Abstract # 1920

Design of a Prospective Registry Study to Evaluate the Decision Impact and Clinical Utility of the lipidomic-based Blood Test BREASTEST Plus in Breast Cancer Screening

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Introduction

Poster summary

BREASTEST Plus is a novel blood-based diagnostic assay used alongside imaging to support breast cancer screening decision-making. While prior validation studies have demonstrated the analytical and clinical performance of the assay, real-world evidence (RWE) on its clinical utility and long-term impact on patient outcomes remains essential. To address this, BCAL Diagnostics has initiated a prospective, observational registry study aimed at evaluating how BREASTEST Plus influences physician decision-making and patient outcomes in routine clinical practice.

What is BREASTEST plus?

BREASTEST-plus is an in-house IVD test that can be requested alongside breast cancer screening imaging (e.g. mammography). The test is indicated for women with dense breasts and is intended to support clinical decision making. The assay uses liquid-chromatography tandem mass spectrometry (LC-MS/MS) to measure a panel of lipids found in the blood-plasma (Figure 1). A proprietary diagnostic algorithm converts the lipid measurements into a test score and a binary test result. The assay was discovered and developed by BCAL Diagnostics in Sydney, Australia. This test is currently available for physicians to order in major Australian cities.

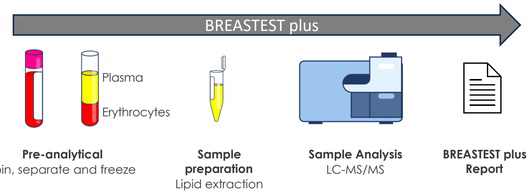


Figure 1. Diagram representing the steps performed for the BREASTEST plus blood test.

The BREASTEST-plus Registry

This study will assess the decision impact of using BREASTEST-plus in the screening setting. Furthermore, by recording the BREASTEST-plus test result and subsequent follow up, the post-marketing, real world performance of BREASTEST-plus can be assessed. The study will only record data that is already generated as part of routine breast screening assessments. No additional, study related procedures are required and no biological samples will be retained for unspecified research.

Registry Design

Study Title

A multicenter, prospective, observational registry study evaluating the impact of BREASTEST-plus on physician decision-making and patient outcomes in routine clinical practice.

Study Design

This multi-centre, prospective registry will aim to enrol 23,150 women across Australia who undergo BREASTEST Plus testing as part of their clinical assessment. Inclusion criteria are broad, reflecting routine clinical use, and will include both symptomatic and asymptomatic women. Treating physicians will complete a structured decision-impact survey following receipt of results to assess how the assay influenced diagnostic or management decisions. A follow up visit will be performed at 24-36 months. Ethics approval has been received for this study as an opt-out study, meaning that subjects are automatically enrolled when test is performed and must choose to withdraw from the study if they don't want to participate. Schema for the study is shown in Figure 2.

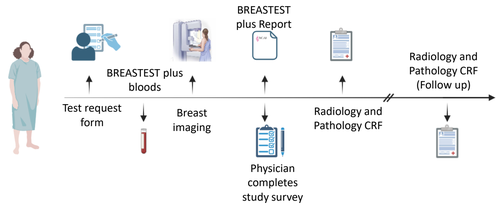


Figure 2. Schema indicating the study procedures, including completion of Case Report Forms (CRF) and standard screening procedures.

Inclusion Criteria

- 30 years or older
- Women (assigned female at birth)
- Must meet all eligibility requirements to receive BREASTEST-plus
- Radiologically confirmed high breast density (BI-RADS category C or D)
- No previous history of cancer (except for non-melanoma skin cancer)
- Will have or have had the BREASTEST-plus blood test

Exclusion Criteria

- Men or biologically male
- Breastfeeding or currently pregnant
- Previous history of cancer (except for non-melanoma skin cancer)
- Not prescribed BREASTEST-plus blood test
- Withdrawn consent from the study

Study Procedures

The study will only record data that is already generated as part of routine breast screening assessments. No additional, study related procedures are required and no biological samples will be retained for unspecified research. The study procedures and visits are shown (Table 1).

	Month (visit #)		
Procedure	**-3 – 0 (0)**	**0 (1)**	**24-36 (2)**
Inc./Exc. Criteria	X	X	
Demo./Hx/Tx		X	
Radiology		X	X
Histology		X	X
BREASTEST plus	X		
Physician survey		X	
Participation follow up call			X

Table 1. Study visits and procedures. Inc., inclusion; Exc., exclusion; Demo., demographics; Hx, history; Tx, treatment.

Results

Study Objectives

Primary:

1. To measure the impact of BREASTEST-plus for clinician decision making in breast cancer screening and diagnosis

Secondary:

1. To determine the real-world performance of BREASTEST plus
2. To assess the potential of using BREASTEST-plus to de-escalate further investigation

Exploratory:

1. Evaluate the use of the BREASTEST-plus test score for potential detection of breast cancer

Analysis Plan

Analyses will primarily be descriptive and will follow the pre-specified Statistical Analysis Plan (SAP). For the primary objective, clinician survey responses will be summarised to assess changes in management decisions. For the secondary objectives, test results will be compared with clinical outcomes to estimate real-world performance (sensitivity, specificity, PPV, NPV, and AUC) with confidence intervals. The follow up visit will enable the capture of any interval cancers and enable calculation of sensitivity and specificity metrics.

The potential for safe de-escalation of further investigations will also be assessed by combing survey responses (Q1=yes; physicians' intent to conduct further investigations) with BREASTEST-plus results and clinical outcomes. The exploratory objective will evaluate the potential of using the BREASTEST-plus test score as a predictor of breast cancer.

Physician Survey

Physician survey will be completed on the day that the BREASTEST plus result are reviewed by the physician. The survey contains two questions:

Question 1 - Based on the patient's breast imaging alone, were you going to request any further investigations (imaging/biopsy)? <Select one of the following>

a) Yes
b) No

Question 2 - After receiving the BREASTEST-plus report, how did the result change your decision on management for the patient? <Select one of the following>

a) Conduct further immediate investigations (answered 'No' to Q1)
b) Did not conduct the planned immediate further investigations (answered 'Yes' to Q1)
c) No change in immediate management but change in recommended screening frequency or imaging type (answered 'No' to Q1)
d) No change to management (answered 'Yes' or 'No' to Q1)

Discussion and Conclusions

This RWE registry is the first of its kind for a lipid-based breast cancer diagnostic test and will provide critical insights into the utility, impact, and long-term value of BREASTEST Plus in everyday practice. Primary objective outcomes will be reported annually and the remainder of the objectives will be reported once 24-36 month follow ups begin being conducted. Study results will inform guidelines, potential reimbursement decisions, and broader adoption strategies across healthcare systems.

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