

Detection of A β oligomers in cerebrospinal fluid using flow cytometry: The AlzAlert™ assay as a tool for the diagnosis of Alzheimer's Disease

ACGT ProGenomics AG i.I. introduced its Alzheimer diagnostic assay AlzAlert™ in an important journal for this research area, the "Journal of Alzheimer's Disease" / Detection of oligomers in CSF samples of aged people was successful

Halle (Saale), 2007-01-31. The company ACGT ProGenomics AG i.I., Germany, announced the publication of relevant clinical data on its AlzAlert™ assay in CSF in the renowned journal "*Journal of Alzheimer's Disease*" (cf. <http://www.j-alz.com/issues/11/vol11-1.html>). The paper appears in Vol. 11, No. 1 (2007) of the journal. It describes an initial study using CSF from aged people with and without neurological disorders, which was performed in a close collaboration of the company with the clinical laboratory of Dr. Friedrich-Wilhelm Tiller in Munich, Germany. CSF samples that were investigated demonstrated that A β oligomers are present in CSF in measurable amounts.

The neuropathology of Alzheimer's disease (AD) has recently been linked to the non-fibrillar forms of neurotoxic amyloid- β (A β) oligomers. This suggests that A β oligomers may play a crucial role in the early events of AD, underlining their enormous potential as a primary marker for the early diagnosis of the disease.

William Klein, Professor of Alzheimer's at Northwestern University, U.S.A., was one of the first who formulated a new hypothesis for Alzheimer's disease in which the oligomeric forms of A β were the 'hidden toxins' in the pathology of the disease. Several recent results suggest that those oligomers may cause the death of neurons and neurological dysfunctions relevant to memory. Other researchers found that oligomer levels are increased in brain samples from people with Alzheimer's disease. Therefore, a test that accurately measures the concentration of oligomers in body fluids could be a most valuable diagnostic assay for the disease.

The company ACGT ProGenomics AG i.I. had developed such an extremely sensitive assay for the reliable detection of oligomeric and fibrillar structures of A β which was based on multiparametric analysis of data obtained by flow cytometry, in conjunction with fluorescence resonance energy transfer (FRET). The assay clearly detected A β oligomers in human cerebrospinal fluid (CSF), as verified for example by dot blot of isolated molecules.

A total of 174 distinct CSF samples of non-demented patients with various neurological disorders was measured with the assay. The results that are now published in the "*Journal of Alzheimer's Disease*" demonstrated a high reliability and reproducibility of the novel method for the quantification of A β oligomers in body fluids.

The results are the basis for the development of an assay for the early detection of Alzheimer's Disease in CSF samples of aged people. Also, the development of new therapeutic strategies which specifically target the oligomeric form of the key molecule A β is supported by the results from the company's research. Vaccination which is specifically directed against the A β oligomers may become the key treatment for Alzheimer's Disease in the future, corresponding nicely to the diagnostic approach of AlzAlert™.

Dr. Böhm, former CEO of ACGT ProGenomics AG i.I.: "*The positive responses to the concept and data we presented in the publication is a further confirmation of the outstanding quality of our team's work. We all believe that the company was on the right track for being the first in the race for a reliable lab-based assay for Alzheimer's Disease.*"

Dr. Navarrete Santos, head of the development team at ACGT ProGenomics AG i.I.: "*The measurement of A β oligomers in CSF could become a routine method in the clinical routine, due to the simple and reliable flow cytometry method that we developed. If a controlled clinical trial proves that those oligomers are a primary marker of the disease, this would be a key for the diagnosis of AD.*"

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The biotechnology company ACGT ProGenomics AG i.I. was founded in January 2000 in Halle (Saale), Germany. Its business units comprised bioinformatics, diagnostics, and therapeutics. The application fields ranged from diagnostic methods for amyloidogenic diseases (Alzheimer, BSE) to the development of novel and cost-effective methods for drug delivery. The major product of the company was a blood-based

and liquor-based assay for the early diagnosis of suspected Alzheimer's Disease named AlzAlert™ which had undergone several successful clinical trials so far for its usage in serum samples of AD patients. The company went out of business at the end of 2006, when the initiation of a GMP production for the serum-based AlzAlert™ assay failed due to financial reasons.