

A PATIENT-FRIENDLY BREAST CANCER BLOOD TEST

BCAL Diagnostics Limited (ASX:BDX)
Presentation – November 2022

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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

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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



**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)

Limited accuracy (prone to false positives)

Guide lines limit access to over 40 y/o only



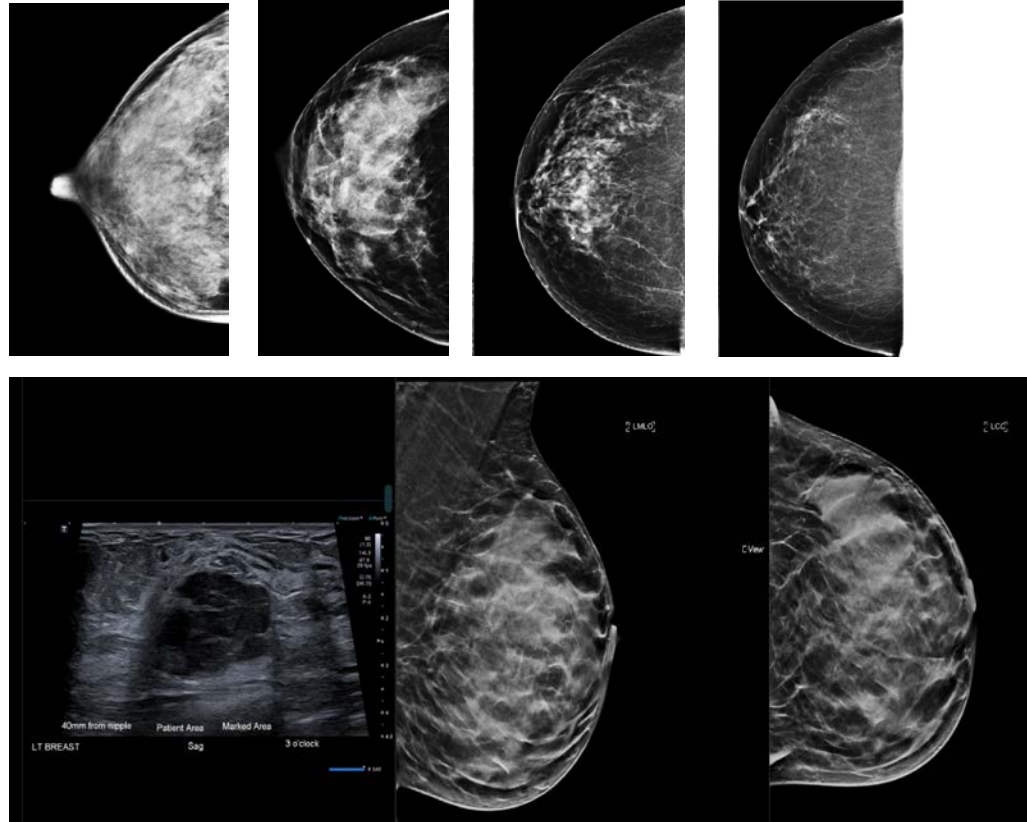
Prone to self-exclusion (painful, uncomfortable, cultural reasons)

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

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

Follow-on market

Initial market

Australia



20,000

Annual
new cases



3,000

Annual
deaths

Initial market

Global



2,000,000

Annual
new cases



627,000

Annual
deaths

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

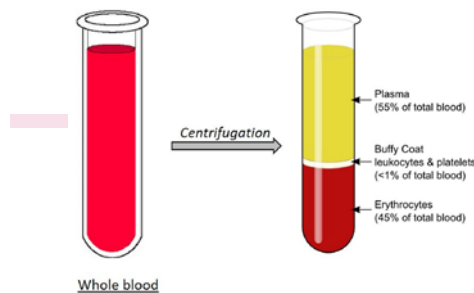
HOW THE BCAL TEST WORKS

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

BCAL Blood Test



Blood collected at
standard blood
collection point



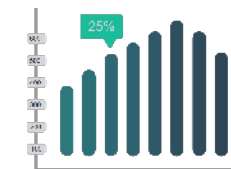
Plasma is
separated from the
cellular
components of the
blood



