ersonal use only

A PATIENT-FRIENDLY BREAST CANCER BLOOD TEST

BCAL Diagnostics Limited (ASX:BDX)

Presentation – November 2022

BCAL diagnostics

Breast cancer blood screening. For every woman, everywhere

IMPORTANT NOTICE & DISCLAIMER

This presentation (**Presentation)** has been prepared by BCAL Diagnostics Ltd ABN 51 142 051 223 (**BCAL** or the **Company**).

The information in this Presentation is of a general background nature, is in summary form and does not purport to be complete. The information in this Presentation is subject to change without notice and, subject only to any legal obligation to do so, BCAL does not have any obligation to correct or update the contents of this Presentation.

The Presentation contains certain "forward-looking statements". The words "forecast", "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this Presentation are based on assumptions and contingencies which are subject to change without notice and involve known and unknown risks and certainties and other factors which are beyond the control of BCAL, and its directors and management, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct. This includes statements about market and industry trends, which are based on interpretations of current market conditions. In particular, the market data was prepared before the onset of COVID-19, the final economic effect of which is currently not possible to predict with any certainty. Consequently, while the Company has no reason to believe that the markets to which the data relates will not return to the operating levels experienced before COVID-19, the impact of COVID-19 (if any) on the market data that is referenced is not possible to currently predict with any certainty and investors are cautioned against placing undue reliance on such data.

Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. Actual results, performance or achievements may differ materially from those expressed or implied in such statements and any projections and assumption on which these statements are based. Recipients are cautioned not to place undue reliance on forward-looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this Presentation. The forward-looking statements are based on information available to BCAL as at the date of this Presentation. Circumstances may change and the contents of this Presentation may become out-dated as a result. Except as required by law or regulation, none of BCAL, its representatives or advisers undertakes any obligation to provide any additional or updated information whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.

No party other than BCAL has authorised or caused the issue, lodgement, submission, dispatch, or provision at the end of this Presentation, or takes any responsibility for, or makes or purports to make any statements, representations, or undertakings in this Presentation. To the maximum extent permitted by law, BCAL (including related bodies corporate, shareholders, affiliates, advisers, and agents):

- disclaims all responsibility and liability (including, without limitation, any liability arising from fault, negligence or negligent misstatement) for any loss arising from this Presentation or reliance on anything contained in or omitted from it or otherwise arising in connection with this Presentation,

- disclaims any obligations or undertaking to release any updates or revision to the information in this Presentation to reflect any change in expectations or assumptions; and

- does not make any representation or warranty, express or implied, as to the accuracy, reliability, completeness of the information in this Presentation or the likelihood of fulfilment of any forward-looking statement or any event or results expressed or implied in any forward-looking statement.

BCAL is commercialising a blood test for early breast cancer diagnosis

There are currently NO simple early detection and monitoring testing options for breast cancer
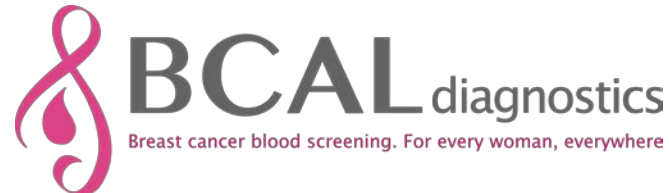
INTRODUCTION

1in7

Women affected by breast cancer globally

Currently the primary means for detecting breast cancer is
self examination for women under 40 and
mammography for women within the guidelines, 40-75

Up to 50% of women over 30 yo are excluded from mammography

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

The BCAL proprietary blood test is simpler, more convenient and less intimidating than current testing options

LIMITATIONS OF MAMMOGRAPHY

Not definitive (20% of breast cancers are missed – false negatives)

Prone to self-exclusion (painful, uncomfortable, cultural reasons)

Limited accuracy (prone to false positives)

Most effective above 50yo due to breast density and fatty tissue

Guide lines limit access to over 40 y/o only

Limited remote access

MAMMOGRAPHIC BREAST DENSITY
'PROBLEM' FOR MAMMOGRAPHIC SCREENING

- Density due to fibroglandular tissue is highest in young women and decreases with age

- High density is a problem at any age but particularly in young women (below 50yo)

- Dense fibroglandular tissue (white) can obscure cancers (white)

