

Agappe to Begin Manufacturing of US FDA-Approved Plasma Markers for Alzheimer's Disease Detection in India

COCHIN, KERALA, INDIA, June 20, 2025

/EINPresswire.com/ -- Agappe

Diagnostics Ltd is poised to pioneer a transformative chapter in Alzheimer's diagnostics by commencing manufacturing of US FDA-approved plasma biomarkers—Amyloid Beta 1-42 and phosphorylated Tau (pTau) 217—making it the first company in India to undertake production of these cutting-edge diagnostic tools.

This initiative follows the landmark FDA clearance of the Lumipulse G pTau217/ β -Amyloid 1-42 Plasma Ratio test developed by Fujirebio Diagnostics in May 2025. The test, which measures

key biomarkers in a simple blood sample, offers a revolutionary alternative to costly and invasive positron emission tomography (PET) scans and cerebrospinal fluid (CSF) analysis, drastically enhancing accessibility for patients and clinicians alike [FDA Announcement](#).

Agappe's entry into this space signals a significant stride for Indian biotechnology in addressing the country's rising neurodegenerative disease burden. Alzheimer's disease, which affects nearly 7 million Americans and is rapidly increasing among populations aged 55-70 globally, has seen diagnostic advancements thanks to plasma-based detection methods .

The Science Behind the Innovation

Traditional Alzheimer's diagnostics have relied heavily on PET imaging or spinal fluid analysis to detect amyloid plaques and tau protein tangles—hallmarks of the disease. These techniques, while accurate, pose challenges: high cost, patient discomfort, limited availability, and radiation exposure.



Agappe Corporate Office

By contrast, plasma-based assays such as those using the pTau217 and Amyloid Beta 1-42 markers deliver comparable diagnostic accuracy through a much simpler blood draw. Recent studies show that the pTau217/Aβ1-42 ratio in plasma correlates strongly with amyloid presence in the brain, yielding over 90% concordance with PET or CSF findings.

Research has also validated the real-world applicability of these tests, noting their clinical utility in early detection, especially in memory clinics and specialized settings. Notably, plasma biomarkers can predict disease progression even in cognitively unimpaired individuals who are amyloid-positive, opening doors to early intervention and clinical trial enrolment.

Transforming Alzheimer's Care in India

Alzheimer's disease is a growing concern in India, where increased longevity and lifestyle shifts are driving up neurodegenerative disorders. Yet, diagnostic pathways have remained limited by access to advanced neuroimaging and CSF testing. Agappe's manufacturing of these blood-based diagnostic tools will not only localize production but also democratize access to [early and affordable Alzheimer's detection](#) across urban and rural healthcare settings.

"Bringing plasma biomarker production to India is a game-changer. It embodies our commitment to transforming diagnostics through science and innovation," said Thomas John, Managing Director, Agappe.

The manufacturing license is expected by June 2025, with the initial focus on clinical-grade pTau217 and Amyloid Beta 1-42 reagents compatible with high-throughput analyzers - [Mispa i60](#) and Mispa i121.

Global and Scientific Endorsements

The adoption of plasma biomarkers is backed by an expanding corpus of international studies. Research from Kornhuber and Mroczko has emphasized the growing clinical relevance of pTau in Alzheimer's diagnostics, while comprehensive reviews by Kulczyńska-Przybik et al. underline the diagnostic robustness of blood-based markers compared to traditional modalities.

Toward a New Diagnostic Standard

With the advent of this technology, Alzheimer's diagnostics are on the cusp of a paradigm shift—from complex imaging centres to outpatient clinics and primary healthcare providers. Agappe's manufacturing efforts will ensure that India plays a pivotal role in this transformation, aligned with global scientific rigor and local health priorities.

Agappe Digital
Agappe Diagnostics Ltd
+ +916282903297
[email us here](#)
Visit us on social media:

[LinkedIn](#)
[Instagram](#)
[YouTube](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/824038849>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2025 Newsmatics Inc. All Right Reserved.