The lipids are
extracted from the
plasma

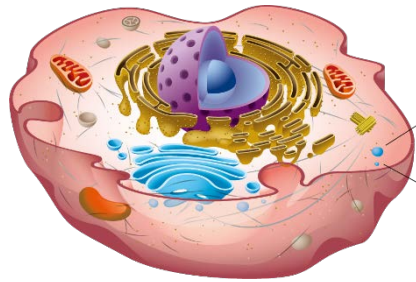


Extracted lipids are
analysed by Liquid
Chromatography
Mass Spectrometry
(LCMS)



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



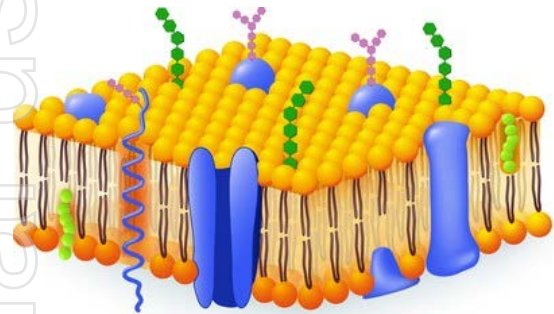
Cells contain the nucleus and essential organelles surrounded by a membrane

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.

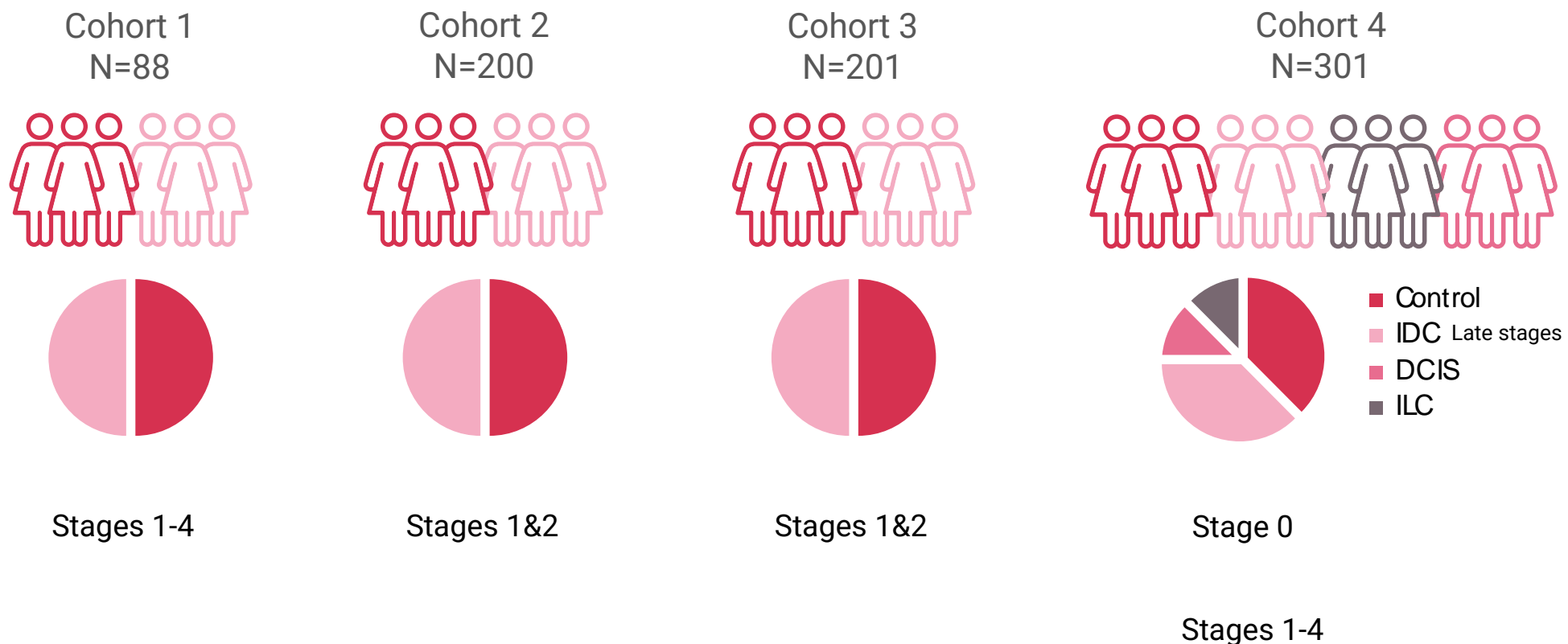
The plasma lipids tell us what is already happening rather than what could happen (genes).



