

Capillary BD-P-tau217 meets CLIA/CAP validation in a community-recruited cohort for remote early detection of Alzheimer’s disease

Elisabeth H. Thijssen¹, Ansam Eghzawi¹, Federica Gibellini², Nicholas Ashton³, Inge M.W. Verberk⁴, Salman Khwaja², Lakshmi Chandramohan⁵, Vanessa Higgins¹, Iyad Alnachefi¹, Zaki Mallick¹, Maya Barakat¹, Michelle M. Mielke⁶, Cara Leahy⁷, Kenneth Bahk¹, Rany Aburashed¹

1 Neurogen Biomarking, Chicago, IL · 2 AccessDx, Houston, TX · 3 Banner Sun Health Research Institute, Sun City, AZ · 4 Amsterdam UMC, Amsterdam, NL · 5 ADVI Solutions LLC, Houston, TX · 6 Dept. of Epidemiology & Prevention, Wake Forest University School of Medicine, Winston-Salem, NC · 7 Memorial Healthcare, Owosso, MI

HEADLINE RESULT

0.959 AUC

Capillary BD-P-tau217 discriminating amyloid status across the full cohort (n=244)

90.5%

Sensitivity

89.0%

Specificity

R=0.93

Capillary vs venous correlation (p<0.001)

~90%

Self-collection success rate

01 – BACKGROUND

Expanding access to P-tau217 testing

Blood-based P-tau217 accurately reflects Alzheimer’s disease (AD) pathology, but access is constrained by clinic-based venipuncture — and **92% of mild cognitive impairment goes undetected** in primary care. At-home capillary collection could scale early detection, yet prior capillary P-tau217 has been limited by peripheral tau isoforms (dried blood spot AUC 0.66–0.86; no Tasso-IV correlation shown for P-tau217 so far).

02 – OBJECTIVE

A brain-specific P-tau217 assay, validated for capillary blood

Validate a brain-derived P-tau217 assay (**BD-P-tau217**) — using a brain-specific antibody design to exclude peripheral tau — in capillary blood from the Tasso+ upper-arm device, under CLIA/CAP-certified conditions and following **CEOi criteria**.

- Analytical** — capillary vs venous correlation (n=244)
- Clinical** — performance vs amyloid-PET (n=64)
- Fit-for-purpose** — Tasso vs composite reference at community prevalence

03 – METHODS

Paired sampling, central CLIA/CAP lab

244 participants across 6 U.S. sites (Jan 2025–Apr 2026).

Clinical cohort (n=64): PET-confirmed (46 Amyloid-PET positive, 18 Amyloid-PET negative), from Memorial Healthcare clinic and the ADRC at Wake Forest University School of Medicine. **Community cohort (n=180)**: adults ≥50 y with cognitive concerns recruited at four community events, at two rural and two inner city locations. Paired capillary (Tasso+) and venous samples were drawn the same day, shipped overnight at room temperature, and **processed <24 h via a proprietary capillary-to-assay workflow**. BD-P-tau217 (Alamar) was measured at AccessDx (CLIA-certified / CAP-accredited; inter-assay CV 9.4–12.6%, intra-assay 7.3%). Composite reference = amyloid-PET where available, venous BD-P-tau217 otherwise.

04 – RESULTS

Capillary performance approaches venous

- a** Capillary and venous BD-P-tau217 were **strongly correlated** across the full cohort (R=0.93, p=0.73; p<0.001).
- b** In the PET-confirmed cohort, venous BD-P-tau217 separated PET+ from PET– with **AUC 0.989** (93.5% sens, 100% spec), supporting its use as a reference standard.
- c,d** Capillary BD-P-tau217 discriminated amyloid status across the full cohort: **AUC 0.959**, 90.5% sens, 89.0% spec; PPV 74.0%, NPV 96.4% at 26% prevalence.
- ◆ **Robust & deployable**: CV <20% across freeze–thaw; 75–125% recovery to 48 h at room temperature; self-collection equivalent to professional.
- MEETS THRESHOLDS** • Clears CEOi (sens ≥90%, spec ≥85%) *and* the **Alzheimer’s Association Clinical Practice Guideline** (sens ≥90%, spec ≥75%) criteria for a high-specificity triage test.

