Sensitivity and Specificity of Lucent® Diagnostics Blood-Based Biomarker Assays for Alzheimer's Disease in a Real-World Dementia Subspecialty Clinic

Monday-1012

Mark Eldaief, MD[1,2,4,5,6], Sam Murdock[1], Erin A. Krahn[1], Neguine Rezaii, MD[1,2], Diane Chan, MD, PhD[1,2], Steven Arnold, MD, PhD[2,4], Marina Avetisyan, MD[2], John Dickson, MD, PhD[2,4], Mark Albers, MD, PhD[2,4], Anna Goodheart, MD[2], Matthew Walsh, CNP, Sophal Lam[2], Yedda Li, MD[2], Liliana Ramirez Gomez, MD[2,4], Seth Gale, MD[7], Scott McGinnis, MD[1,7], & Bradford C. Dickerson, MD[1,2,3,4,5]

[1]Frontotemporal Disorders Unit, Department of Neurology, Massachusetts General Hospital and Harvard Medical School, Boston, MA 02114; [2]Memory Disorders Unit, Department of Neurology, Massachusetts General Hospital and Harvard Medical School, Boston, MA 02114; [3]Athinoula A. Martinos Center for Biomedical Imaging, Massachusetts General Hospital, Charlestown, MA 02129; [4]Alzheimer's Disease Research Center, Massachusetts General Hospital, Charlestown, MA 02129; [5]Department of Psychiatry, Massachusetts General Hospital and Harvard Medical School, Boston, MA 02114; [6]Center for Brain Science, Harvard University, Cambridge, MA 02138; [7]Center for Brain Mind Medicine, Department of Neurology, Brigham & Women's Hospital and Harvard Medical School, Boston, MA 02115

KEY TAKE AWAY: Lucent® Diagnostics BBMs for Alzheimer's disease are highly sensitive and specific in a real-world subspecialty clinic.

INTRODUCTION

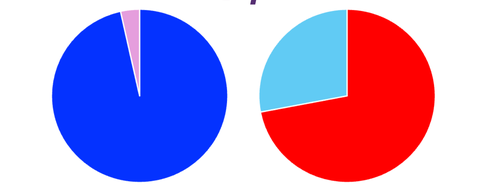
Blood-based biomarkers (BBMs) can detect Alzheimer's disease neuropathologic changes (ADNC) *in vivo*. Because BBMs are minimally invasive, cost-effective and because their use is potentially scalable to non-specialty centers, they have increasingly become part of the clinical diagnostic workflow in AD. However, the sensitivity and specificity of BBMs in real-world clinical settings remains unclear. To contextualize the use of BBMs within a real-world dementia subspecialty practice, we evaluated sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of the LucentAD® p-Tau 217 and the LucentAD® Complete panel in dementia subspecialty clinics at the MassGeneral Brigham by validating these tests against gold standard testing of amyloid PET and/or CSF AD biomarkers. We also evaluated the correlation between clinicians' pre-test predictions of ADNC and BBM results.

METHODS

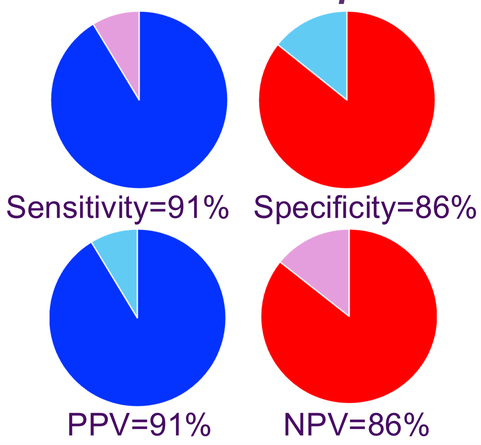
Dementia subspeciality clinicians ordered the LucentAD® p-Tau 217 and/or the LucentAD® Complete panel as standard send-out labs on their clinic patients. Results were read out as low, medium or high likelihood of ADNC. Clinicians served as research subjects and completed forms detailing their differential diagnoses, their pre-test estimates of the likelihood of ADNC and their plans for testing and treatment prior to learning BBM test results. For sensitivity, specificity, positive and negative predictive values, clinically obtained amyloid PET imaging and/or CSF AD biomarkers were used as gold-standard validators. Finally, pre-test probability scores were correlated with BBM results. 378 patients underwent the LucentAD® p-Tau 217 test: 186 had a positive result, 123 had an intermediate result and 69 had a negative result. 111/378 had gold-standard biomarkers. 295 patients underwent the LucentAD® Complete panel: 164 had a positive result, 34 had an intermediate result and 97 had a negative result. 74/295 also had gold-standard biomarkers.