Cell membranes are composed of protein and carbohydrate receptors and gated channels embedded in a lipid structure

SUMMARY OF EARLY CLINICAL STUDIES

Studies carried out on **Extracellular vesicles (EVs)**

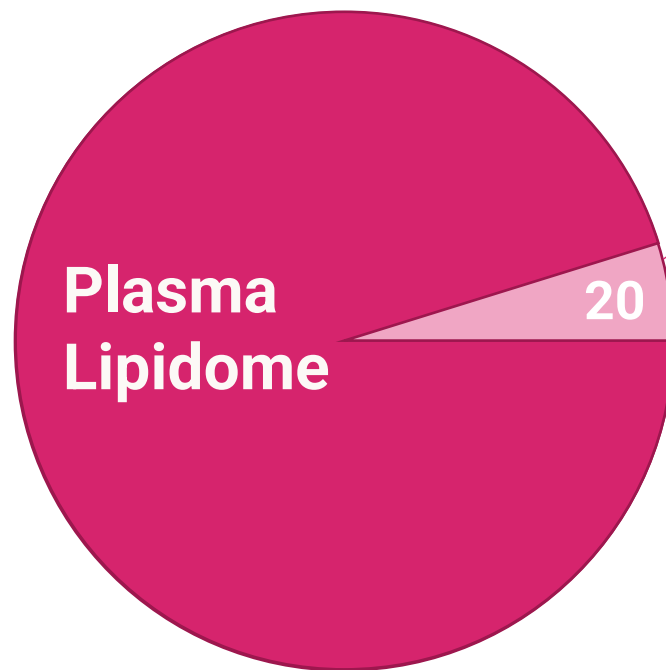


IDC
DCIS
ILC

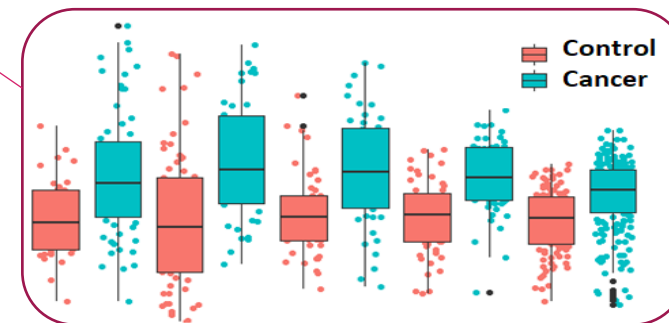
IDC: Invasive ductal carcinoma
DCIS: Ductal carcinoma in situ
ILC: Infiltrative lobular carcinoma

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

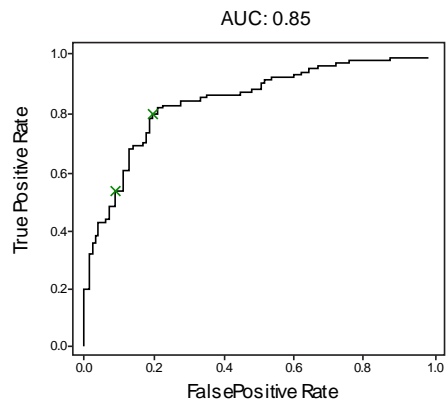


Provisional Patent application filed May 2022

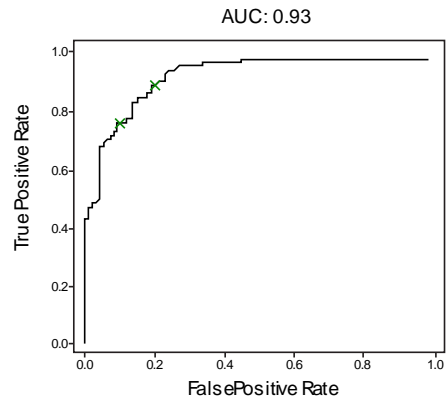
SENSITIVITY AND SPECIFICITY IS CONSISTENTLY STRONG

Lipids were extracted from Extracellular vesicles (EV's)

