



Life Science Products

→ SINGULEX TECHNOLOGY

News & Publications

Corporate Info

For Drug Development

→ Assay Menu

Erenna® Immunoassay System

[← Back to Assays](#)**Aβ-42 (Amyloid beta protein 42)**

The Singulex Aβ-40 and Aβ-42 assays allow the quantification of amyloid beta proteins from human plasma with exceptional sensitivity, enabling use of Aβ-40/Aβ-42 as a velocity biomarker in Alzheimer's disease studies and to evaluate therapeutic interventions.

Biology and Diseases

Amyloid beta proteins (40 and 42 amino acids) are the main constituent of amyloid plaques in the brains of Alzheimer's disease (AD) patients. In healthy and disease states Aβ-40 is the more common form (10–20X higher than Aβ-42) of the two in both cerebrospinal fluid (CSF) and plasma. In patients with AD, Aβ-42 primarily aggregates and deposits in the brain forming plaques. Thus the concentration of Aβ-42 is decreased in the CSF of many AD patients. Recent studies suggest that a decrease in Aβ-42 concentrations (with a paralleled change in the ratio of Aβ-40/Aβ-42) in CSF and plasma are predictive of the onset of AD.

Therapies

There is no cure for Alzheimer's disease and currently available therapeutics minimize some symptoms but do not slow disease progression. Numerous experimental approaches focus on minimizing Aβ-42 levels by preventing production or lowering Aβ-42 concentrations, and stimulating the immune system to attack Aβ proteins as well as preventing Aβ proteins from aggregating and forming plaques. An important component in designing therapeutic trials is to identify patients who are at risk for developing AD, such that studies can be performed in a cost effective and timely manner. Hence these biomarkers would be invaluable for understanding Aβ levels as surrogate endpoints, allowing efficient study design.

Unmet Need

Preventive therapy is a major focus as the best way to manage AD. Guidelines describe the need for noninvasive biomarkers that can be used to predict and diagnose AD. Such information will be invaluable for clinical study design, as well as the evaluation of therapeutic effectiveness. Measuring Aβ-40 and Aβ-42 concentrations in plasma may provide such information. In healthy normal humans, plasma concentrations range from 200–400 pg/mL (Aβ-40) and 15–30 pg/mL (Aβ-42). However with AD, Aβ-42 levels decrease, often undetectable by currently available EIA technology. Furthermore, interventional strategies based on depleting Aβ-42 formation require methods that measure decreases in Aβ-42. Thus there is a need to accurately and precisely quantify low concentrations of amyloid proteins in plasma.

Singulex Answer

The Singulex Aβ-40 and Aβ-42 assays allow for the quantification of very low levels and changes of amyloid beta proteins in plasma. These measurements provide promise for more efficient clinical study design and assessment of therapeutic efficacy. The assays quantify as little as 0.1 pg/mL Aβ-42 and 10 pg/mL Aβ-40 (<20% CV). This enables accurate quantification of Aβ proteins in healthy states and the accurate assessment of Aβ-42 velocity with respect to disease progression and therapeutic intervention.

This assay will allow investigators to:

1. Identify subjects with potential high risk for developing AD and identify subjects in early phases of disease development.
2. Design more robust clinical and preclinical studies when Aβ protein concentrations are used as a therapeutic endpoint.
3. Understand how Aβ protein levels change in humans as they transition from healthy to diseased states.

Application Note

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