

ASX Announcement

30th September 2026

BREASTEST^{plus}™ 2 clinically validated for women 30 years+ and all breast densities; on track for November launch

Highlights

- **Next-generation BREASTEST^{plus}™ 2 applicable for the detection of early-stage breast cancer for all breast densities following clinical validation completion.**
- **Validated for women 30 years+ across all breast densities, broadening the population who can access the test.**
- **Commercial launch on track for November 2026, commencing in Sydney, Melbourne, and Brisbane, ahead of a national rollout.**
- **The second generation of BREASTEST^{plus}™ developed in Australia.**

BCAL Diagnostics Limited (ASX: BDX), an Australian healthcare company pioneering diagnostics for early detection of cancer, has completed clinical validation of its next generation BREASTEST^{plus}™ 2 blood test across all breast densities for the detection of early-stage breast cancer (Stage 0 [DCIS], Stage 1 and Stage 2). The results support the test's clinical use and planned launch in November 2026.

In the clinical validation study, for the detection of early-stage (Stage 0 to 2) breast cancer, BREASTEST^{plus}™ 2 demonstrated:

- Sensitivity of 80.3%, and
- Specificity of 48.5%.

BREASTEST^{plus}™ 2 has been developed to provide women greater surety they do not have the disease. A 'Normal' test result supports reassurance. An 'Elevated' result is an early flag that further investigation is warranted. It is not a diagnosis; as with other screening tests, further assessment is needed to confirm a result, and clinicians should continue their routine management. Of the breast cancers detected in the validation study, 61.9% were Stage 0 or Stage 1.

A significant opportunity exists for women who are not currently participating in mammographic screening, offering a simple, non-invasive blood test that can provide additional information about their breast health. Currently, approximately only 48% of all eligible Australian women are being evaluated regularly with mammogram.

Key features of BREASTEST^{plus}™ 2:

- For women aged 30 years+ developed for use across a broad range of age and all breast densities.
- Provides women and their doctors with additional information to support clinical decision-making with a simple, blood-based test.

- BREASTESTplus™ 2 uses an enhanced lipid biomarker panel with stability and reproducibility supported through analytical validation.

BREASTESTplus™ 2 is a non-invasive blood test designed to be used alongside other diagnostic pathways across all breast densities, with the potential to significantly broaden the population who can access additional information about their breast health. It provides additional information to aid healthcare professionals. It is not intended to diagnose breast cancer as a standalone test.

Women receiving BREASTESTplus™ 2 through participating sites will be offered the opportunity to join the BREASTEST Registry. This data will be used to develop real-world evidence for BREASTESTplus™ 2.

BCAL CEO Annie Arnett said, *“BREASTESTplus™ 2 represents a significant advance in BCAL's offering to the market, expanding patient eligibility and clinician access, and strengthens our position to deliver earlier breast-health assessment to a larger population of Australian women.”*

BCAL worked with OmniOmics.ai, which provided independent bioinformatics validation of BREASTESTplus™ 2, and with Dr David Speakman, who provided clinical input during product development.

OmniOmics.ai CEO and Founder Dr Fatemeh Vafaei said, *“We were pleased to bring OmniOmics’ bioinformatics expertise to the development of BREASTESTplus™ 2 and to provide an independent perspective throughout the process. Our team worked closely with BCAL to develop a multifactorial diagnostic algorithm integrating lipid biomarkers measured in plasma with clinical features, and to rigorously evaluate the locked algorithm on an independent clinical validation dataset for the detection of breast cancer.”*

Breast and Melanoma Surgeon, Clinical Director BreastScreen Victoria and Director Parkville Breast Service, Dr David Speakman said, *“Breast cancer assessment is rarely about a single test. Clinicians build a picture using screening, imaging, clinical assessment and other information. Having an additional blood-based tool adds another important layer of information to support that process and help guide the next steps in a woman’s care. The significance of BREASTESTplus™ 2 is that it can be used across all breast densities, making it relevant to a broader group of women. Earlier identification remains one of the most important opportunities we have to improve breast cancer care and giving clinicians another tool to support that process is a meaningful step forward for Australian women.”*

Associate Professor Sanjay Warriar, Consultant Breast Surgeon, Chris O’Brien Lifehouse and Chief Surgeon at BreastScreen NSW, said, *“Every week I see women for whom a mammogram alone does not tell the whole story, particularly those with dense breasts. Used alongside imaging and clinical assessment, and across all breast densities, a simple blood test gives more women an additional piece of information about their breast health and, where warranted, an earlier prompt to look further. It does not replace mammography, and it is not a diagnosis on its own, but broadening who can access that information, and act on it sooner, is exactly the kind of progress that helps Australian women.”*

BCAL is advancing accreditation and commercialisation activities ahead of planned launch of BREASTESTplus™ 2 in November 2026, with simultaneous rollout across Melbourne, Sydney and Brisbane ahead of a national rollout.

BCAL will be attending the 2nd Australasian International Breast Congress (AIBC) in Brisbane, Australia, October 8-10, 2026 to build awareness for BREASTESTplus™ 2 with key stakeholders in preparation for launch.

Building on learnings from the current BREASTEST*plus*™ test, BCAL will use www.earlydetection.com.au to support patient education and provide a simple route to telehealth, a patient's GP or specialist. Existing referral pathways, including Best Practice, Genie and Medical Director, will be updated to incorporate BREASTEST*plus*™ 2.

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

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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.