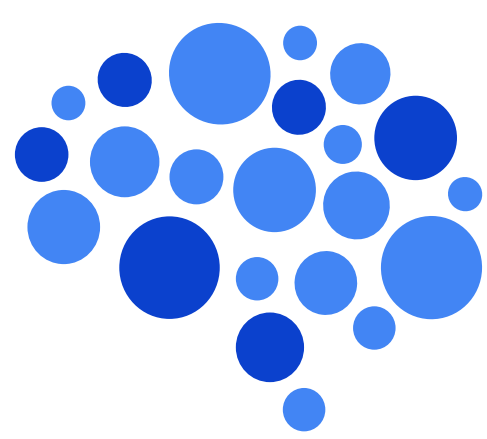


Elecsys pTau181 plasma immunoassay performance against centiloid-based amyloid classification across clinical stages

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Exhibit Hall

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What does this mean for the Alzheimer’s community?

- The Elecsys® Phospho-Tau (181P) Plasma (pT181p) immunoassay (Roche Diagnostics International Ltd) offers a scalable and minimally invasive tool to rule out Alzheimer’s disease (AD)-associated amyloid-beta (Aβ) pathology.
- The consistent discriminative ability of the pT181p immunoassay to detect amyloid pathology across multiple centiloid (CL) thresholds and clinical diagnosis subgroups supports the utility of the test for implementation across care settings and for various clinical purposes.

Background

- Plasma tau phosphorylated at threonine 181 (pTau181) is a key blood-based biomarker that robustly mirrors the development of Aβ pathology in AD.¹
- The Elecsys pT181p immunoassay has been approved for clinical use in Conformité Européenne mark-accepting countries and by the United States Food and Drug Administration as the first blood test for use in primary care to rule out AD pathology.^{2,3}
- The prevalence of amyloid pathology and the diagnostic accuracy of blood-based biomarkers are strongly influenced by the reference method used to define amyloid pathology status.
- While amyloid-positron emission tomography (PET) visual reads are a regulatory approved reference method for amyloid pathology detection, PET CL-based assessments are frequently used in research settings. Depending on the investigated target population, a variety of CL cutoffs may be applied.
- Here, we evaluated the performance of the Elecsys pT181p immunoassay to detect amyloid pathology with respect to varying amyloid-PET CL-based classification cutoffs, across clinical stages in a cohort of individuals representative of real-world clinical practice.

Methodology

The prospective APPROACH study (RD006263), conducted at 30 sites across Australia, Europe and the United States, enrolled adults aged 55–80 years with early signs, symptoms or complaints of cognitive impairment (subjective cognitive decline [SCD], mild cognitive impairment [MCI] or mild dementia [MD]).

The study cohort was representative of clinical routine in terms of age, sex and comorbidities.

Plasma pTau181 concentrations were measured using the Elecsys pT181p immunoassay.

The ability of the pT181p assay to discriminate amyloid positivity and negativity was assessed against amyloid-PET CL-based classifications at varying CL cutoffs, using receiver operating characteristic-area under the curve (ROC-AUC) analysis and cumulative distribution analysis (CDA).

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- ELECSYS is a trademark of Roche.

Results

- Samples from 1,177 adults were included in this analysis; of these, 36.9% had a clinical diagnosis of SCD, 55.8% had MCI and 5.9% had MD (**Table 1**).

Table 1. Participant demographics and clinical characteristics.

