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New biomarker exploration with the NeuroToolkit and evaluation of the Elecsys® β-Amyloid (1-42), Total-Tau and Phospho-Tau(181P) CSF immunoassays for neurodegeneration

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Biography

Gwendlyn Kollmorgen is currently a study manager at Roche Diagnostics in charge of the NeuroToolkit experiments. After completing her undergraduate studies at the University of Michigan-Dearborn, she moved to Germany, where she received her PhD from the Institute for Cell Biochemistry and Clinical Neurobiology and Institute for Human Genetics at the Hamburg University. Gwen began her industry career by working for 7 years in Discovery Oncology at Roche, initially as postdoctoral fellow and then as successful group leader and preclinical project leader. She has also written and illustrated a children's book on cancer.

Abstract

With the possibility of new medications for neurodegenerative diseases on the horizon, it is becoming more important than ever to reliably diagnose patients. Currently, there is an unmet need for reliable biomarker assays to support evaluation of patients with neurodegenerative diseases, including Alzheimer's disease (AD). In collaboration with academia and industry experts, a panel of robust prototype assays have been selected to recognize patients with AD and other neurodegenerative diseases, termed the NeuroToolKit (NTK) immunoassays. In order to assess clinical utility of the NTK, patient cohorts from both academic and industry studies are being investigated with the NTK immunoassays and the data will be analyzed across all cohorts. Preliminary evaluation of the data generated from the Wisconsin ADRC cohort and ALFA+ cohort shows promising results. Subsequently, NTK immunoassays were selected for further evaluation of analytical performance, reproducibility, lot-to-lot comparability and method comparisons with commercially available assays, as was recently performed for the Elecsys® β-Amyloid (1-42), Total-Tau and PhosphoTau (181P) CSF immunoassays. The Elecsys® β-Amyloid (1-42) assay was linear over the measuring range (200–1700 pg/mL) and showed low between-laboratory and lot-to-lot variability. Coefficients of variation (CVs) were: repeatability ≤1.6%; intermediate precision ≤3.6%; between-laboratory variability ≤3.5%; and total reproducibility ≤5.1%. The Elecsys® Total-Tau and Phospho-Tau (181P) assays showed high sensitivity with measuring ranges of 80-1300 pg/mL and 8-120 pg/mL, respectively. Multicenter evaluation demonstrated good overall performance. Coefficients of variation (CVs) were as follows: repeatability <1.8%; intermediate precision <2.8%; between-laboratory variability <2.7% (both assays); and total reproducibility <6.7% for tTau and <4.7% for pTau. Evaluating patient cohorts with NTK assays in addition to using the Elecsys® β-Amyloid (1-42), Total-Tau and PhosphoTau (181P) CSF immunoassays may help elucidate the complex etiology of neurodegenerative diseases by aiding in initial clinical diagnosis and monitoring progression.

Publications

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