**P4-467** LUMIPULSE® G TOTAL TAU: KEY PERFORMANCES OF A FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY

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**Background:** Today levels of β-amyloid(1-42) peptide and total Tau in cerebrospinal fluid (CSF) are well-accepted biomarkers representing Alzheimer’s disease (AD) from the earliest stages on. Widespread use of these biomarkers in AD diagnosis requires reliable, highly precise, and accurate measurements. Analytical requirements and performance of CSF samples on the novel Lumipulse G Total Tau assay (CE-marking ongoing), a fully automated chemiluminescent enzyme immunoassay were verified. Methods: The LUMIPULSE G instruments use single analyte, ready-to-use immunoreaction cartridges with a throughput of 60 and 120 tests/hour for the G600II and the G1200 instrument, respectively. Sequential immunoreaction steps are carried out while the cartridge is transported through the system. Each cartridge generates quantitative results within approximately 30 minutes and multiple assays can be easily combined in the system. The Lumipulse G Total Tau assay has been developed using established monoclonal antibodies. The analytical assay performance was characterized according to CLSI guidelines. Quantitative determination of total Tau levels on CSF samples from patients visiting a memory clinic was performed at an external lab and used for a measurement comparison versus INNOTEST® hTau Ag. Results: Using a panel of CSF and control samples, assay variability was determined and the obtained coefficient of variation seen for the different variability components show a high level of precision: a clear result from the use of a standardized and automated assay platform. Low concentrated CSF samples were used to demonstrate the good analytical sensitivity (LoD and LoQ) of the assay. Linearity was shown between-vial homogeneity and long-term stability (one year) both were fully characterised. They were found to have suitable behaviour, stability, and commutability were assessed and found to be suitable for the purpose. The value-assignment resulted in acceptable uncertainties. The reference materials are expected to be released in the near future. The next step is to outline the concepts on the use of the CRMs for calibration of the routine assays.

**Conclusions:** Automation, the mono test cartridge principle, short throughput times, and instrument flexibility are key attributes of the LUMIPULSE G instrument series making it the ideal platform to fulfill today’s needs for rapid and accurate quantification of CSF biomarkers in both low and high throughput clinical laboratories. The novel Lumipulse G Total Tau assay shows good sensitivity and precision, and correlates well with the established INNOTEST assay.

**P4-468** PROGRESS ON THE DEVELOPMENT OF CERTIFIED REFERENCE MATERIALS FOR Aβ1-42

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**Background:** Early diagnosis and treatment of Alzheimer’s Disease (AD) remain challenging. The use of cerebrospinal fluid (CSF) biomarkers could contribute to an early diagnosis, however there are still large variations among results from different assays for CSF biomarkers. This is partly due to a lack of standardization of those assays. It highlights the need for a common Certified Reference Material (CRM) for each clinically relevant AD biomarker.

**Methods:** Three candidate CRMs were prepared, with low, medium and high Aβ1-42 concentrations by pooling CSF samples obtained from a large number of donors. Homogeneity and short- and long-term stability were assessed by measurements with two immunoassay formats (Roche Elecsys and Euroimmun ELISA). A commutability study was performed using the major routine immunoassays. Value-assignment was performed using liquid-chromatography mass-spectrometry (LC-MS). A recombinant peptide calibrant (source: rPeptide) was used for the calibration of the reference methods applied for the value-assignment of the candidate CRMs.

**Results:** The candidate CRMs were fully characterised. They were found to have suitable between-vial homogeneity and long-term stability (one year) for both Aβ1-42 as well as Aβ1-40. The materials are commutable to patient samples for the major immunoassays for Aβ1-42 and the LC-MS reference methods. The characterisation using reference methods resulted in uncertainties that were acceptable. Three CRMs for Aβ1-42 have been fully characterised. Homogeneity, stability, and commutability were assessed and found to be suitable for the purpose. The value-assignment resulted in acceptable uncertainties. The reference materials are expected to be released in the near future. The next step is to outline the concepts on the use of the CRMs for calibration of the routine assays.

**Conclusions:** Three CRMs for Aβ1-42 have been fully characterised. Homogeneity, stability, and commutability were assessed and found to be suitable for the purpose. The value-assignment resulted in acceptable uncertainties. The reference materials are expected to be released in the near future. The next step is to outline the concepts on the use of the CRMs for calibration of the routine assays.

**P4-469** USE FOR CALIBRATION OF CERTIFIED REFERENCE MATERIALS FOR Aβ1-42

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