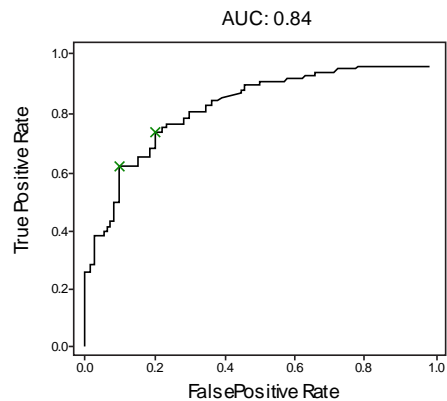
Cohort 2



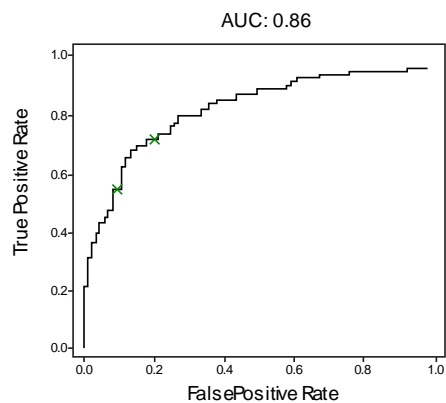
Cohort 3



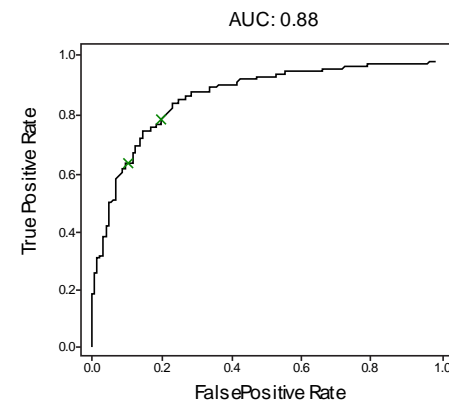
Cohort 4



Cohort 4 – DCIS ILC Only

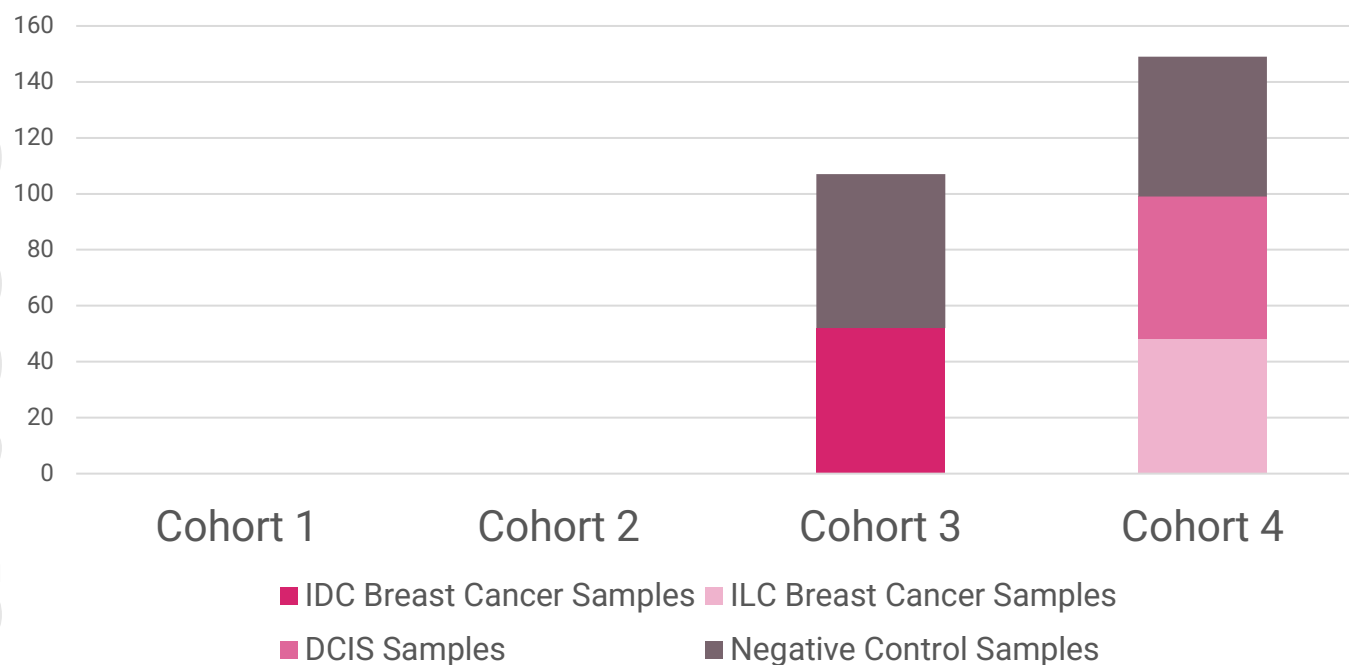


Cohort 2,3,4

