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US FDA clears first blood test for diagnosing Alzheimerâ??s Disease

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New test provides less invasive option, reduces reliance on PET scans and increases diagnosis accessibility



The US Food and Drug Administration (FDA) has cleared for marketing the first in vitro diagnostic device that tests blood to aid in diagnosing Alzheimer's disease. The Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio (by Fujirebio Diagnostics, Inc.) is for the early detection of amyloid plaques associated with Alzheimer's disease in adult patients, aged 55 years and older, exhibiting signs and symptoms of the disease.

The Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio measures two proteins, pTau217 and ?-amyloid 1-42, found in human plasma, a component of blood, and calculates the numerical ratio of the levels of the two proteins. This ratio is correlated to the presence or absence of amyloid plaques in the patient's brain, reducing the need for a PET scan.

Similar FDA-authorised/cleared tests, one from the same company as this new test, are used with cerebrospinal fluid (CSF) samples, which are collected through an invasive lumbar puncture, also called a spinal tap. This new Lumipulse test only requires a simple blood draw, making it less invasive and much easier for patients to access.

The new blood test can reliably predict the presence or absence of amyloid pathology associated with Alzheimer's disease at the time of the test in patients who are cognitively impaired. The test is intended for patients presenting at a specialized care setting with signs and symptoms of cognitive decline. The results must be interpreted in conjunction with other patient clinical information.