Introduction: Biomarkers are being actively sought for numerous disorders including common neurodegenerative and neuropsychiatric diseases. CSF is in direct contact with the brain and is thus likely to yield analytes that may reflect alterations in brain biology. For initial discovery of biomarkers for neurodegenerative and other diseases of the brain, it is essential to perform lumbar puncture (LP) with simultaneous blood draws on diseased subjects and matched controls. Younger normal subjects must also be studied.

Aims: The SAMPLE©CSF Registry protocol calls for regular cognition testing with simultaneous sampling of CSF, plasma, serum, PAXGene (RNA) and cells for DNA, every 6 months, in subjects with clinically diagnosed AD (NINCDS-ADRDA) and MCI (Petersen). The study is ongoing and this is the May 2011 update.

Methods: The methods used to evaluate cognition are the Modified ADAS-Cog, CDRs, Wechsler Memory Scale and MMSE. In addition CSF $A\beta_{1-42}$ and t-tau were assayed in 20 AD subjects and 20 controls. Lumbar puncture and blood draw are performed using accepted methods.

Results: One hundred and twenty cognitively impaired males and females have been enrolled to date. Mean cognition scores have generally worsened in both the AD and MCI subgroups over the period of longitudinal testing. Results of the CSF AlzBio3 assay (AD subgroup vs. Normal control CSF) were similar to ADNI.

Conclusions: The change in longitudinal cognition scores as well as the results of the CSF AlzBio3 analysis lend validation to the accuracy of the clinical diagnosis in this sample set.