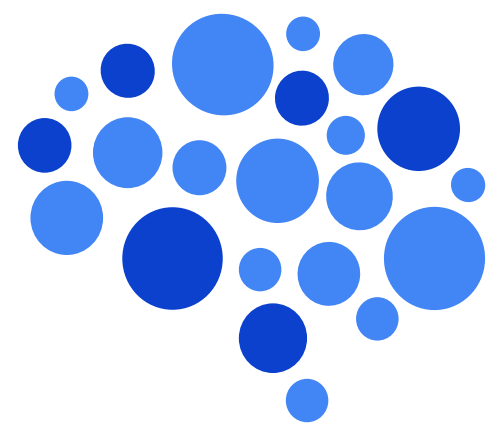


Sample stability for a new pTau181 plasma assay: implications for rule-out testing for Alzheimer’s disease in routine clinical practice



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What does this mean for the Alzheimer’s community?

- Implementing a blood-based biomarker (BBBM) test to enable early rule out of Alzheimer’s disease (AD)-associated amyloid-beta (Aβ) pathology can streamline the AD diagnostic pathway and potentially offer earlier diagnosis for adults presenting with cognitive decline.
- These results highlight the importance of adhering to assay protocol, to prevent sample contamination and unmeasurable or misleading results and maintain diagnostic confidence within primary care.

Background

- Plasma tau phosphorylated at threonine 181 (pTau181) is a key BBBM that robustly mirrors the development of Aβ pathology in AD.¹
- The Elecsys® Phospho-Tau (181P) Plasma (pT181p) immunoassay (Roche Diagnostics International Ltd) was developed to rule out AD-related Aβ pathology in adults aged ≥55 years presenting with signs, symptoms or complaints of cognitive decline.²
- The immunoassay is approved for clinical use in Conformité Européenne mark-accepting countries and was recently cleared by the United States Food and Drug Administration as the first blood test for use in primary care to rule out AD pathology.^{3,4}
- We evaluated the stability of plasma pTau181 measured using the pT181p immunoassay under different pre-analytical and storage conditions in samples from an intended-use population.

Methodology

- Whole blood samples from individuals presenting at LMU Hospital with symptom severity ranging from non-specific cognitive impairment to moderate AD dementia were collected in three different tubes for plasma preparation, 60 mL total blood; 20 mL/plasma type:
 - lithium-heparin (Li-Heparin) - 2 × 10 mL
 - dipotassium ethylenediaminetetraacetic acid (K2-EDTA) - 2 × 10 mL
 - tripotassium ethylenediaminetetraacetic acid (K3-EDTA) - 5 × 4 mL
- Samples were transported under cooled (never frozen) conditions to the measurement site (TRIGA-S, Habach, Germany) and processed within 6 hours of collection.
- Plasma samples were stored under various conditions (25°C, 4°C, –20°C and –80°C) for differing time intervals, and impact on analyte recoveries was assessed.
- The effect of a single freeze/thaw cycle (–20°C for 1–3 days) on stability was also evaluated.

Optimisation of study design

- Additional experiments were performed to investigate whether initial out-of-specification results were due to sample instability or a sample handling issue.
- Pre-analytical handling procedures were modified to prevent contamination during post-centrifugation plasma transfer.
- Previous samples were excluded, and blood draws from different individuals were used for the main evaluation of plasma pTau181 sample stability.

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- ELECSYS is a trademark of Roche.

Results

Optimisation of study design

- Out-of-specification results observed in samples from 14 participants and subsequent optimisation, indicated that analyte recovery was reduced in plasma samples due to buffy coat contamination:
 - Samples with a safety buffer showed no issues; however, a sample without a safety buffer showed reduced analyte recovery after freezing. It was therefore determined that a plasma safety buffer should be left in the primary tube to prevent sample contamination.

Baseline characteristics

- A separate set of non-contaminated samples was obtained from 10 participants (n=5 male, n=5 female) who were all White and not of Hispanic or Latino ethnicity.
- Five participants had a diagnosis of non-specific cognitive impairment and five had confirmed mild AD dementia.