- Problem can be reduced by ultrasound examination or other imaging techniques
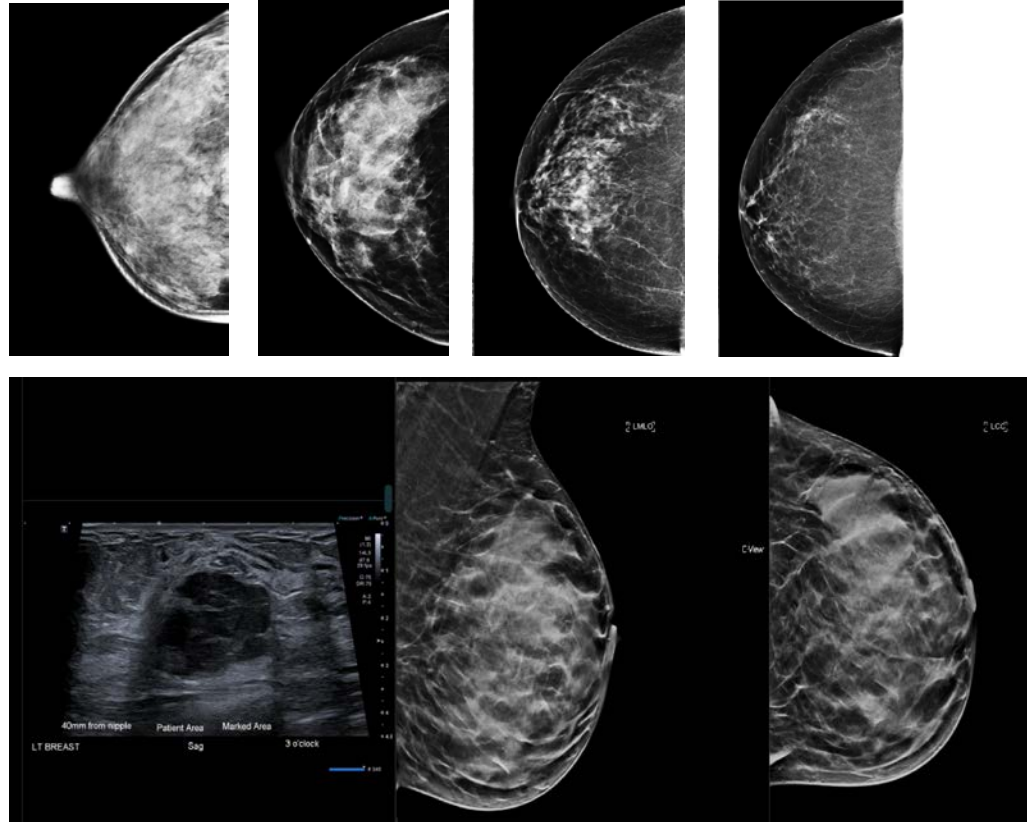
Courtesy Dr Mary Rickard AO. Director, Sydney Breast Clinic

At BCAL we want to improve access to breast screening for all women and to provide an additional value added tool to clinicians and patients in the screening, diagnosis and monitoring of breast cancer

BREAST CANCER IS A LEADING CAUSE OF DEATH

Estimated 1-in-7 women at risk of a breast cancer diagnosis

Follow-on market

US

281,550 — **Annual new cases**
43,600 — **Annual deaths**

Global

2,000,000 — **Annual new cases**
627,000 — **Annual deaths**

50% of breast cancer cases and 58% of deaths come from developing economies

Initial market

Australia

20,000 — **Annual new cases**
3,000 — **Annual deaths**

Follow-on market

Initial market

HOW THE BCAL TEST WORKS

Patient-friendly test, easy to collect as any blood test

BCAL Blood Test

Blood collected at standard blood collection point
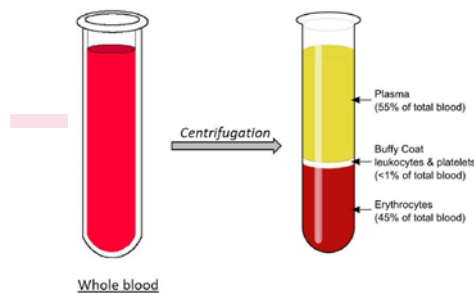
Plasma is separated from the cellular components of the blood

The lipids are extracted from the plasma

Extracted lipids are analysed by Liquid Chromatography Mass Spectrometry (LCMS)
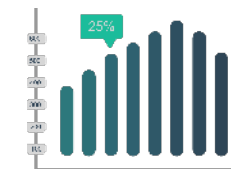
Data analysis of of the lipid content of the plasma shows the presence or absence of the lipid signature indicative of breast cancer

LIPIDS ARE ESSENTIAL FOR RAPID CELL GROWTH
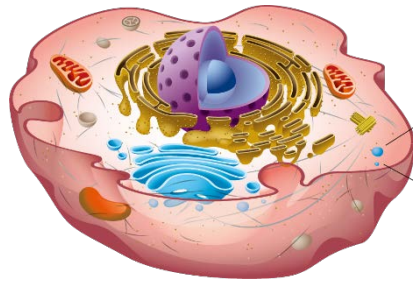
Cells contain the nucleus and essential organelles surrounded by a membrane

Lipids are a source of energy, building blocks and signal messengers for tumour cell growth

Deregulation of lipid metabolism is a very early step in the transformation of a normal cell to a cancerous one