RESULTS

LucentAD® p-Tau 217

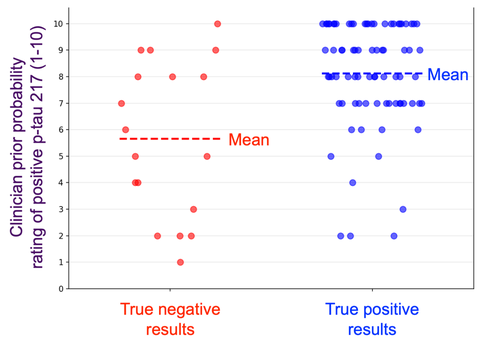


LucentAD® Complete



RESULTS (CONT'D)

Clinician prior probability accuracy



CONCLUSIONS

In a real-world dementia subspecialty clinical practice, both the Lucent® p-Tau 217 assay and the LucentAD® Complete panel were highly sensitive and specific for detecting likely AD pathologic changes when measured against widely accepted gold standard AD biomarkers (with greater sensitivity than specificity). Additionally, clinician's pre-test assessments were highly predictive of test results. These findings support the use of BBMs in the early clinical workflow of dementia subspecialists.

REFERENCES

1. Hansson O, Edelmayer RM, Boxer AL, et al. The Alzheimer's Association appropriate use recommendations for blood biomarkers in Alzheimer's disease. Alzheimers Dement. Dec 2022;18(12):2669-2686.
2. Janelidze S, Bali D, Ashton NJ, et al. Head-to-head comparison of 10 plasma phospho-tau assays in prodromal Alzheimer's disease. Brain. Apr 19 2023;146(4):1592-1601.
3. Mattsson-Carlgren N, Janelidze S, Bateman RJ, et al. Soluble P-tau217 reflects amyloid and tau pathology and mediates the association of amyloid with tau. EMBO Mol Med. Jun 7 2021;13(6):e14022.
4. Zetterberg H, Bendlin BB. Biofluid biomarkers in Alzheimer's disease and other neurodegenerative dementias. Nature. Feb 2026;650(8100):49-59.
5. VandeVrede L, Schindler SE. Clinical use of biomarkers in the era of Alzheimer's disease treatments. Alzheimers Dement. Jan 2025;21(1):e14201.
6. Pahlke S, Kahale LA, Mahinrad S, et al. Blood-based biomarkers for detecting Alzheimer's disease pathology in cognitively impaired individuals within specialized care settings: A systematic review and meta-analysis. Alzheimers Dement. Nov 2025;21(11):e70828.
7. Palmqvist S, Whitson HE, Allen LA, et al. Alzheimer's Association Clinical Practice Guideline on the use of blood-based biomarkers in the diagnostic workup of suspected Alzheimer's disease within specialized care settings. Alzheimers Dement. Jul 2025;21(7):e70535.
8. Teunissen CE, Verberk IMW, Thijssen EH, et al. Blood-based biomarkers for Alzheimer's disease: towards clinical implementation. Lancet Neurol. Jan 2022;21(1):66-77.
9. Valletta M, Briel N, Yuksekel I, et al. Fluid biomarkers for neurodegenerative diseases: a comprehensive update. Alzheimers Res Ther. Dec 20 2025;18(1):12.
10. Atri A, Dickerson BC, Clevenger C, et al. Alzheimer's Association clinical practice guideline for the Diagnostic Evaluation, Testing, Counseling, and Disclosure of Suspected Alzheimer's Disease and Related Disorders (DETeCD-ADRD): Executive summary of recommendations for primary care. Alzheimers Dement. Jun 2025;21(6):e14333.

CONTACT

mark.eldaief@mgh.harvard.edu