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Alzheimer's Disease Normative Cerebrospinal Fluid Biomarkers Validated in PET Amyloid- β Characterized Subjects from the Australian Imaging, Biomarkers and Lifestyle (AIBL) study

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Authors: Li, Qiao-Xin^a | Villemagne, Victor L.^{a; b} | Doecke, James D.^c | Rembach, Alan^{a; †} | Sarros, Shannon^a | Varghese, Shiji^a | McGlade, Amelia^a | Laughton, Katrina M.^a | Pertile, Kelly K.^a | Fowler, Christopher J.^a | Rumble, Rebecca L.^a | Trounson, Brett O.^a | Taddei, Kevin^{e; f} | Rainey-Smith, Stephanie R.^{e; f} | Laws, Simon M.^{e; f} | Robertson, Joanne S.^a | Evered, Lisbeth A.^g | Silbert, Brendan^g | Ellis, Kathryn A.^{a; h} | Rowe, Christopher C.^{a; b} | Macaulay, S. Lanceⁱ | Darby, David^a | Martins, Ralph N.^{e; f; j} | Ames, David^{h; k} | Masters, Colin L.^a | Collins, Steven^{a; d; *} | and for the AIBL Research Group^l

Affiliations: [a] Florey Institute of Neuroscience and Mental Health, The University of Melbourne, VIC, Australia | [b] Department of Nuclear Medicine and Centre for PET, Austin Health, Heidelberg, VIC, Australia | [c] CSIRO Digital Productivity/Australian e-Health Research Centre and Cooperative Research Centre

for Mental Health, Brisbane, QLD, Australia | [d] Department of Pathology, The University of Melbourne, Parkville, Australia | [e] Centre of Excellence for Alzheimer's Disease Research & Care, School of Medical Sciences, Edith Cowan University, Joondalup, Western Australia, Australia | [f] Sir James McCusker Alzheimer's Disease Research Unit (Hollywood Private Hospital), Perth, WA, Australia | [g] Centre for Anaesthesia and Cognitive Function, Department of Anaesthesia, and Department of Surgery, St. Vincent's Hospital, The University of Melbourne, VIC, Australia | [h] The University of Melbourne Academic Unit for Psychiatry of Old Age, St George's Hospital, Kew, VIC, Australia | [i] CSIRO Food and Nutrition Flagship, Parkville, VIC, Australia | [j] School of Psychiatry and Clinical Neurosciences, University of Western Australia, Perth, Western Australia, Australia | [k] National Ageing Research Institute, Parkville, VIC, Australia | [l] <http://aibl.csiro.au/>

Correspondence: [*] Correspondence to: Steven Collins, MD, Department of Pathology, The University of Melbourne, Parkville 3010, Australia. Tel.: +61 3 9035 7682; Fax: +61 3 9035 3105; stevenjc@unimelb.edu.au

Note: [†] Unexpectedly deceased 20 November 2014.

Abstract: Background: The cerebrospinal fluid (CSF) amyloid- β ($A\beta$)₁₋₄₂, total-tau (T-tau), and phosphorylated-tau (P-tau_{181P}) profile has been established as a valuable biomarker for Alzheimer's disease (AD). Objective: The current study aimed to determine CSF biomarker cut-points using positron emission tomography (PET) $A\beta$ imaging screened subjects from the Australian Imaging, Biomarkers and Lifestyle (AIBL) study of aging, as well as correlate CSF analyte cut-points across a range of PET $A\beta$ amyloid ligands. Methods: $A\beta$ pathology was determined by PET imaging, utilizing ¹¹C-Pittsburgh Compound B, ¹⁸F-flutemetamol, or ¹⁸F-florbetapir, in 157 AIBL participants who also underwent CSF collection. Using an INNOTEST assay, cut-points were established ($A\beta$ ₁₋₄₂ >544 ng/L, T-tau <407 ng/L, and P-tau_{181P} <78 ng/L) employing a rank based method to define a "positive" CSF in the sub-cohort of amyloid-PET negative healthy participants (n=97), and compared with the presence of PET demonstrated AD pathology. Results: CSF $A\beta$ ₁₋₄₂ was the strongest individual biomarker, detecting cognitively impaired PET positive mild cognitive impairment (MCI)/AD with 85% sensitivity and 91% specificity. The ratio of P-tau_{181P} or T-tau to $A\beta$ ₁₋₄₂ provided greater accuracy, predicting MCI/AD with $A\beta$ pathology with 92% sensitivity and specificity. Cross-validated accuracy, using all three biomarkers or the ratio of P-tau or T-tau to $A\beta$ ₁₋₄₂ to predict MCI/AD, reached 92% sensitivity and specificity. Conclusions: CSF $A\beta$ ₁₋₄₂ levels and analyte combination ratios demonstrated very high correlation with PET $A\beta$ imaging. Our study offers additional support for CSF biomarkers in the early and accurate detection of AD pathology, including enrichment of patient cohorts for treatment trials even at the pre-symptomatic stage.

Keywords: Alzheimer's disease, amyloid- β , cerebrospinal fluid biomarkers, positron emission tomography $A\beta$ imaging, tau

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