BCAL diagnostics
Breast cancer blood screening. For every woman, everywhere.

NOV 2022

# BCAL secures development and clinical services lab

Recently we were very pleased to announce the securing of a lease for a Sydney-based facility that will act as BCAL's development and clinical services laboratory.

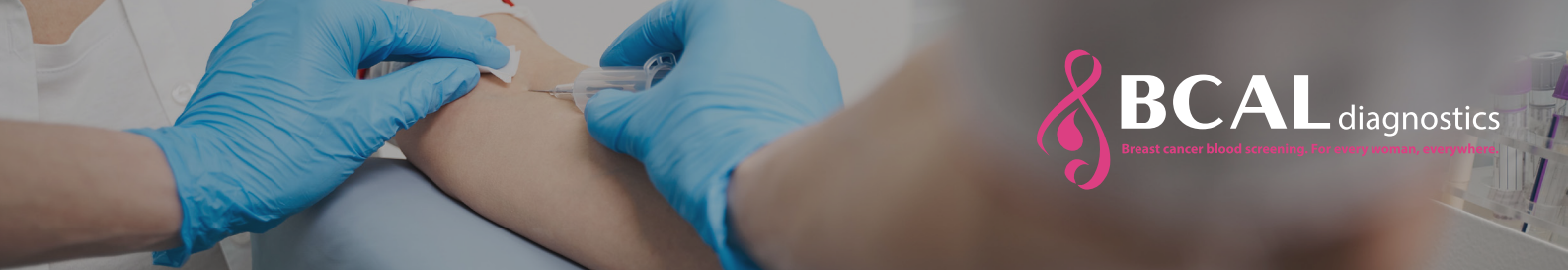
As BCAL advances in the commercialisation of its blood test to diagnose breast cancer, the laboratory will further work being undertaken to establish and validate workflows, test protocols and algorithms for the technology.

Located in the suburb of North Ryde, the lab will also act as a testing site for the ongoing clinical program and maintain compliance with standards required by the Australian Therapeutic Goods Act.

With BCAL's technology being developed as a LDT (laboratory developed test), patient samples collected will be processed at the new site using the proprietary BCAL test that is indicative for breast cancer.

The new BCAL clinical services laboratory will be established and managed by the newest member of the BCAL team, Kathy Koskiris, who joined BCAL in mid-October as Director of Clinical Services. Kathy has extensive experience is setting up and managing clinical service laboratories and maintaining the necessary ISO, NATA (National Association of Testing Authorities, Australia) and NPAAC (National Pathology Accreditation Advisory Council) certifications. In a previous position Kathy also gained US CLIA certification for an Australian laboratory. We are excited that Kathy has joined our team to enable us to deliver the BCAL test to clinicians and patients.

BCAL anticipates the new laboratory site will be operational by the end of February 2023.




## Precion to progress US development of BCAL test

In June, we announced that we had entered into an agreement with US company Precion for the next stage of development for our blood-based test to detect breast cancer, marking a significant milestone on the road to commercialising this product and making it available to women. It also reaffirms our commitment to bringing to market novel diagnostic blood tests based on proprietary technology to advance cancer detection.

Our US and Sydney-based teams will work with Precion's North Carolina laboratories to develop standardised commercial assays based on our proprietary lipid biomarker signature identified in blood samples of early and late-stage breast cancer cohorts.

We have applied our patented technology and extensive research developed over the past five years using the novel approach of molecular lipid analysis for cancer detection, with preliminary findings for breast cancer presented recently at ASCO 2022 in Chicago.

The Master Services Agreement (MSA) between the two companies proposes to:

- Execute Statements of Work (SOW) to collaborate in the development of standardised biomarker tests
- Validate the algorithm required for reporting results
- Carry out clinical studies in the US.

Subsequent to the signing of the MSA, a SOW was put in place which provides the detailed objectives for the work being carried out by Precion. Precion is working closely with our US-based lipidomics consultant, Dr David Peake and our team in Sydney lead by our CSO, Dr Amani Batarseh.

Precion brings advanced technology, an experienced team of scientists, and a track record of successfully developing and validating commercial biomarker assays using Mass Spectrometry. In addition, the instrumentation used by the Precion team will be similar to what is currently available in clinical laboratories. This work will also facilitate similar technology transfer and validation activities we are establishing with laboratories in Sydney.

Breast cancer statistics:

Breast cancer is the most prevalent cancer among women, with >2 million new cases registered and 685,000 deaths recorded yearly.

Improvements in medical and patient awareness have emphasised the importance of early detection for effective treatment.