Characteristics	SCD (n=434; 36.9%)	MCI (n=657; 55.8%)	MD (n=69; 5.9%)	Clinical diagnosis missing (n=17; 1.4%)	All (N=1,177; 100%)
 Age, years					
Mean (SD)	67.5 (6.23)	70.3 (6.35)	71.8 (7.07)	70.5 (5.34)	69.4 (6.49)
Min–Max	55–80	55–80	55–80	63–79	55–80
Sex, n (%)					
Female	281 (64.7)	376 (57.2)	35 (50.7)	10 (58.8)	702 (59.6)
Race, n (%)					
White	347 (80.0)	529 (80.5)	62 (89.9)	12 (70.6)	950 (80.7)
Asian	6 (1.4)	11 (1.7)	1 (1.4)	0 (0.0)	18 (1.5)
Black or African American	75 (17.3)	97 (14.8)	3 (4.3)	4 (23.5)	179 (15.2)
Other*	6 (1.4)	20 (3.0)	3 (4.3)	1 (5.9)	30 (2.5)
Total CDR, n (%)					
0	135 (31.1)	15 (2.3)	0 (0.0)	0 (0.0)	150 (12.7)
0.5	282 (65.0)	598 (91.0)	23 (33.3)	0 (0.0)	903 (76.7)
1	6 (1.4)	41 (6.2)	45 (65.2)	0 (0.0)	92 (7.8)
2	1 (0.2)	0 (0.0)	1 (1.4)	0 (0.0)	2 (0.2)
3	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)
Missing	9 (2.1)	3 (0.5)	0 (0.0)	17 (100)	29 (2.5)
ApoE4p, n (%)					
Non-reactive	289 (66.6)	413 (62.9)	33 (47.8)	15 (88.2)	750 (63.7)
Reactive	145 (33.4)	244 (37.1)	36 (52.2)	2 (11.8)	427 (36.3)
eGFR group†, n (%)					
≥60	397 (91.5)	558 (84.9)	59 (85.5)	17 (100)	1,031 (87.6)
45–59	24 (5.5)	79 (12.0)	8 (11.6)	0 (0.0)	111 (9.4)
30–44	7 (1.6)	13 (2.0)	1 (1.4)	0 (0.0)	21 (1.8)
≤29	4 (0.9)	4 (0.6)	1 (1.4)	0 (0.0)	9 (0.8)
Missing	2 (0.5)	3 (0.5)	0 (0.0)	0 (0.0)	5 (0.4)

*Includes Middle Eastern.
†eGFR categories (mL/min/1.73m²) were defined according to the KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease and grouped as G1–G2 (≥60), G3a (45–59), G3b (30–44) and G4–G5 (≤29).⁴
ApoE4p, apolipoprotein E4 plasma; CDR, clinical dementia rating; eGFR, estimated glomerular filtration rate; Max, maximum; Min, minimum; SD, standard deviation.

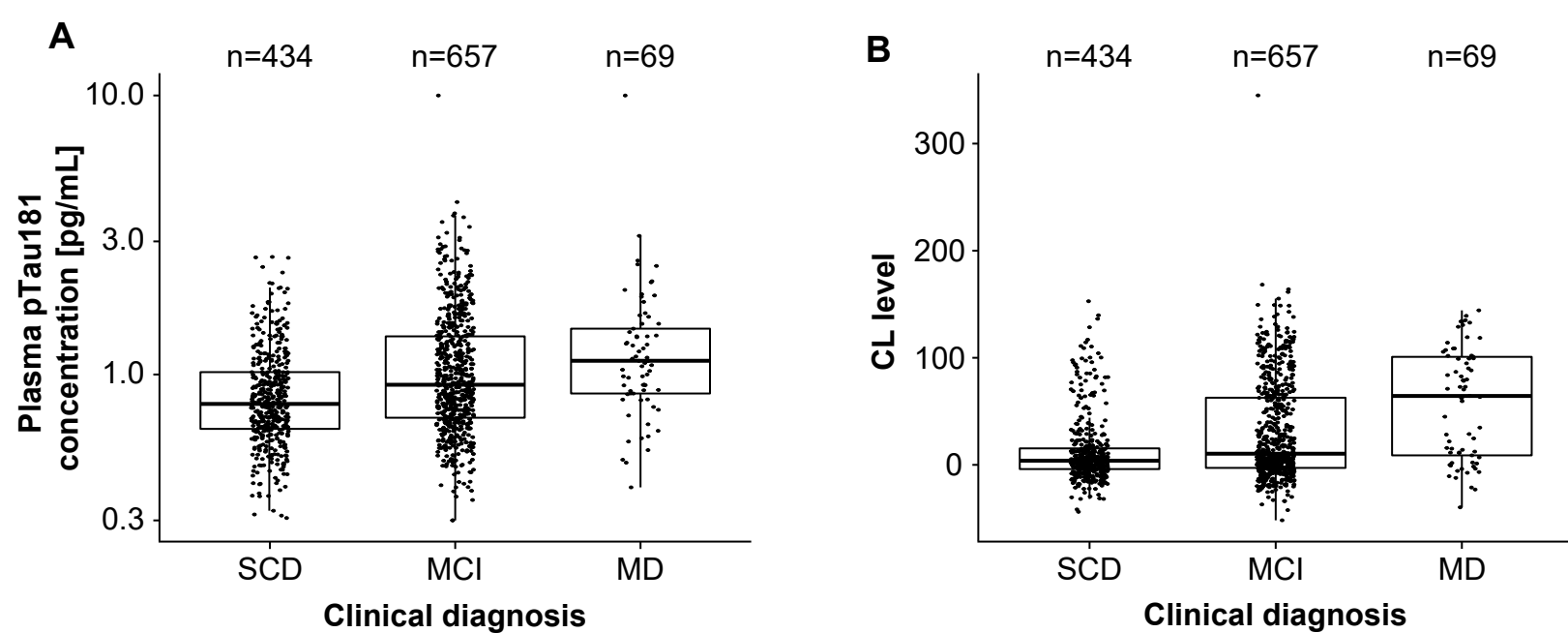
- Plasma pTau181 levels and CL values both increased with increasing clinical severity. For individuals with SCD, MCI and MD, respectively, median plasma pTau181 concentrations were 0.785 pg/mL, 0.919 pg/mL and 1.12 pg/mL (**Figure 1A**) and median CL values were 3.9, 10.4 and 64.3 (**Figure 1B**).