Optimal analyte stability

- After considering safety margins, analyte stability for all matrices was determined to be 2 days at 25°C, 7 days at 4°C, 12 weeks at –20°C and 16 weeks at –80°C; analyte remained stable after one freeze/thaw cycle (Table 1).

Table 1. Sample stability: summary of maximum storage conditions tested using pT181p*.

Matrix type	Storage (°C)	Intercept (%)		Slope (%/unit)		p-value	Criterion (%)	Maximum storage		Unit
		PE	SE	PE	SE			Actual	Claimed	
Li-Heparin	25	99.1	0.375	–0.00374	0.00923	0.6868	100±10	72.0	65.0	hours
	4	99.6	0.583	–0.133	0.109	0.2292	100±10	8.00	7.00	days
	–20	101	1.05	–0.334	0.123	0.0086	100±10	13.0	12.0	weeks
K2-EDTA	25	99.6	0.403	0.00903	0.00992	0.3661	100±10	72.0	65.0	hours
	4	99.3	0.685	–0.0260	0.129	0.8413	100±10	8.00	7.00	days
	–20	101	0.748	–0.363	0.0873	0.0001	100±10	13.0	12.0	weeks
K3-EDTA	25	99.4	0.357	–0.00174	0.00879	0.8438	100±10	72.0	65.0	hours
	4	99.7	0.502	–0.125	0.0941	0.1887	100±10	8.00	7.00	days
	–20	101	0.818	–0.357	0.0955	0.0004	100±10	13.0	12.0	weeks
	–80	99.6	1.06	–0.397	0.0915	<0.0001	100±10	18.0	16.0	weeks

*Maximum storage conditions based on linear regression estimates of recovery over time for three matrix types under four storage conditions. Data are based on n=10 plasma samples per matrix type. PE, point estimate; SE, standard error.

Linear regression modelling

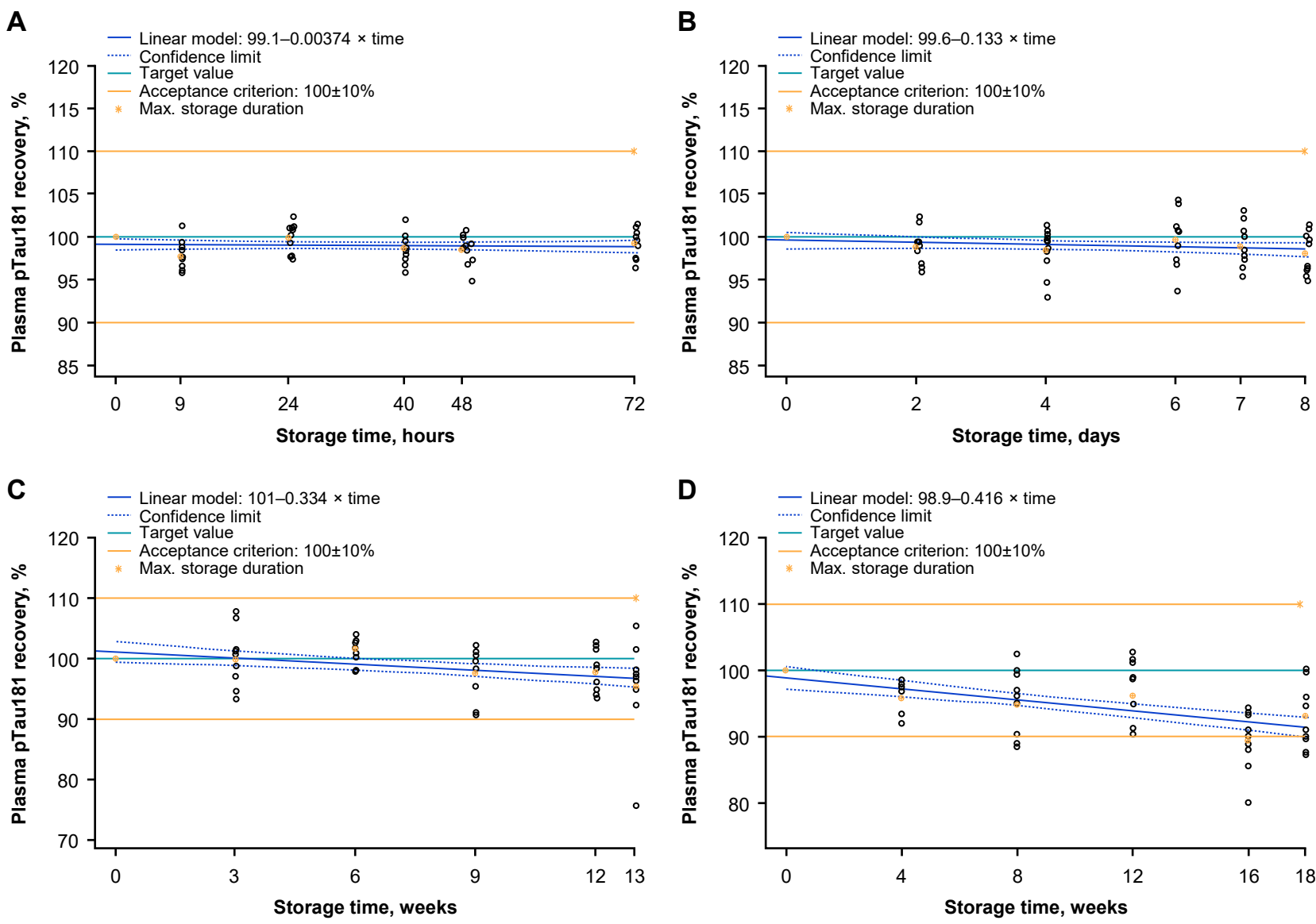
- Scatter plots of linear regression modelling based on plasma pTau181 recoveries across storage conditions for the Li-Heparin, K2-EDTA and K3-EDTA matrices are shown in **Figures 1, 2 and 3**.