The BCAL test detects the changes in level of lipids that spill over into the plasma of breast cancer patients even at an early stage of development.
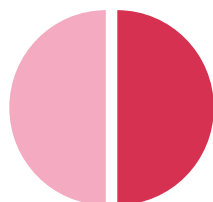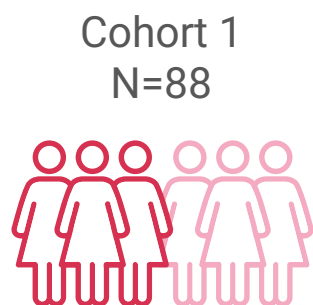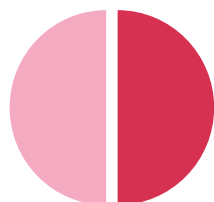
Cell membranes are composed of protein and carbohydrate receptors and gated channels embedded in a lipid structure

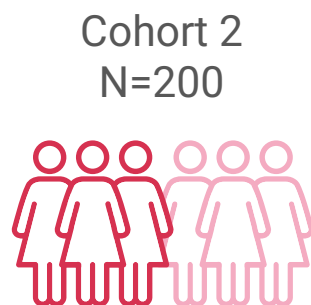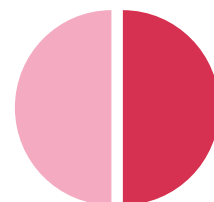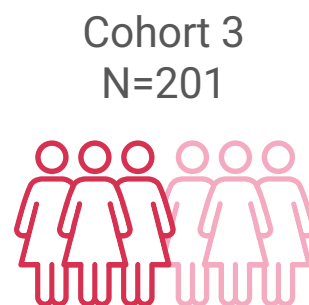**The plasma lipids tell us what is already happening rather than what could happen (genes).**

Studies carried out on Extracellular vesicles (EVs)

Cohort 1 N=88	Cohort 2 N=200	Cohort 3 N=201	Cohort 4 N=301

Legend:
- Control
- IDC Late stages
- DCIS
- ILC

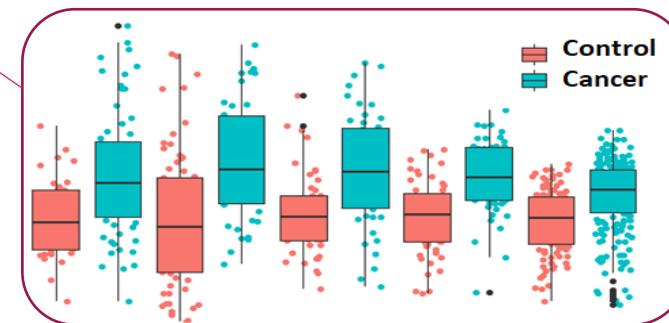|	Cohort 1	Cohort 2	Cohort 3	Cohort 4
IDC	Stages 1-4	Stages 1&2	Stages 1&2	Stage 0
DCIS				
ILC				Stages 1-4
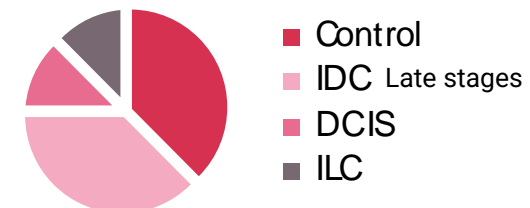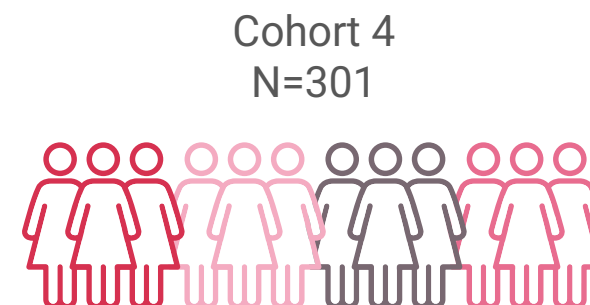
IDC: Invasive ductal carcinoma
DCIS: Ductal carcinoma in situ
ILC: Infiltrative lobular carcinoma

