

ASX Announcement

3 December 2025

BCAL establishes national registry to evaluate clinical impact of BREASTEST for Australian women

Highlights

- BCAL receives national ethics approval¹ to establish The BREASTEST Registry for up to 24,000 women
- Women receiving BREASTESTplus™ through participating sites will be offered the opportunity to join the BREASTEST Registry
- Registry provides a catalyst to help drive doctor decision making, adoption of BREASTESTplus™, and to collect evidence to support reimbursement

BCAL Diagnostics Limited (ASX: BDX), an Australian healthcare company pioneering diagnostics for early detection of cancer, announces national ethics approval has been granted for a registry study on up to 24,000 women who will have BREASTESTplus™ as part of their clinical treatment - The BREASTEST Registry.

The BREASTEST Registry enables BCAL to generate real-world clinical performance data on the impact of BREASTESTplus™ in breast cancer diagnosis. The clinical publications that will follow from the analysis of the data will underpin the clinical utility of BREASTESTplus™, support doctor decision making, and Australian reimbursement for BREASTESTplus™."

The registry will examine how BREASTESTplus™ is used in routine care, including its impact on follow-up imaging and biopsy decisions. By tracking clinical outcomes over 24–36 months, BCAL will strengthen the clinical utility and adoption of BREASTESTplus™ for women with dense breast tissue, a group historically underserved by traditional screening tools and technology. Participating doctors will provide feedback on how the test influenced their decision making and integrates into standard of care.

Breast Surgeon Dr David Speakman said, *"This registry will generate the kind of longitudinal data and peer-reviewed publications that clinicians rely on to guide best practice. By studying BREASTESTplus™ in everyday diagnostic environments, we can more accurately assess its impact on patient pathways and ensure that women receive the most informed, evidence-based care."*

BCAL CEO Shane Ryan said, *"The BREASTEST Registry will help accelerate doctor adoption while collecting real-world data to support future reimbursement. This bold initiative reinforces BCAL's commitment to equip medical professionals with the tools and evidence they need to optimise the use of BREASTESTplus™ and use for women with dense breast tissue."*

This announcement has been approved for release by the Board of BCAL.

ENDS

¹ All clinical studies require approval by a qualified Human Research Ethics Committee

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About BCAL Diagnostics

BCAL is an Australian health care company engaged in early cancer detection. BCAL launched its first test BREASTEST*plus*[™] as a 'rule-out' test designed to be used in the clinical evaluation of breast disease for women with dense breasts. BREASTEST*plus*[™] is a simple, non-invasive blood test used in conjunction with mammography to improve screening and diagnostic outcomes for breast health in women.

BCAL holds exclusive license with ClearNote Health Inc., a US-based precision diagnostics company, for the sale and distribution of Avantect Pancreatic, Avantect Ovarian and Avantect multi-cancer blood tests in Australia and New Zealand.

BCAL is headquartered in Sydney, Australia and listed on the Australian Securities Exchange (ASX: BDX). For more information: <https://www.bcaldiagnostics.com/> or contact info@bcaldiagnostics.com.