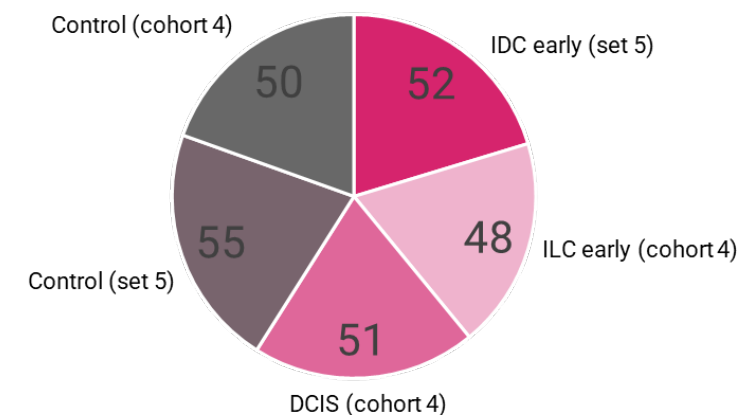


1-SPECIFICITY

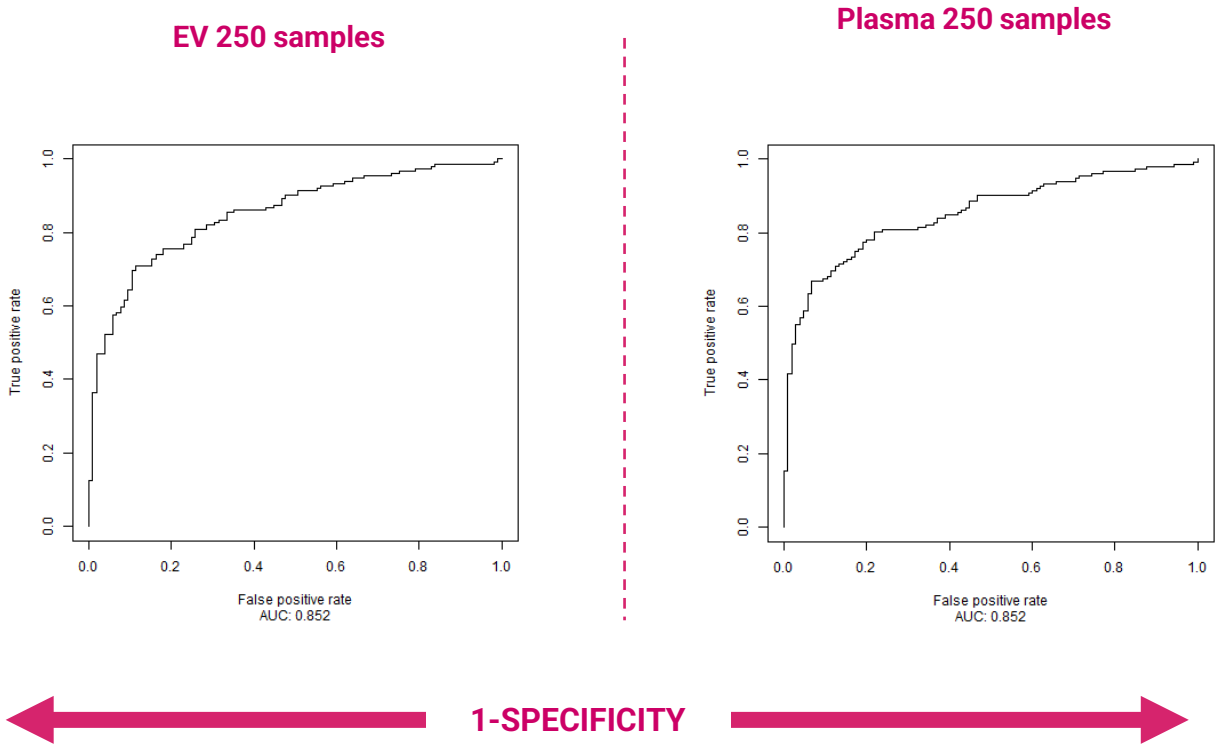
PLASMA SAMPLES FOR 250 SUB-STUDY



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



PERFORMANCE OF THE TOP LIPIDS OF INTEREST IS COMPARABLE IN PLASMA AND EXTRACELLULAR VESICLES



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

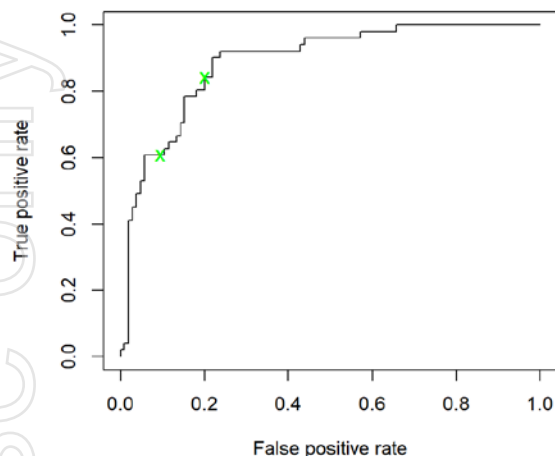
The performance of the lipid signature in the plasma samples available is similar to the performance of the lipid signature in the same EV samples.