ALGORITHM DEVELOPMENT AND BIOMARKERS

Panels of lipids combine the discriminating power of individual lipids to deliver a likelihood of cancer for a new sample. Algorithms are trained on the BCAL cohorts of cancer patients and matched controls. The focus is on detection of early-stage cancer.
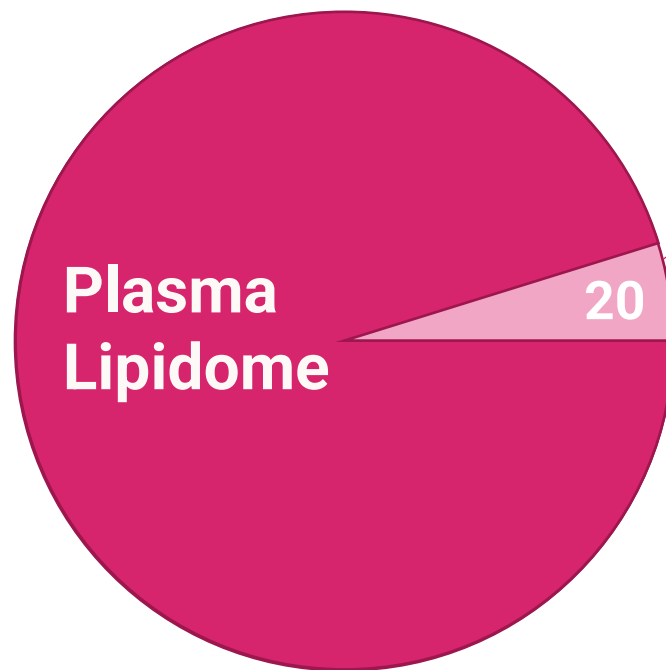
biomarker panels were tested for the ability to discriminate between cancer and control across several cohort subsets
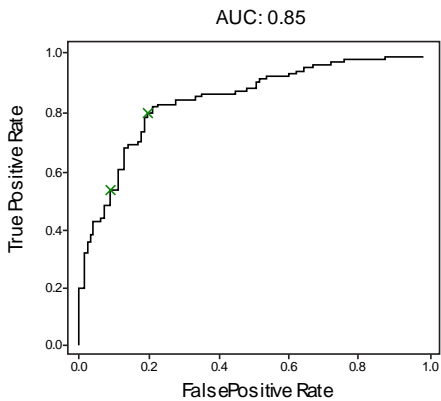
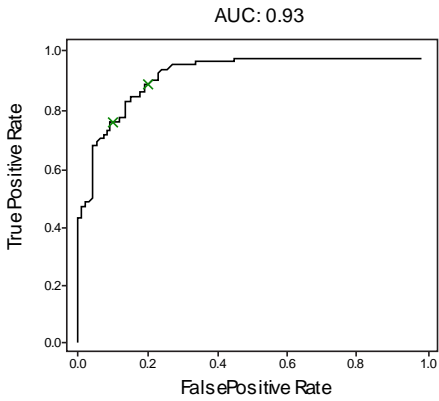**Provisional Patent application filed May 2022**

SENSITIVITY AND SPECIFICITY IS CONSISTENTLY STRONG

Lipids were extracted from Extracellular vesicles (EV's)

PLASMA SAMPLES FOR 250 SUB-STUDY
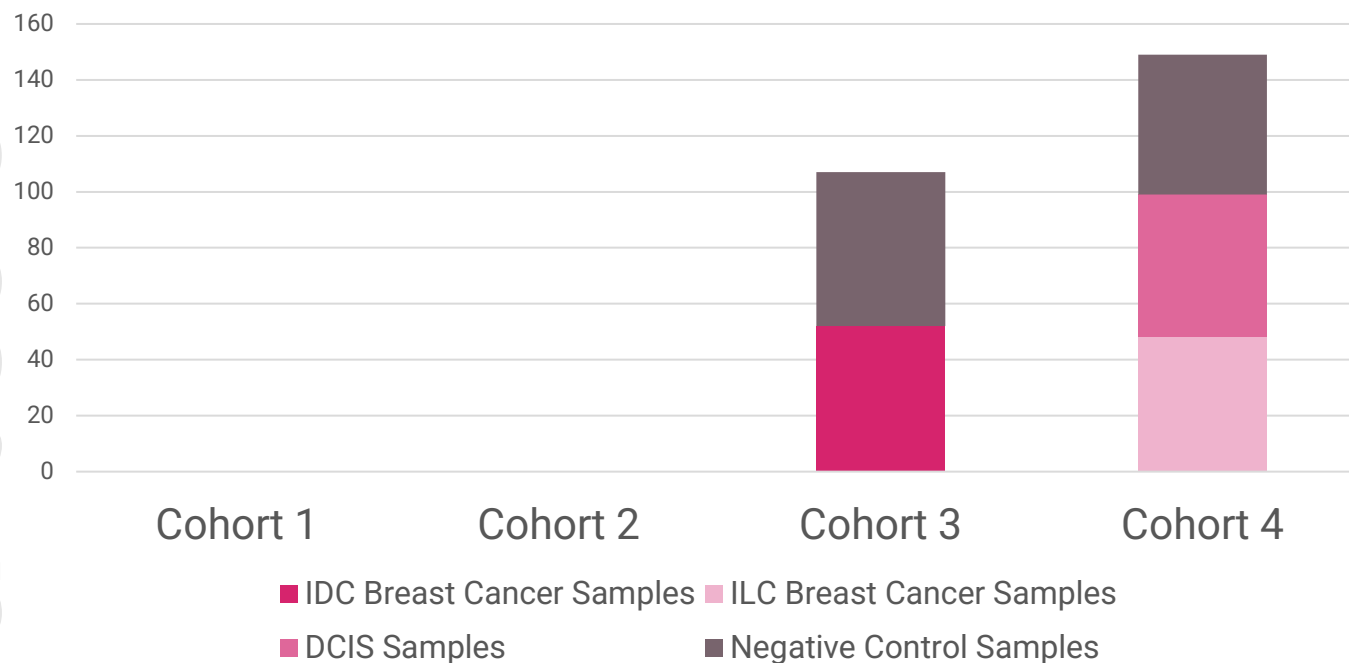
The plasma samples analysed in the 250 sub study are a subset of Cohorts 3 and 4, containing all cancer subtypes: DCIS, IDC and ILC