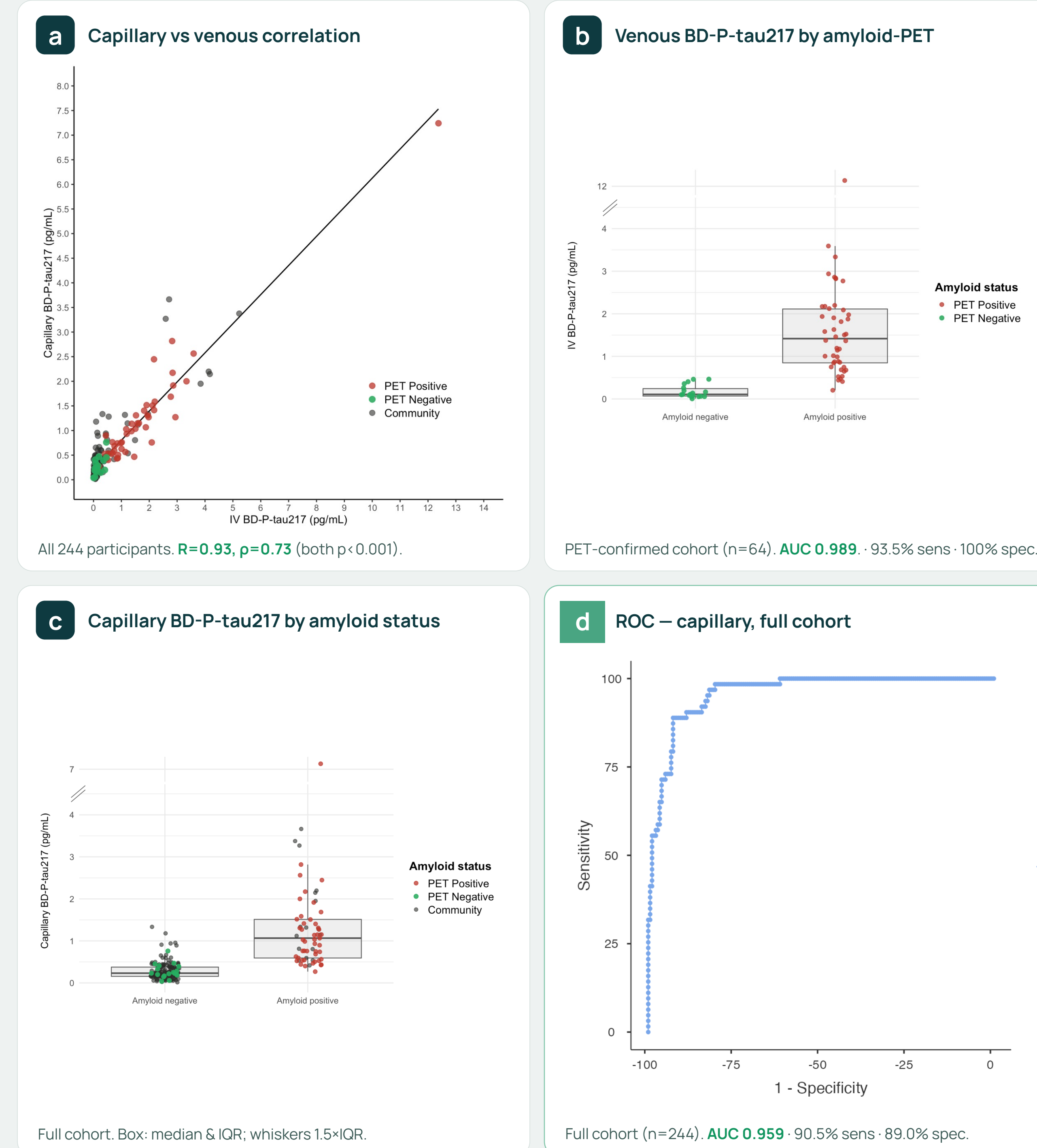
TABLE 1 – PARTICIPANTS

Cohort characteristics

Characteristic	Overall N=244	Community N=180	PET-conf. N=64
Age, mean ± SD	64.3 ± 11.9	60.3 ± 10.8	75.4 ± 6.6
Female, n (%)	153 (62.7)	118 (65.6)	35 (54.7)
Black / African American, n (%)	51 (20.9)	46 (25.6)	5 (7.8)
Hispanic ethnicity, n (%)	12 (4.9)	12 (6.7)	0 (0.0)
Family history of AD, n (%)	77 (31.6)	47 (26.1)	30 (46.9)
Amyloid positive, n (%)	63 (25.8)	17 (9.4)	46 (71.9)

Amyloid status by composite reference (PET where available; venous BD-P-tau217 otherwise); PET-confirmed cohort by visual PET read. Consolidated from manuscript Table 1.

FIGURE 1 – IV & CAPILLARY BD-P-TAU217



CONCLUSION

A validated capillary triage for amyloid pathology

To our knowledge, this is the first demonstration that capillary-collected P-tau217 meets CLIA/CAP analytical standards and clinical-guideline thresholds for high-specificity triage of amyloid pathology. By enabling biological triage before — or alongside — a primary-care visit, it can shorten diagnostic delays and concentrate scarce specialist capacity on those most likely to have underlying AD.

→ Remote, self-collected sampling at ~90% success

→ Meets CEOi + Alzheimer’s Association guideline criteria

→ 25.6% Black representation in the community cohort

DISCLOSURES

E.T., A.E., V.H., I.A., K.B., R.A. are employees of Neurogen Biomarking; Z.M., M.B. contributed during internships there. F.G., S.K. are employees of AccessDx (contracted lab). L.C. (ADVI Solutions) provided CAP/CLIA consultation. N.A., I.V., M.M.M., C.L. are compensated members of the Neurogen Scientific Advisory Committee. Full disclosures in the manuscript (submitted).

FUNDING & ETHICS

Sample collection funded by Neurogen Biomarking. Amyloid PET and clinical data at the Wake Forest University ADRC supported by NIA/NIH award P30AG072947. Approved by Sterling IRB (protocol 12951); all participants provided written informed consent.

SELECTED REFERENCES

Schindler SE et al. *Nat Rev Neurol* 2024;20:426–439. · Huber H et al. *Nat Med* 2026. · Corbett A et al. *Nat Commun* 2026;17:3699. · Palmqvist S et al. *Alzheimers Dement* 2025. · Whitson HE et al. *JAMA* 2026.