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

PLASMA PERFORMANCE IS STRONG IN CANCER SUBTYPES

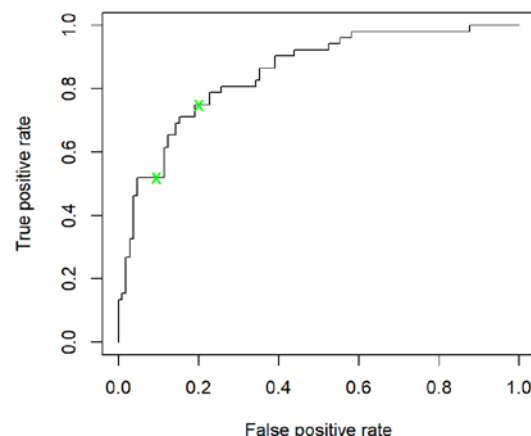
Plasma BCAL– DCIS vs Control

AUC= 0.89



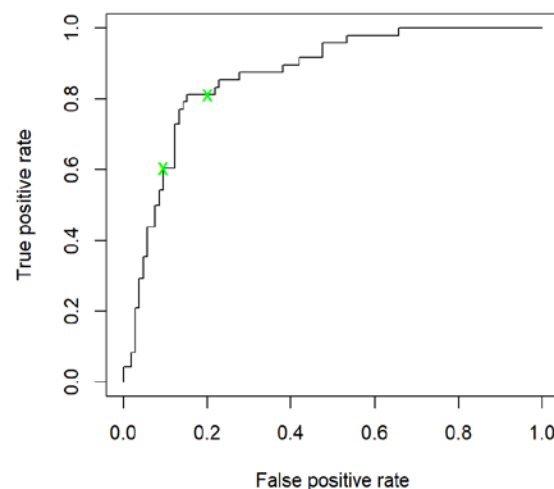
Plasma BCAL– IDC vs Control

AUC= 0.85



Plasma BCAL – ILC vs Control

AUC= 0.87



Performance (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

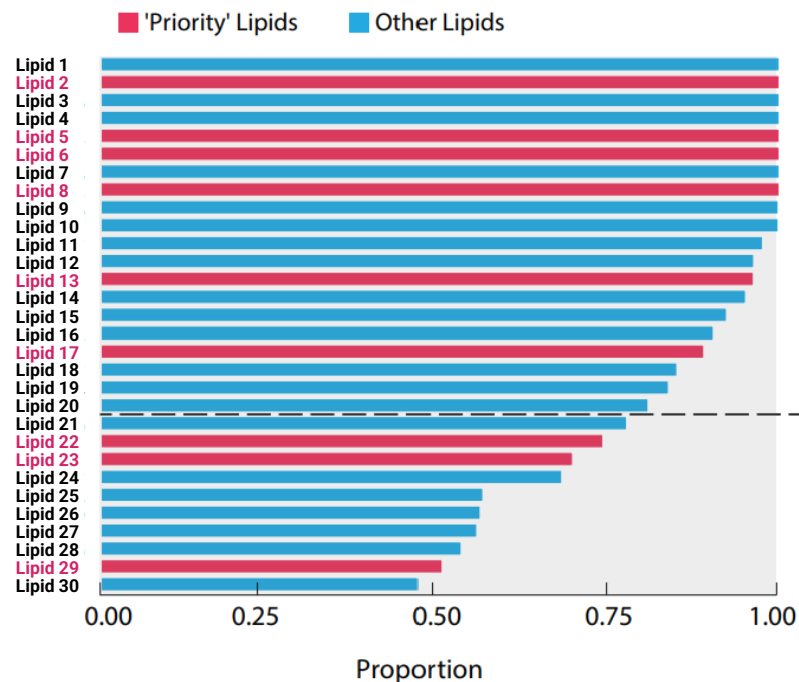
Results are for just one bioinformatics model that confirms the robust nature of the BCAL breast cancer lipidomic signature

Performance of the lipid signature in plasma for various disease subtypes versus available control samples.

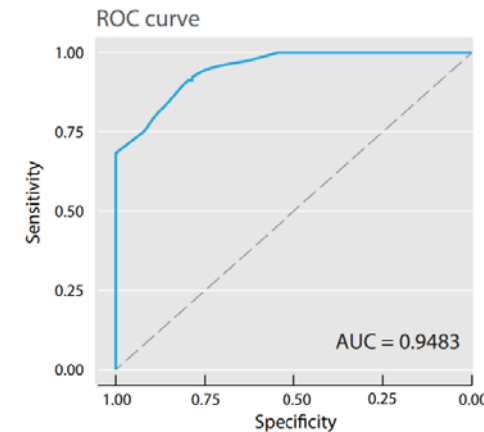
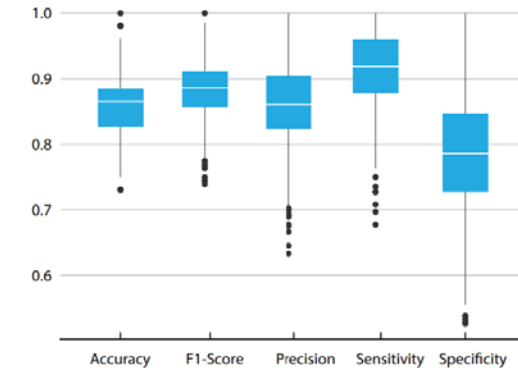
APPLICATION OF AI AND ML TECHNIQUES

