

ASX Announcement

12 December 2024

BCAL Diagnostics receives NATA accreditation

- **BCAL's laboratory in North Ryde, Sydney, has received formal notification of NATA accreditation**
- **The laboratory meets ISO15189, NPAAC and NATA standards**

BCAL Diagnostics Limited (ASX: BDX) ("BCAL" or "the Company") is pleased to announce that its development and clinical services laboratory in North Ryde, NSW, has received formal accreditation from the National Association of Testing Authorities Australia (NATA).

BCAL's laboratory meets the NATA, ISO15189 and National Pathology Accreditation and Advisory Council (NPAAC) standards. NATA accreditation was awarded for the laboratory's quality systems. This achievement represents another pivotal step on the pathway to BCAL's planned commercialisation of BREASTEST®.

BCAL's CEO, Shane Ryan commented, *"NATA accreditation sends a very positive message to the medical community and women in Australia that our quality systems and processes meet the highest standards as outlined by NATA and NPAAC. The laboratory is now ISO 15189 certified which is an international standard for clinical laboratories and certifies that the laboratory quality systems, documentation and protocols meet the international and Australian standards."*

BCAL is now finalising the necessary analytical and clinical validation of BREASTEST®, and once validation is successfully completed, BCAL will ask NATA to add BREASTEST® to its scope of tests able to be performed at BCAL's NATA-accredited laboratory. The first phase of BREASTEST® commercial launch is in partnership with the Sydney Breast Clinic. As planned, BREASTEST® will be offered as an adjunct to mammography.

BCAL's Executive Chair, Jayne Shaw commented, *"With NATA accreditation now secured, BCAL is closer to introducing our cutting-edge technology that will empower clinicians and women, leading to better health outcomes across the country, and ensure that women have access to high-quality breast cancer screening methods."*

This announcement has been approved by the Board for release to the ASX.

ENDS

For further information:

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About BCAL Diagnostics

BCAL Diagnostics Limited is an Australian screening and diagnostic company committed to the early, accurate diagnosis of breast cancer, and therefore early intervention and improved outcomes for women. Over the past decade BCAL has developed a blood test for the detection of breast cancer. The test is initially designed to complement current imaging technologies, such as the mammogram, with the aim of becoming a monitoring and screening tool suitable for women of all ages and backgrounds in any location. With more than two million new cases of breast cancer diagnosed globally each year, a substantial opportunity exists for BCAL to improve patient outcomes.

Founded in 2010, BCAL is headquartered in Sydney and listed on the Australian Securities Exchange (ASX: BDX). For more information: <https://www.bcaldiagnostics.com/>

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