

**ASX Announcement**

3 December 2025

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

### **Highlights**

- **BCAL receives national ethics approval<sup>1</sup> 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**

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<sup>1</sup> 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](mailto:info@bcaldiagnostics.com).