two years two drugs that attack amyloid, Leqembi and Kisunla, have been approved for patients with cognitive impairment who are in the early stages of Alzheimer's disease. The drugs appear to modestly slow cognitive decline in mildly impaired patients, but also carry risks of swelling and bleeding in the brain.

Drug companies have been encouraging efforts to diagnose more people early to identify patients eligible for these drugs. And experts say it is just as important to identify patients who are not candidates for the drugs so they don't receive inappropriate treatment.

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