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ASIA EDITION

Beckman Coulter receives US FDA breakthrough device designation for Alzheimer's disease blood test

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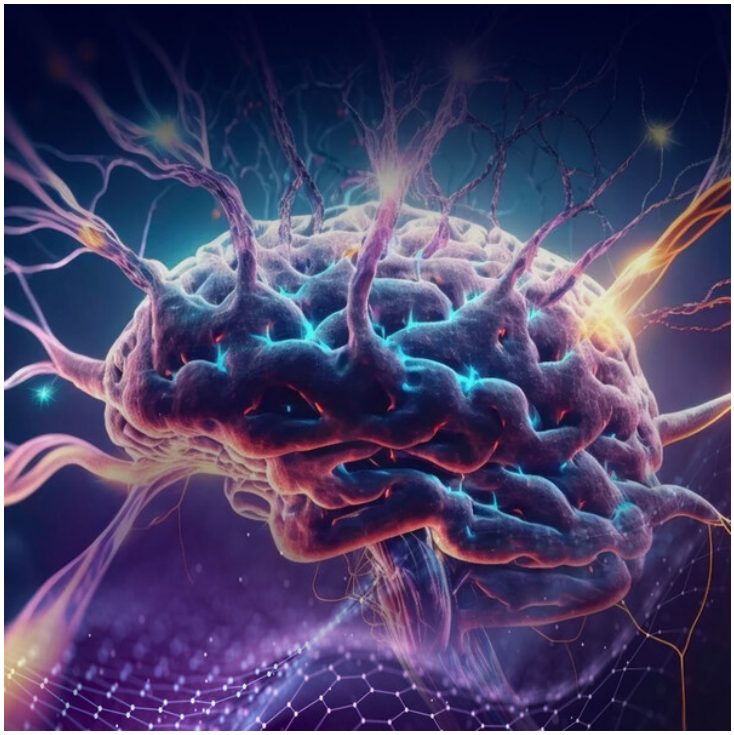
To transform how Alzheimer's disease is diagnosed and managed



Beckman Coulter Diagnostics, a global leader in clinical diagnostics, has announced that the US Food and Drug Administration (FDA) has granted Breakthrough Device Designation to Beckman Coulter's Access p?Tau217/?-Amyloid 1-42 plasma ratio. This blood test is designed to aid healthcare providers identify patients with amyloid pathology associated with Alzheimer's disease.

The Access p-Tau217/?-Amyloid 1-42 plasma ratio blood test measures the ratio of phosphorylated tau protein (p-Tau217) to ??Amyloid 1-42, two key biomarkers implicated in the neurodegenerative processes of Alzheimer's disease. A blood-based IVD test that can quantify these biomarkers in plasma could provide a non-invasive, accessible, and earlier method of detecting Alzheimer's-related pathology. This capability is important for improving early diagnosis, enabling timely intervention, and stratifying patients for therapeutic trials, ultimately accelerating progress in Alzheimer's research and treatment.

Kathleen Orland, Senior Vice President, General Manager, Clinical Chemistry and Immunoassay for Beckman Coulter Diagnostics. said, "Beyond the Access p-Tau217/?-Amyloid 1-42 plasma ratio blood test, Beckman Coulter is committed to developing a full suite of next-generation neurodegenerative disease tests. The ageing global population combined with emerging drug treatments is expected to create widespread demand for Alzheimer's disease testing, which will require accurate, high-throughput assays. The proprietary technologies on the Beckman Coulter DxI 9000 Immunoassay Analyzer

coupled with its novel Lumi-Phos PRO substrate has enabled development of precise, clinically relevant assays and shown capability to detect targeted neurological biomarkers on an automated, high-throughput platform."