

KCAS Bioanalytical & Biomarker Services is a contract research organization (CRO) with 35+ years of bioanalytical and immunoanalytical expertise. We specialize in the development and validation of robust small, large molecule and biomarker methods for discovery, preclinical and clinical studies.

Biomarker for Phase III Clinical Trial

Challenge

Client needed to quantify Amyloid beta 42 (A β -42) levels in human Cerebral Spinal Fluid (CSF) for inclusion/exclusion for a Phase III Alzheimer's Clinical Trial. Client required a turn around time of three business days. Additional Alzheimer biomarkers A β -38 and A β -40 were to be measured as well.

Solution

KCAS has experience with ECL platform and CSF matrix. KCAS successfully validated Meso Scale Discovery (MSD) 3-plex A β -38, A β -40, and A β -42 in human CSF. While performing validation KCAS identified low binding tubes for collection of CSF to avoid under recovery of the three Amyloid beta biomarkers.

Results

Transferred and Validated assay in ten weeks. During the assay validation, client requested -20°C long term stability **because not at all clinical** sites had -80°C storage. KCAS has successfully validated the stability of A β 3-plex for three months at -20°C and -80°C, with additional long term storage studies for up to thirty-six months.

Additional Studies

KCAS was contracted and successfully validated Total Tau in human CSF for the same phase III clinical trial.