The global market for breast cancer diagnostic products is expected to reach US$8.7bn by 2027

## BCAL expands US operations

BCAL now has three team members in the US, in line with the dual focus of the business there and in Australia. In addition to our CEO John Hurrell, we recently contracted Brian Kolasinski as Director of Business Strategy and Development. Brian lives in Denver, Colorado, and brings many years' experience in commercialising technology and managing marketing and sales functions. He also has experience in selling products into the breast cancer market. Brian is working closely with our Director of Clinical Affairs, Amanda Koegelenberg, to identify sources of patient samples in the US, as well as carrying out market research into the US and Australian breast cancer markets and identifying collaborative opportunities for BCAL globally.

In addition to Brian, we have contracted Dr David Peake as our US based lipidomics mass spectrometry expert. David brings considerable expertise in the analysis of lipid biomarkers having codeveloped some of the analytical software used broadly in lipidomics research. David previously worked for Eli Lilly and ThermoFisher. He is working closely with the team at Precion and BCAL's team in Sydney as we progress the development of our standardised lipid biomarker assays.

We have also identified and have consulting agreements with two experts in US regulatory processes. These consultants are assisting us to define the clinical requirements for our blood breast cancer test.

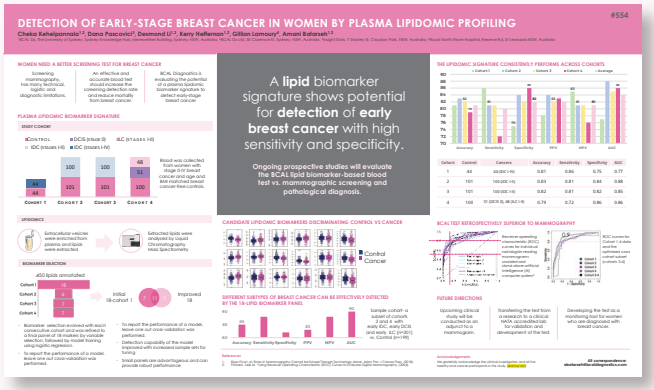

# BCAL showcased at ASCO

We presented at the prestigious American Society of Clinical Oncology Annual Meeting in June. Clinical Associate Professor Gillian Lamoury of the University of Sydney, also a Radiation Oncologist at Genesis Care, joined Chief Scientific Officer Dr Amani Bataresh to present our poster in the Breast Cancer Local/Regional/ Adjuvant session.

The annual event took place in Chicago, USA and was attended by upwards of 40,000 oncology professionals, where clinical advances in every area of cancer research were discussed and presented.

The poster presentation titled “Detection of early-stage breast cancer in women by plasma lipidomic profiling” focused on the potential of our blood test to detect early-stage breast cancer in women and its potential to be adjunct to the current gold standard technique of mammography.

DETECTION OF EARLY-STAGE BREAST CANCER IN WOMEN BY PLASMA LIPIDOMIC PROFILING




# The latest in diagnostics for breast cancer awareness month

For Breast Cancer Awareness Month during October, the BCAL team was busy with participation in several events.

Alongside fellow ASX-listed breast cancer diagnostic provider Volpara Health (ASX:VHT), BCAL hosted a well-attended investor evening at Sydney Breast Clinic to discuss the latest innovations in breast cancer diagnosis, with a focus on earlier and more accurate detection.

Professor Mary Rickard kicked off the session with a detailed look at breast cancer in Australia and the dynamics of mammography, before Volpara CEO Teri Thomas and BCAL CEO Dr John Hurrell discussed the role of their respective adjunct technologies.

Later in the month, Sydney Breast Clinic again played host to a Doctor’s Night information session which invited general practitioners to hear about the latest trends and innovation in the sector.


# Breast Cancer Associated Lipids Found in Plasma (Biospecimen Collection) Study (SLHD HREC; 2020/ETH02051)

As we continue to expand our study across Australia, we welcome our newest site to be initiated, the Specialist Breast Cancer Surgery in Victoria. The Specialist Breast Cancer Surgery is led by Principal Investigator (and Breast Surgeon) Dr Chantel Thornton.

To date, we have consented over 622 participants across all study sites*, with >730 blood samples collected.

We are grateful to all our study participants for their ongoing time and contributions to the study. It is through the provision of samples, and associated data, that BCAL can conduct the vital research needed to help make BCAL's breast cancer test available to people across Australia and abroad.

Find out more information about the study here.

*Study sites include: BreastScreen NSW (Royal Prince Alfred Hospital), Sydney Breast Clinic (Central Sydney), Chris O'Brien Lifehouse (Camperdown) and Specialist Breast Cancer Surgery.


The 'Breast Cancer Associated Lipids Found in Plasma Study' aims to develop a sensitive and specific diagnostic screening test based on lipids (fatty substances) in blood. With a target enrolment of up to 3500 participants, participation is entirely voluntary.

**WHAT IS INVOLVED?**

- Provision of informed consent (which includes linking of health-related data)
- Completion of a participant questionnaire
- Collection of up to 20ml blood sample (preferably fasted)
- Option to provide additional 20ml blood samples up to 4 times throughout the year.

Note: All data collected is de-identified

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