

ASX Announcement

28 May 2026

BCAL Diagnostics Signs Validation Agreement with Sonic Healthcare USA, for BreastestPlus™ Version 2.0

Validation Agreement signed with the future aim of establishing a Laboratory Developed Test in the United States

Highlights

- **BreastestPlus™ Version 2 test validation agreement signed with Sonic Healthcare USA**
- **Validation will be conducted in a CLIA-certified Sonic Reference Laboratory in Austin Texas**
- **Sonic Healthcare USA is the 3rd largest pathology provider in the United States**
- **The Laboratory Developed Test (LDT) pathway is the fastest and simplest US market entry route for BreastestPlus™ Version 2**
- **Successful validation represents a key milestone on the LDT pathway**
- **Post-validation, Sonic Healthcare USA has the option to negotiate a commercial licence for BreastestPlus™ Version 2**

BCAL Diagnostics Limited (ASX: BDX) is pleased to announce that it has executed a Validation Agreement with Sonic Healthcare USA, Inc. ("Sonic Healthcare USA"), the third largest pathology provider in the United States. This agreement marks another milestone towards the commercialisation of BCAL's flagship product, BreastestPlus™ Version 2, in the world's largest breast cancer diagnostics market — a market with more than 40 million mammograms performed annually, 376,000 new breast cancer cases each year, and a breast cancer diagnostic market expected to reach USD 4.53 billion by 2033.

Under the Validation Agreement, BreastestPlus™ Version 2 assay will be transferred to Sonic's CLIA-certified Sonic Reference Laboratory in Austin, Texas where it will be optimised for the US market. This validation is a key milestone on the LDT pathway, the fastest and most efficient means for our important test to be available to US patients. Following validation, Sonic Healthcare USA has the option to negotiate a licence for BreastestPlus™ and any related intellectual property and know-how required to use or perform the test. The potential financial terms of the Validation Agreement are confidential.

It is BCAL's objective is to establish BreastestPlus™ Version 2 as a Laboratory Developed Test (LDT) in the United States — bringing a potentially life-changing diagnostic tool to the millions of US women who undergo breast cancer screening every year.

In parallel, BCAL continues to actively collect clinical samples from patients across the United States, working directly with leading breast cancer specialists. The clinical samples collected from US patients will support BCAL's Clinical Outcomes studies, a requirement for submissions to regulatory and reimbursement and health insurance authorities.

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Shane Ryan, Chief Executive Officer, BCAL *“This Validation Agreement with Sonic Healthcare USA is an important milestone for BCAL Diagnostics and our US commercialisation strategy. Sonic’s CLIA-certified laboratory infrastructure and deep expertise in clinical diagnostics provide the right environment to validate BreastestPlus™ Version 2. What excites me most is what this brings together – two highly capable teams, united by a shared purpose of delivering better diagnostic solutions for women at scale. We look forward to progressing through the validation process and advancing towards commercial deployment in the world’s largest breast cancer diagnostics market.”*

Dr Mohamed Salama, Chief Medical Officer, Sonic Healthcare USA. *“Sonic Healthcare USA is committed to advancing access to innovative diagnostic solutions that make a real difference to patients. The validation of BreastestPlus™ Version 2 at our CLIA-certified Sonic Reference Laboratory in Austin, Texas reflects that commitment, and we look forward to assessing its performance through a rigorous validation process.”*

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

ENDS

For further information:

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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.

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