Conclusions

- The Elecsys pT181p immunoassay accurately detected amyloid pathology status in a real-world cohort presenting with subjective or objective cognitive impairment.
- Plasma pTau181 concentrations increased with amyloid burden and discriminative ability remained consistent across multiple CL thresholds that represent clinically relevant definitions of amyloid positivity.

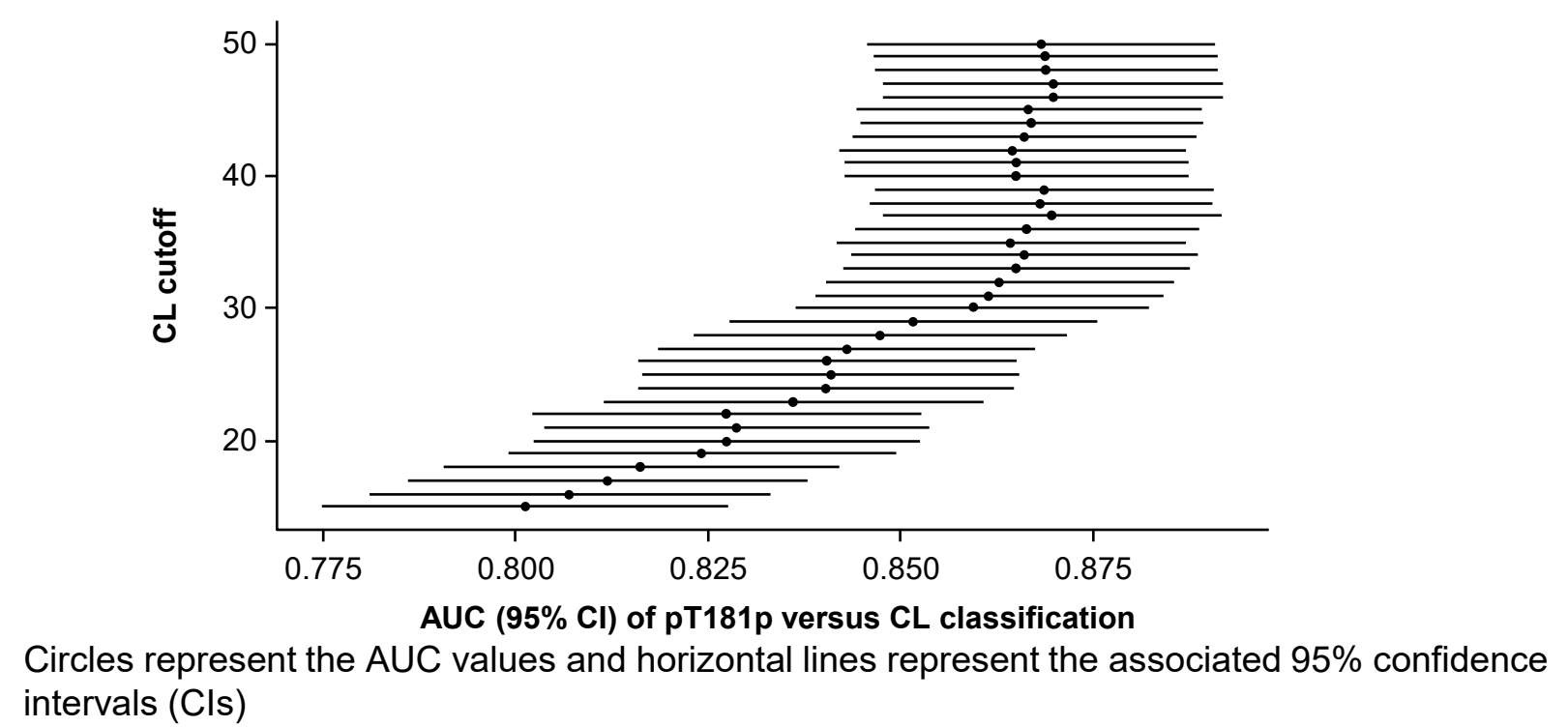
Results cont.

