For clinical use, CSF biomarker assays should demonstrate high precision, reproducibility, and sample stability suitable for clinical use to aid Alzheimer's disease diagnosis.

Introduction
- For use in diagnosis of Alzheimer's disease (AD).1
- CSF Aβ42 and pTAu181 can discriminate between AD and age-matched controls and sample stability.

Methods
- This multicenter study was conducted at four external sites (Amsterdam, Netherlands; Baltimore, MD; St Louis, MO, USA; and Munich, Germany) between February and December 2021.
- Post-frozen spiked CSF samples were generated from uncharacterized CSF sourced from third-party vendors and from residual routine clinical samples, and two PreciControl samples were analyzed using the Elecsys Aβ42 (Aβ42) CSF II and Elecsys Phospho-Tau-181P (pTAu181P) CSF immunoassays on the cobas e 601 analyzer.
- Precision was evaluated at the internal site by Clinical and Laboratory Standards Institute (CLSI) EP23-A2, run in duplicate over 21 days (n=40).
- Reproducibility was determined as the coefficient of variation for the ratio on the internal site.

Results
- Sample stability was determined at one external site (Munich, Germany) from CSF aliquots (n=13) stored at ≤30°C for 13 weeks at -20°C.
- Table 3. Lot-to-lot reproducibility of the Elecsys Aβ42 (Aβ42) CSF II and Elecsys Phospho-Tau-181P (pTAu181P) CSF immunoassays.

Sample stability
- 2 to 8°C.
- At maximum sample storage duration of 8 days at room temperature (25°C) (Figure 1) and 15 days at 2-8°C (Figure 2), mean percent recoveries of 95% and 96%, respectively, were observed, and 94% and 97%, respectively, were observed for Aβ42.
- Table 1. Repeatability and intermediate precision of the Elecsys Aβ42 (Aβ42) CSF II and Elecsys Phospho-Tau-181P (pTAu181P) CSF immunoassays.

Objectives
- To assess the effect of storage conditions on CSF sample stability.
- To assess the effect of storage conditions on CSF sample stability.

Second-generation fully automated Elecsys cerebrospinal fluid immunoassays demonstrate high precision, reproducibility, and sample stability suitable for clinical use to aid Alzheimer’s disease diagnosis.