Bar chart legend:
- IDC Breast Cancer Samples
- ILC Breast Cancer Samples
- DCIS Samples
- Negative Control Samples

Bar chart categories: Cohort 1, Cohort 2, Cohort 3, Cohort 4

Pie chart:
- IDC early (set 5): 52
- ILC early (cohort 4): 48
- DCIS (cohort 4): 51
- Control (set 5): 55
- Control (cohort 4): 50
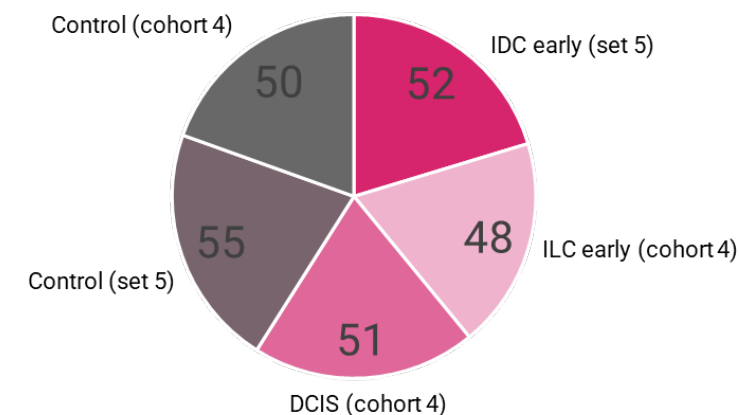
PERFORMANCE OF THE TOP LIPIDS OF INTEREST IS COMPARABLE IN PLASMA AND EXTRACELLULAR VESICLES