Figure 1. Boxplots of (A) plasma pTau181 and (B) CL levels stratified by clinical diagnosis.



- At CL24.1 (CL30) cutoff, the median plasma pTau181 levels were 0.758 pg/mL (0.762 pg/mL) in CL-negative individuals and 1.32 pg/mL (1.37 pg/mL) in CL-positive individuals.
- The AUC for the pT181p assay versus CL classification for discriminating amyloid pathology varied slightly according to the CL cutoff, with stable AUCs observed for CL values of 32 and above (**Figure 2**).

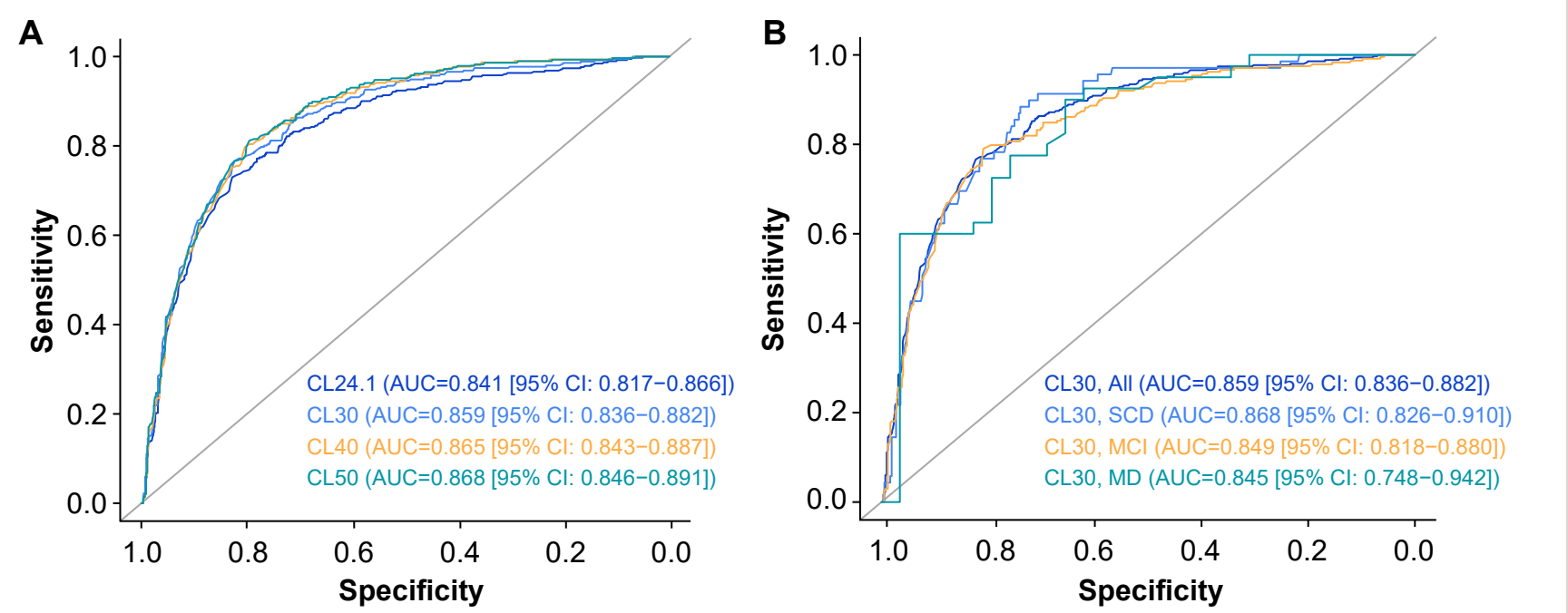
Figure 2. AUC of pT181p versus CL classifications at varying CL cutoffs.



- The observed discriminative performance was AUC=0.841 for CL24.1, AUC=0.859 for CL30, AUC=0.865 for CL40 and AUC=0.868 for CL50 (**Figure 3A**).
- The pT181p immunoassay maintained consistent AUCs across clinical diagnosis subgroups (CL30 cutoff: 0.868 for SCD, 0.849 for MCI and 0.845 for MD; **Figure 3B**).
- The choice of CL cutoff influenced the positive percent agreement (PPA) and negative percent agreement (NPA) of the pT181p immunoassay when evaluated for various pT181p thresholds.