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

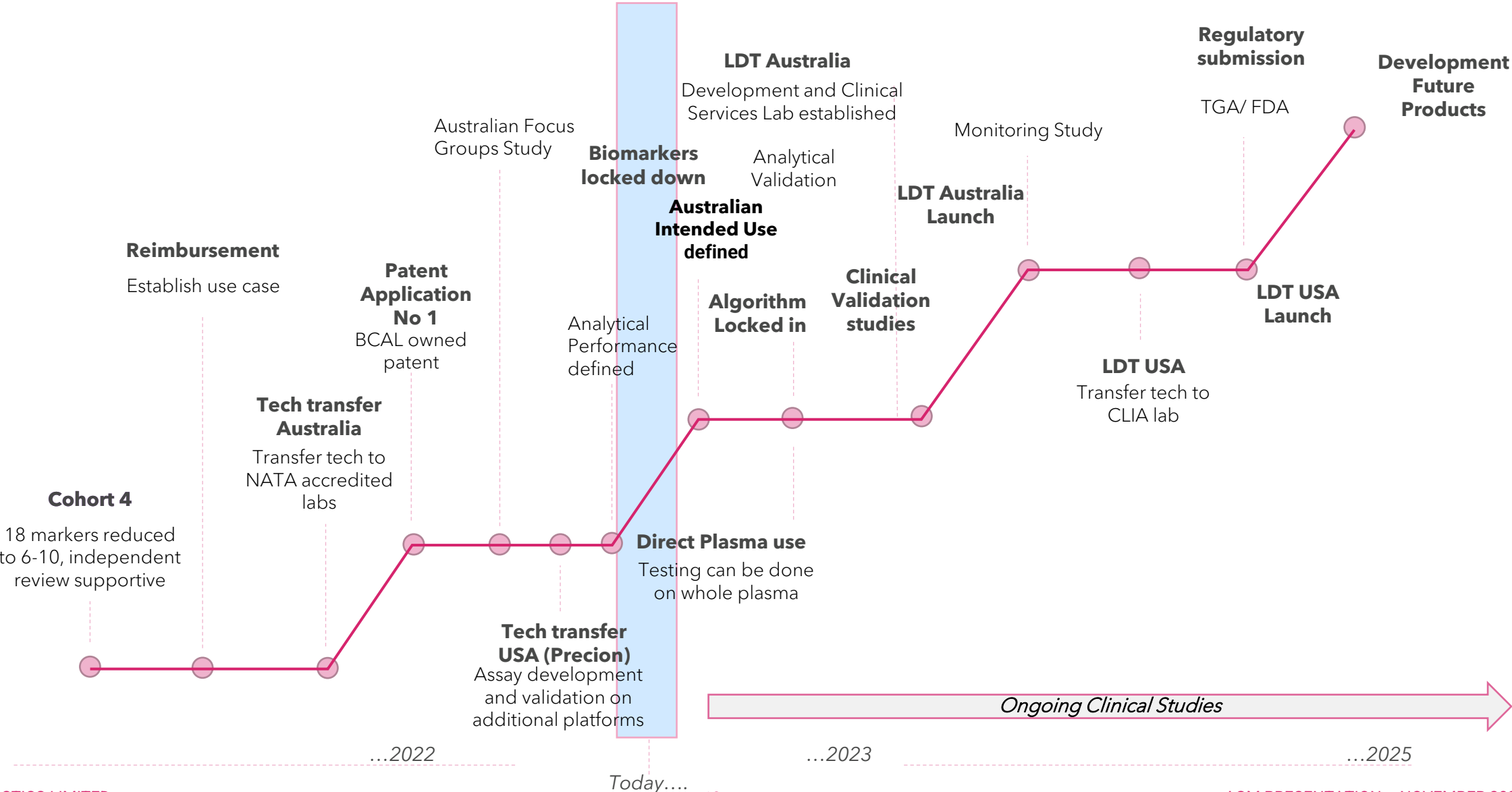


Identification of lipids in the breast cancer signature



Performance of lipid signature in 250 plasma samples using AI/ML models

BCAL MILESTONES AND INFLECTION POINTS



Board of Directors



Jayne Shaw
Executive Chair

- Successful businesswoman, entrepreneur and cofounder. Previously co-founder and owner of the Sydney Breast Clinic



The Hon Ron Phillips AO
Non-executive Director

- Health policy expert, previously Minister for Health in NSW Parliament and co-founder and owner of the Sydney Breast Clinic



Jonathan Trollip
Independent Non-executive Director

- International businessman and lawyer. Many years experience as NED of large ASX-listed companies



Dr. Merilyn Sleight
Independent Non-executive Director

- Over 30 years' experience as a senior executive and non-executive director in Australia's biotechnology sector and academia.



Mark Burrows AO
Independent Non-executive director

- 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
Chief Executive Officer

- 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



Dr. Amani Batarseh, PhD
Chief Scientist

- PhD from Georgetown University, Washington, DC Completed post-doctoral studies at Harvard, McGill and Wollongong Universities. Expert in molecular biology lipidomics and mass spectrometry



Guy Robertson
Chief Financial Officer &
Company Secretary

- 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



Alison Cook (Mew), MSc
Regulatory and Quality Manager

- 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.



Amanda Koegelenberg
M.Bio. M. Comm.
Director, Clinical Affairs

- 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



Kathy Koskiris
BSc. MBA.
Director, Clinical Laboratory Services

- 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.



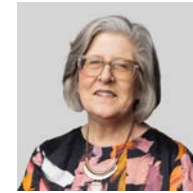
Dr Sanjay Warriar (Associate Prof.)
BSc (Med) MBBS FRACS MS

- 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