EV 250 samples

Plasma 250 samples

SENSITIVITY
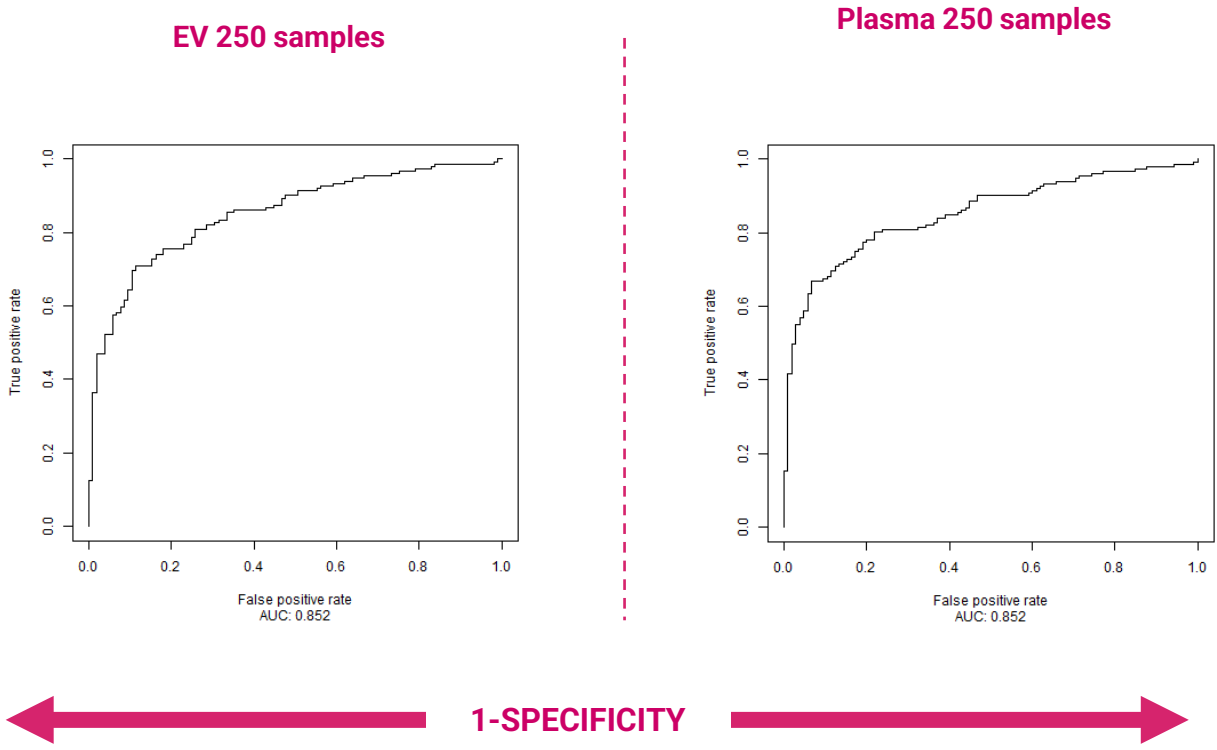
1-SPECIFICITY

Performance (LOOCV)	EV 250 samples	Plasma 250 Samples
Accuracy	0.78	0.79
Sensitivity	0.81	0.79
Specificity	0.74	0.78
Pos Pred Value	0.82	0.84
Neg Pred Value	0.73	0.73
AUC	0.85	0.85

The performance of the lipid signature in the plasma samples available is similar to the performance of the lipid signature in the same EV samples.

The performance of the more conservative PLSDA algorithm is shown here , with no further panel selection.

PLASMA PERFORMANCE IS STRONG IN CANCER SUBTYPES

Plasma BCAL – DCIS vs Control

AUC= 0.89
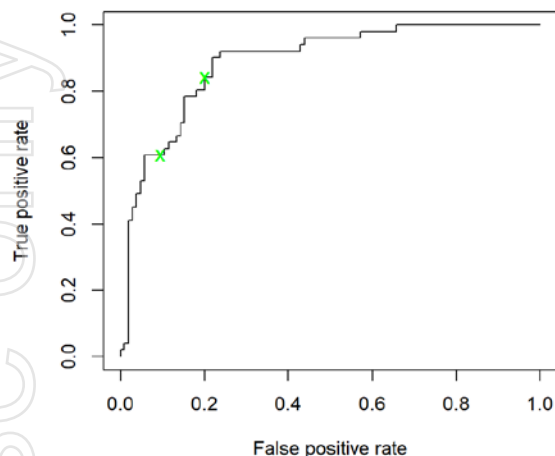
Plasma BCAL – IDC vs Control

AUC= 0.85
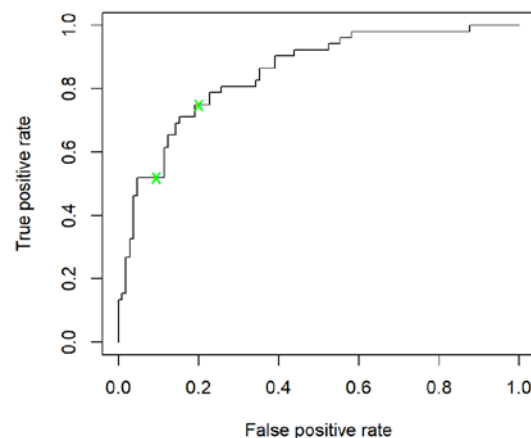
Plasma BCAL – ILC vs Control

AUC= 0.87

Performance of the lipid signature in plasma for various disease subtypes versus available control samples.
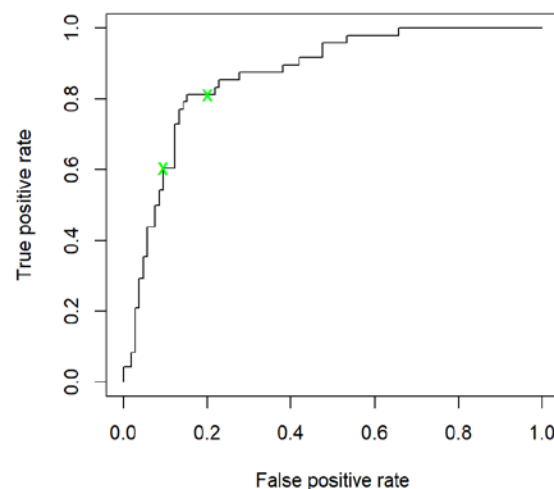
Performance (LOOCV)	DCIS vs all Control	IDC vs all Control	ILC vs all Control
Accuracy	0.83	0.8	0.84
Sensitivity	0.78	0.69	0.81
Specificity	0.85	0.86	0.85
Pos Pred Value	0.71	0.71	0.71
Neg Pred Value	0.89	0.85	0.91
F1	0.75	0.7	0.76
Sens at Spec Cut-off: 0.8	0.84	0.75	0.81
AUC	0.89	0.85	0.87

Results are for just one bioinformatics model that confirms the robust nature of the BCAL breast cancer lipidomic signature

APPLICATION OF AI AND ML TECHNIQUES

Recent analysis of the data by AI/ML obtained from the 250 plasma sample study has lead to an improvement of the lipid signature to between patients with and without breast cancer.

