**International Multi-Center Training and Validation of CSF Alzheimer’s Biomarker Assays**

Pankaj Oberoi, Robert Umek, Nyssa Puskar, Jennifer Lewis, Jill Dunty, David Stewart, and Jacob N. Wohlstadter; Meso Scale Discovery, Rockville, Maryland, USA

**Abstract**

To analyze the power of tangential markers, Alzheimer’s biomarker assays must excel along, consistent analytical performance is as crucial as minimized variability from sample to sample. The involved in this study aims to assess and determine variability of results from different human auto-samples, human CSF, and human plasma. The results obtained are important for training and validating methods to minimize variability and for determining overall assay performance.

**Methods: MSD Assays**

- **Human Ab42 Kit and Human Total Tau Kit**
- **CSF Pools**

**Performance Assessment**

- **Human Total Tau Kit:**
  - Human Anti-Total Tau (
  - Human Anti-β-Amyloid (

**Validation: Intra-Run CV for the Human Ab42 Kit**

- Back-salced data set for 8 to 12 CSF samples (x-axis) and at least 7 run-in CSF samples (open square). For this, the intra-run %CV was examined using 5% dilutions of CSF samples and undiluted controls.

**Validation: Intra-Run CV for the Human Total Tau Kit**

- Back-salced data set for 8 to 12 CSF samples (x-axis) and at least 7 run-in CSF samples (open square). For this, the intra-run %CV was examined using 5% dilutions of CSF samples and undiluted controls.

**Validation: Comparison of Site-to-Site Variation**

- The intra-run %CV values are plotted below for calibration, 10% control, and CSF samples. The intra-run %CV for calibration was examined using 5% dilutions of CSF samples and dilutions of the calibration used.

**Validation: Dilution Linearity**

- Each sample measured directly from 5 to 12 samples (x-axis) for 8 to 12 samples. For the Total Tau assay, the mean of the 10% control was 42.8 ± 0.5 units. This assay's dilution linearity was assessed by measuring the dilution of the 10% control using 10% dilution of 1:2, 1:4, and 1:8 samples.

**Conclusion**

- The results show that the MSD Ab42 and Total Tau kits are suitable for use in different human auto-samples, plasma, and CSF. The validated assays are a significant step forward in the field of Alzheimer’s biomarker research.