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Stability of Biomarkers Associated with Alzheimer's Disease by using Immunomagnetic Reduction Assay Reagent

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Short Communication

Bio-fluid biomarker tests for Alzheimer's Disease (AD) have become popular in risk assessment. The quantitative identification of amyloid 1-40 (A1-40), A1-42 and total tau protein (Tau) in Cerebrospinal Fluid (CSF) has piqued the interest of researchers and neurologists as pathological markers of Alzheimer's disease [1]. Many investigations have confirmed that the levels of these CSF biomarkers correspond strongly with the clinical diagnosis of Alzheimer's disease. For example, as compared to normal controls, the amount of CSF A1-42 drops while the level of CSF tau increases in AD. Furthermore, the concentration ratio of CSF A1-42 to A1-40 is consistent with the normal uptake value ratio from Positron Emission Tomography (PET). Despite the clinical importance of CSF biomarker tests, lumbar puncture remains a substantial burden in practise.

The development of ultrasensitive immunoassay technology has permitted the development of tests for extremely low plasma quantities of A1-40, A1-42, and Tau [2]. CSF biomarkers and plasma biomarkers have been linked with Alzheimer's disease. When compared to normal controls, the levels of composited A1-42 and Tau are promising indicators for differentiating Amnesic Mild Cognitive Impairment (aMCI) from early-stage Alzheimer's Disease (AD) [3]. Furthermore, baseline values of aMCI composited plasma A1-42 and Tau predict cognitive deterioration in 1-1.5 years.

In magnetic resonance imaging pictures of patients with brain atrophy, the amount of plasma Tau is increased. The plasma A1-42-to-A1-40 ratio changes substantially between amyloid PET negative and amyloid PET positive Alzheimer's disease. Clinical data suggests that plasma biomarkers can help in Alzheimer's disease diagnosis [4].

Immunomagnetic Reduction (IMR) reagent kits have been documented with CE data for In Vitro Diagnosis (IVD) and authorised by the Taiwan Food and Drug Administration as one of the ultrasensitive technologies for assaying plasma A1-40, A1-42, and Tau (TFDA). In Europe, the Middle East, Southeast Asia, and Taiwan, IMR reagents for A1-40, A1-42, and Tau have been used in research and clinical applications [5]. Previously, preclinical assays of IMR reagents for A1-40, A1-42 and Tau, such as the hook effect, assay detection limit, assay linearity, precision and repeatability, spike recovery rate, dilution recovery rate, and interference, were investigated using Clinical and Laboratory Standards Institute and ICH Q2 guidelines (R1). The stability of these chemicals was investigated in this study based on their typical lengthy delivery and storage durations following synthesis. Reagent stability, which encompasses storage stability and open-vial stability, is a critical problem in the clinic.

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