A second patent application is under development
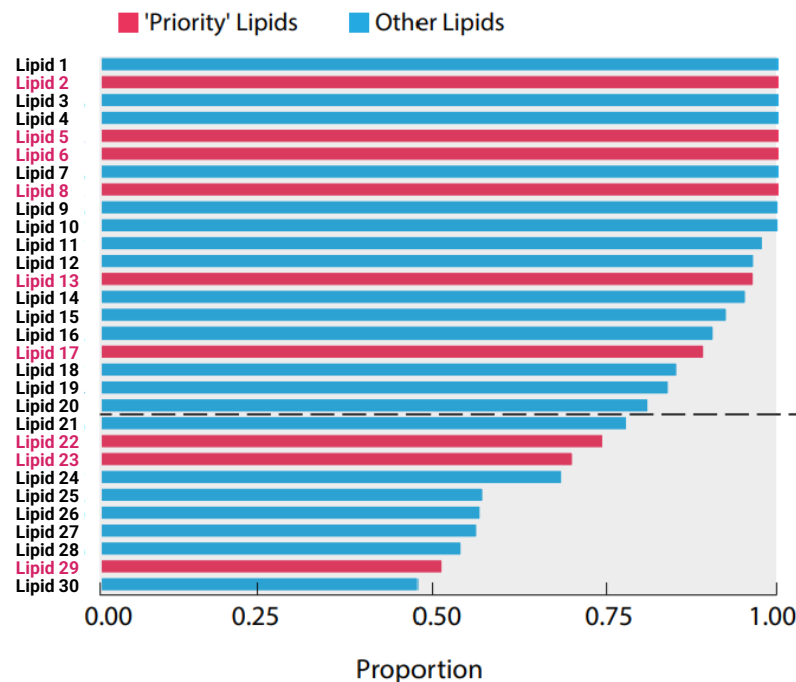
Identification of lipids in the breast cancer signature
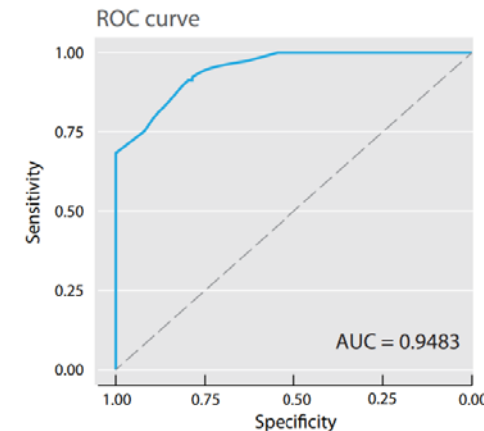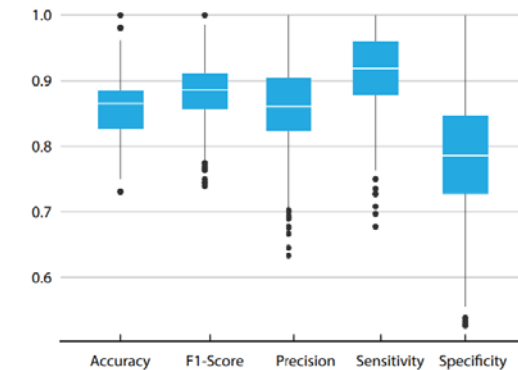
Performance of lipid signature in 250 plasma samples using AI/ML models

BCAL MILESTONES AND INFLECTION POINTS

Cohort 4
18 markers reduced to 6-10, independent review supportive

Reimbursement
Establish use case

Tech transfer Australia
Transfer tech to NATA accredited labs

Patent Application No 1
BCAL owned patent

Australian Focus Groups Study

Tech transfer USA (Precion)
Assay development and validation on additional platforms

Analytical Performance defined

Biomarkers locked down
Australian Intended Use defined

Direct Plasma use
Testing can be done on whole plasma

Algorithm Locked in

LDT Australia
Development and Clinical Services Lab established

Analytical Validation

Clinical Validation studies

LDT Australia Launch

Monitoring Study

LDT USA
Transfer tech to CLIA lab

LDT USA Launch

Regulatory submission
TGA/ FDA

Development Future Products

Ongoing Clinical Studies

…2022

Today….

…2023

…2025

Board of Directors

Jayne Shaw	The Hon Ron Phillips AO	Jonathan Trollip	Dr. Merilyn Sleigh	Mark Burrows AO
Executive Chair	Non-executive Director	Independent Non-executive Director	Independent Non-executive Director	Independent Non-executive director
• Successful businesswoman, entrepreneur and cofounder. Previously co-founder and owner of the Sydney Breast Clinic	• Health policy expert, previously Minister for Health in NSW Parliament and co-founder and owner of the Sydney Breast Clinic	• International businessman and lawyer. Many years experience as NED of large ASX-listed companies	• Over 30 years' experience as a senior executive and non-executive director in Australia's biotechnology sector and academia.	• An advocate for early diagnosis of breast cancer and other cancers. International banking expert and has held positions of Chairman and NED of major ASX listed corporations.