Conclusions

- pT181p immunoassay measurements were stable and robust with respect to different sample handling procedures and storage conditions.
- These data support implementation of the assay into routine, non-specialist healthcare settings to facilitate practical blood-based testing to rule out AD-related Aβ pathology.

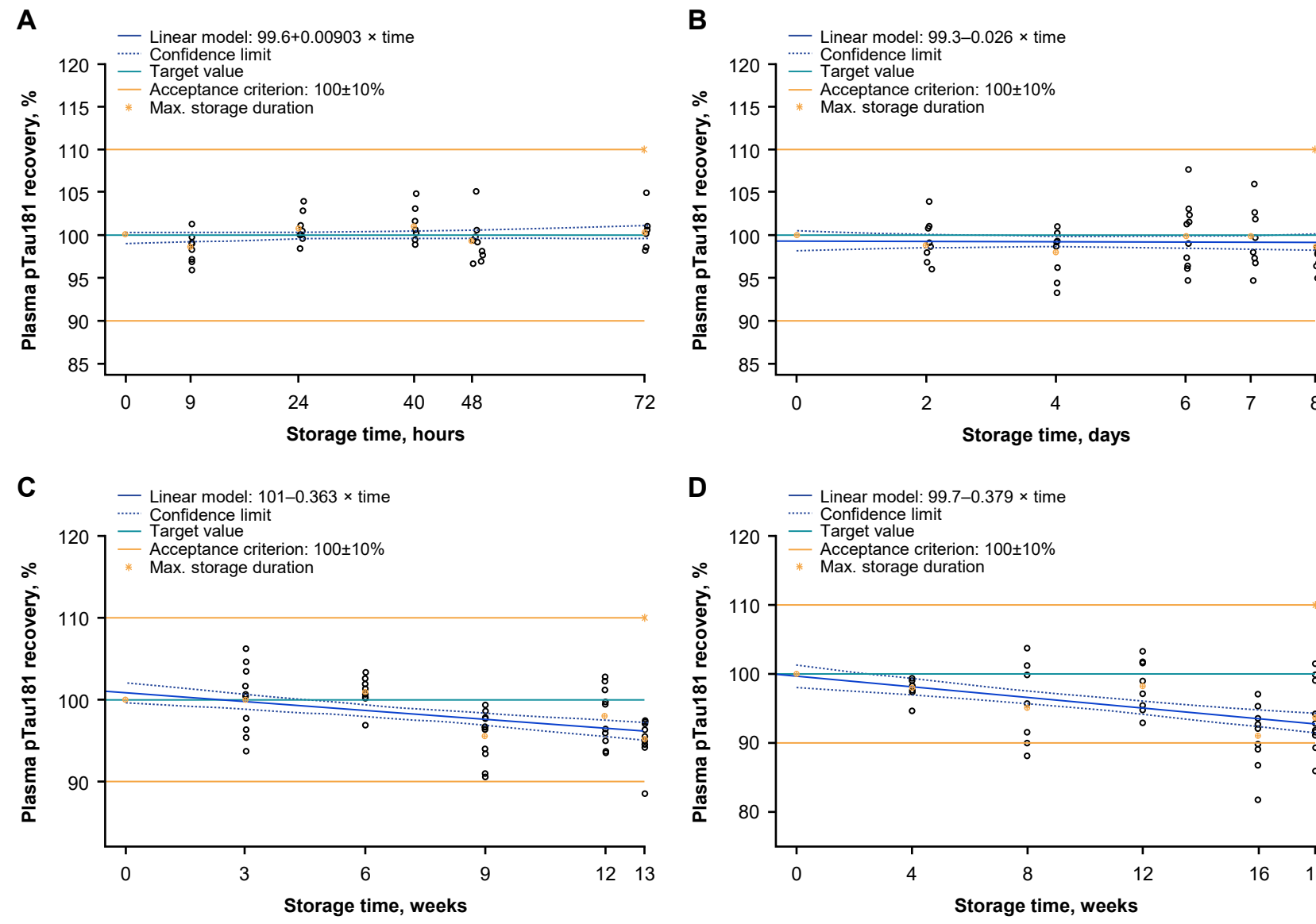
Results cont.

Figure 1. Scatter plot of plasma pTau181 stability regression in Li-Heparin tubes stored at (A) 25°C, (B) 4°C, (C) –20°C and (D) –80°C.



The solid blue line represents the fitted linear regression model, the dashed blue lines indicate the confidence limit, the solid green line represents the target value, solid orange lines indicate the acceptance criterion (100±10%), and the orange asterisks indicate the maximum storage duration, Max, maximum.