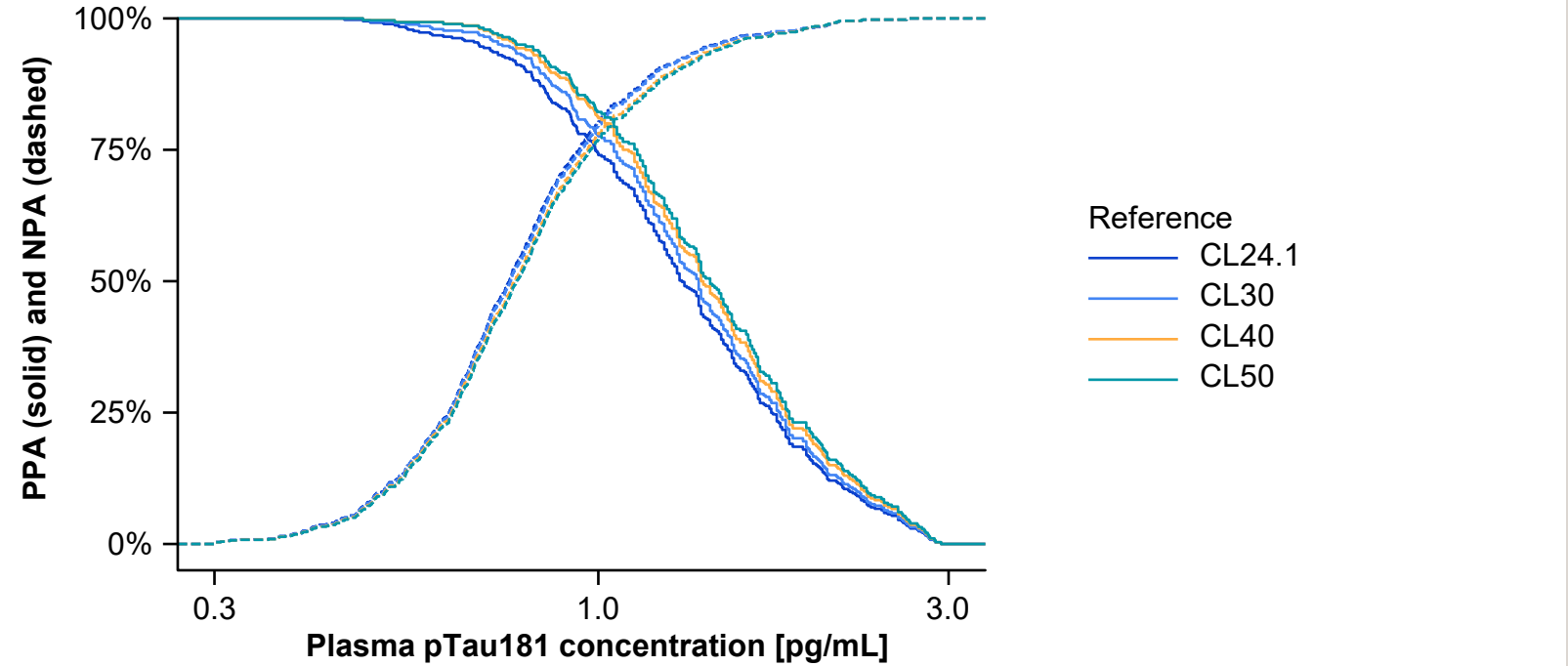
Results cont.

Figure 3. ROC-AUC analysis of pT181p immunoassay performance with respect to (A) CL cutoffs 24.1–50 and (B) CL30 cutoff across clinical diagnosis subgroups.



- The CDA confirmed a stable, high-sensitivity region, supporting the intended rule-out use of the pT181p immunoassay for identifying individuals with a low likelihood of amyloid pathology (**Figure 4**).

Figure 4. CDA curve showing PPA and NPA with respect to CL cutoffs 24.1–50.



Discussion

- While visual assessment remains the diagnostic standard, quantitative CL thresholds are increasingly utilised to support clinical interpretation and risk stratification: CL<10 excludes pathology, CL10–30 indicates evolving pathology and CL>30 confirms established disease, with the CL24–30 range considered optimal for initiating therapies.⁵
- Our findings demonstrate that the pT181p immunoassay maintains robust discriminative ability in the clinically relevant region. Since pT181p scales reliably with amyloid burden, cutoffs can be precisely calibrated for tailored risk-stratification in clinical trials. Concurrently, a highly sensitive, fixed cutoff is validated for routine clinical rule-out across diverse care settings.

References

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