

ASX Announcement

18 June 2026

BCAL develops new blood test for evaluation of local breast cancer recurrence

Highlights

- **BCAL has developed a diagnostic blood test, BREASTEST Monitor, to make it simple and easy for women to be evaluated for local recurrence of breast cancer following treatment.**
- **BREASTEST Monitor, has been shown to accurately rule out women for recurrence of breast cancer. Results from BCAL's preliminary findings in women aged 50 years and above show BREASTEST Monitor identified 20 of 23 confirmed local recurrence cases at Sensitivity 91% and Negative Predictive Value (NPV) 95%.**
- **BREASTEST Monitor addresses one of the biggest issues in breast cancer management post treatment, with disease recurrence occurring in up to ~ 15% of women following treatment.**

BCAL Diagnostics Limited (ASX: BDX) an Australian healthcare company pioneering diagnostics for early detection of cancer, is developing BREASTEST Monitor, a new blood test for evaluating women for local recurrence of breast cancer following treatment.

BREASTEST Monitor is being developed to address one of the biggest challenges in post-treatment breast cancer care: Cancer returning in the breast or armpit/lymph nodes following treatment occurs in up to 15% of breast cancer patients and can occur at any time for many years following initial treatment, signalling potential treatment failure and substantially elevates the risk of distant metastatic spread. Local recurrence detected early is considered curable, and early treatment is directly linked to improved outcomes for patients. BREASTEST Monitor is a blood test that rules out the presence of local recurrence of breast cancer.

In BCAL's first study in women, 50 years and above, with a known previous breast cancer, BREASTEST Monitor correctly identified 20 of 23 confirmed local recurrences (91% sensitivity with NPV 95%). More than 450 samples were used to develop the test algorithm and applied to a held-out test set of 100 samples. This included 23 confirmed local cancers, and 77 imaging-negative previously treated women as controls. The held-out samples were not used in the training of the algorithm but were used to optimise the ability of the model to detect early stage, local recurrence, in treated breast cancer patients at various age groups.

BREASTEST Monitor targets a significant unmet clinical need for women aged 50 years and older who have been treated for breast cancer or are undergoing treatment. There is currently no simple blood-based test available to help assess local recurrence in this patient group, with post-treatment monitoring largely reliant on time consuming and costly imaging such as mammography, ultrasound or MRI. Mammography misses up to 25–32% of recurrences, with higher failure rates in women with dense breast tissue or scarring and tissue thickening changes post-treatment

There are more than 4 million breast cancer survivors in the United States and 200,000+ in Australia requiring ongoing surveillance, with the global breast cancer surveillance and monitoring market

projected to reach \$4.5 billion by 2030. BREASTEST Monitor will enter the market as an adjunct to imaging; however, the longer-term plan will be to develop BREASTEST Monitor as a standalone surveillance test.

There are additional clinical validation studies to complete prior to commercial launch. BCAL is now seeking additional breast cancer patients, including those under 50 years of age, who have undergone treatment for breast cancer.

Anne-Louise Arnett, Chief Executive Officer, said, *“BREASTEST Monitor is an important clinical development milestone for BCAL and extends our blood-based diagnostics platform into one of the most significant areas of unmet need in breast cancer care. The team will now work through the validation processes to advance the test.”*

Shane Ryan, Executive Manager Clinical Affairs Breast Cancer, said, *“For women who have been treated for breast cancer, fear of recurrence can remain a major burden. BREASTEST Monitor is being developed to give women and their clinicians an easier, faster and non-invasive way to help evaluate the risk of local recurrence. This is about supporting women after treatment, when reassurance, and ongoing care are critically important.”*

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

ENDS

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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.

For more information: <https://www.bcaldiagnostics.com/> or contact info@bcaldiagnostics.com.