Executive Team - Australia

Dr. John Hurrell, PhD	Dr. Amani Batarseh, PhD	Guy Robertson	Alison Cook (Mew), MSc	Amanda Koegelenberg M.Bio. M. Comm.	Kathy Koskiris BSc. MBA.
Chief Executive Officer	Chief Scientist	Chief Financial Officer & Company Secretary	Regulatory and Quality Manager	Director, Clinical Affairs	Director, Clinical Laboratory Services
• More than 35 years experience in life sciences & healthcare. Has developed & successfully commercialised multiple products & services as well as managing start up/early-stage companies .	• PhD from Georgetown University, Washington, DC Completed post-doctoral studies at Harvard, McGill and Wollongong Universities. Expert in molecular biology lipidomics and mass spectrometry	• A Finance Director/Chief Financial Officer for a number of companies within the Jardine Matheson Group over a period of 16 years. Provides CFO and company secretary consulting services to many large corporations and SMEs	• Management and leadership experience of more than 30 years across the biopharmaceutical, diagnostic and health service sectors. Spent 13 years in senior executive roles at CSL Limited. Consulted widely across the life sciences industry,.	• Former Associate Director of Research, Research Program Director for NSW Health Pathology. Extensive experience in Biobank development and clinical research. Has managed multisite clinical studies including sites outside Australia	• More than 20 years experience in building and managing clinical laboratories under TGA and US CLIA regulations. Managed CLIA certification for multiple new products, CLEP certification and NATA Accreditation with ISO15189 & NPAAC standards.

Key People - USA

Dr. John Hurrell
Chief Executive Officer

- More than 35 years experience in life sciences & healthcare. Has developed & successfully commercialised multiple products & services and managed start up/early-stage companies

Kim Ekroos, PhD
Scientific Advisor

- Founder and CEO of Lipidomics Consulting Ltd., a global consulting business in the field of Lipidomics with over 20 years experience.

Dr David Peake, PhD
Scientific Lead, Technology Transfer

- Expert in Lipidomics and mass spectrometry. Expertise with both qualitative and quantitative methods.

Dr Raji Pillai PhD
Regulatory Consultant

- Expertise in developing innovative molecular diagnostics under FDA and CLIA regulations, and fielding effective interactions with regulatory agencies.

Brian Kolasinski
Director, Business Strategy and Development

- Broad experience in the Diagnostics Industry.. Launched multiple products in US and Europe and build sales and marketing teams.

Clinical and Scientific advisors - Australia

A/Prof Craig Gedye
BSc(Hons), MBChB, FRACP, PhD

- A medical oncologist and cancer researcher at the Calvary Mater Newcastle, and is the Clinical Research Director at the NSW Health State-wide Biobank.

Dr Sanjay Warrier (Associate Prof.)
BSc (Med) MBBS FRACS MS

- Consultant Breast Oncology and Oncoplastic Surgeon at Chris O'Brien Lifehouse, Royal Prince Alfred and Mater Hospitals. He is also a Visiting Medical Officer at BreastScreen NSW.

Dr Cindy Mak MBBS (Hons)
Sydney University FRACS

- Currently Director of Breast Services at Chris O'Brien Lifehouse and also operates at the Mater Hospital (North Sydney) and Royal Prince Alfred Hospital.

Prof. Dr Mary Rickard AO

- A leading expert in mammography. Involved in consulting with numerous breast screening and diagnostic training programs across South East Asia.

Prof Peter Meikle PhD
Baker Institute

- NHMRC Senior Research Fellow Leads the Obesity and Diabetes Program and is Head of the Metabolomics laboratory.

TECHNICAL MILESTONES ACHIEVED IN 2022

☑ A lipidomic signature has been identified in the blood of breast cancer patients

☑ The signature is seen in all breast cancer types tested and at the earliest stages of the disease

☑ A Provisional patent application has been filed by the Company: a second is in development

☑ The signature is detected in plasma directly

☑ The lipids within the signature have been identified, confirmed and standards produced

☑ The algorithm defining the breast cancer signature has been confirmed and is being "stressed"

☑ A Development and Clinical Services laboratory is being established and certified

☑ The Intended Use for the Australian launch of an LDT has been defined

☑ The Science, Clinical and Development team to take the product to launch is being built

SUMMARY OF PROGRESS

☑ There is a large unmet need for a simple, accurate blood test for breast cancer

☑ The BCAL blood test has high sensitivity, specificity and accuracy for the detection of breast cancer

☑ It is cheaper, easier and more accessible than mammography, the current gold standard

☑ The global market potential is in excess of $2 Billion (USD)

☑ BCAL has moved into a clear commercialisation pathway and is meeting milestones

☑ Clinical studies underway to confirm and validate the BCAL test performance

☑ Complexity of sample preparation reduced

☑ A Development and Clinical Services laboratory is being established

☑ Studies to understand the market and how to enter are in progress in US and Australia

☑ Experienced team of board members, management team and advisors is in place