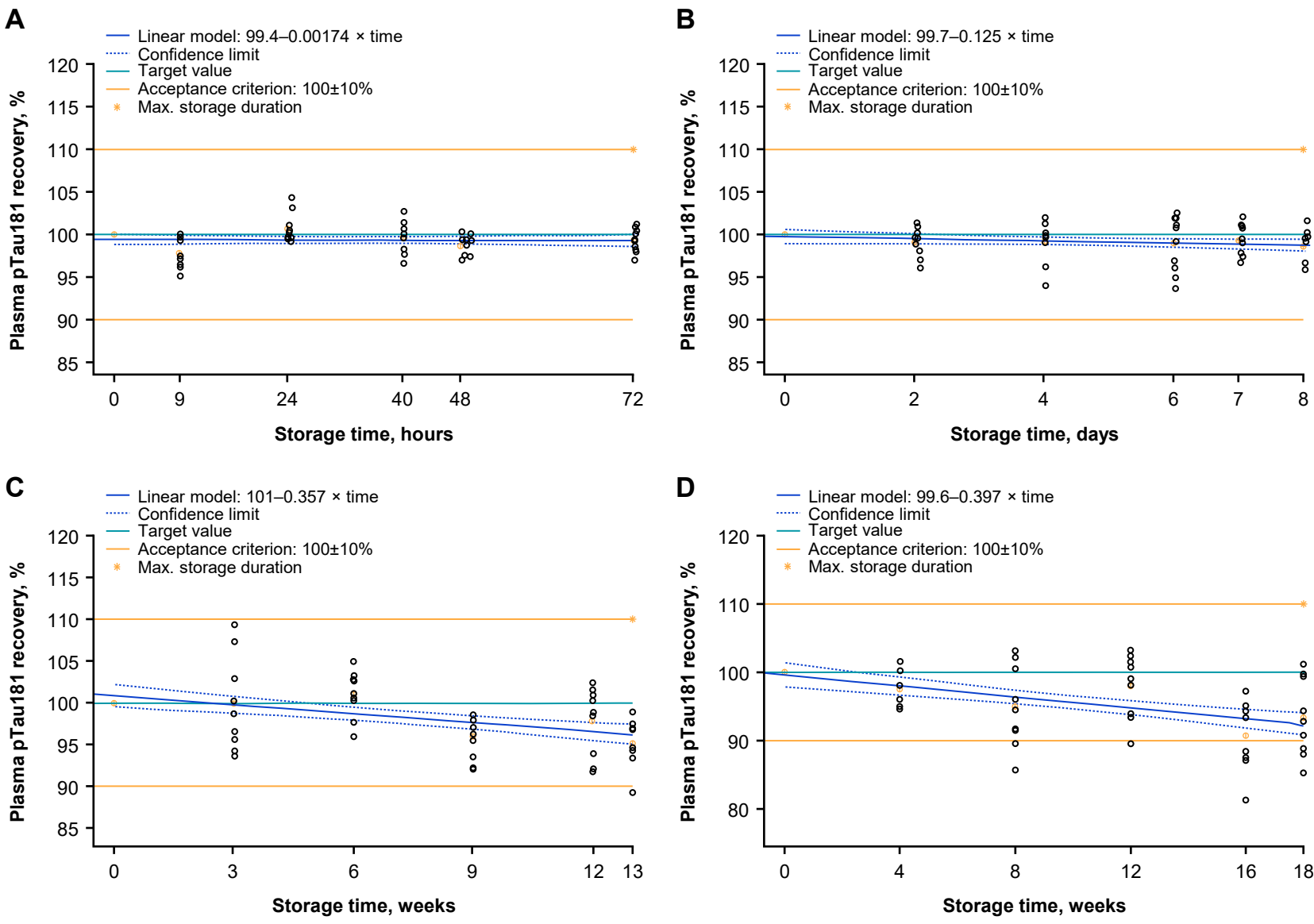
Figure 2. Scatter plot of plasma pTau181 stability regression in K2-EDTA tubes stored at (A) 25°C, (B) 4°C, (C) –20°C and (D) –80°C.



The solid blue line represents the fitted linear regression model, the dashed blue lines indicate the confidence limit, the solid green line represents the target value, solid orange lines indicate the acceptance criterion (100±10%), and the orange asterisks indicate the maximum storage duration.

Results cont.

Figure 3. Scatter plot of plasma pTau181 stability regression in K3-EDTA tubes stored at (A) 25°C, (B) 4°C, (C) –20°C and (D) –80°C.



The solid blue line represents the fitted linear regression model, the dashed blue lines indicate the confidence limit, the solid green line represents the target value, solid orange lines indicate the acceptance criterion (100±10%), and the orange asterisks indicate the maximum storage duration.

Linear regression

- No instabilities were observed and linear regression acceptance criteria were met.

Discussion

- After sample collection and handling procedures were optimised, contamination of plasma samples with buffy coat and erythrocytes was prevented.
- Plasma pTau181 was stable across the tested matrices for a maximum of 2 days at 25°C, 7 days at 4°C, 12 weeks at –20°C and 16 weeks at –80°C and after a single freeze/thaw cycle.
- Primary care settings could collect whole blood samples and pTau181 would remain stable throughout transportation, supporting its feasibility for use in frontline healthcare settings.
- In addition to the stability of plasma pTau181 for implementing the BBBM test in frontline care settings, the stability at –80°C for 16 weeks has implications in clinical trial settings.
- Although implementing the pT181p BBBM test into primary care settings is feasible, training and education are essential for correct interpretation of results.⁵

References

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