

Clinical Translation of Targeted Lipidomics: Validation of BREASTEST plus™ 2 for Early Breast Cancer Detection



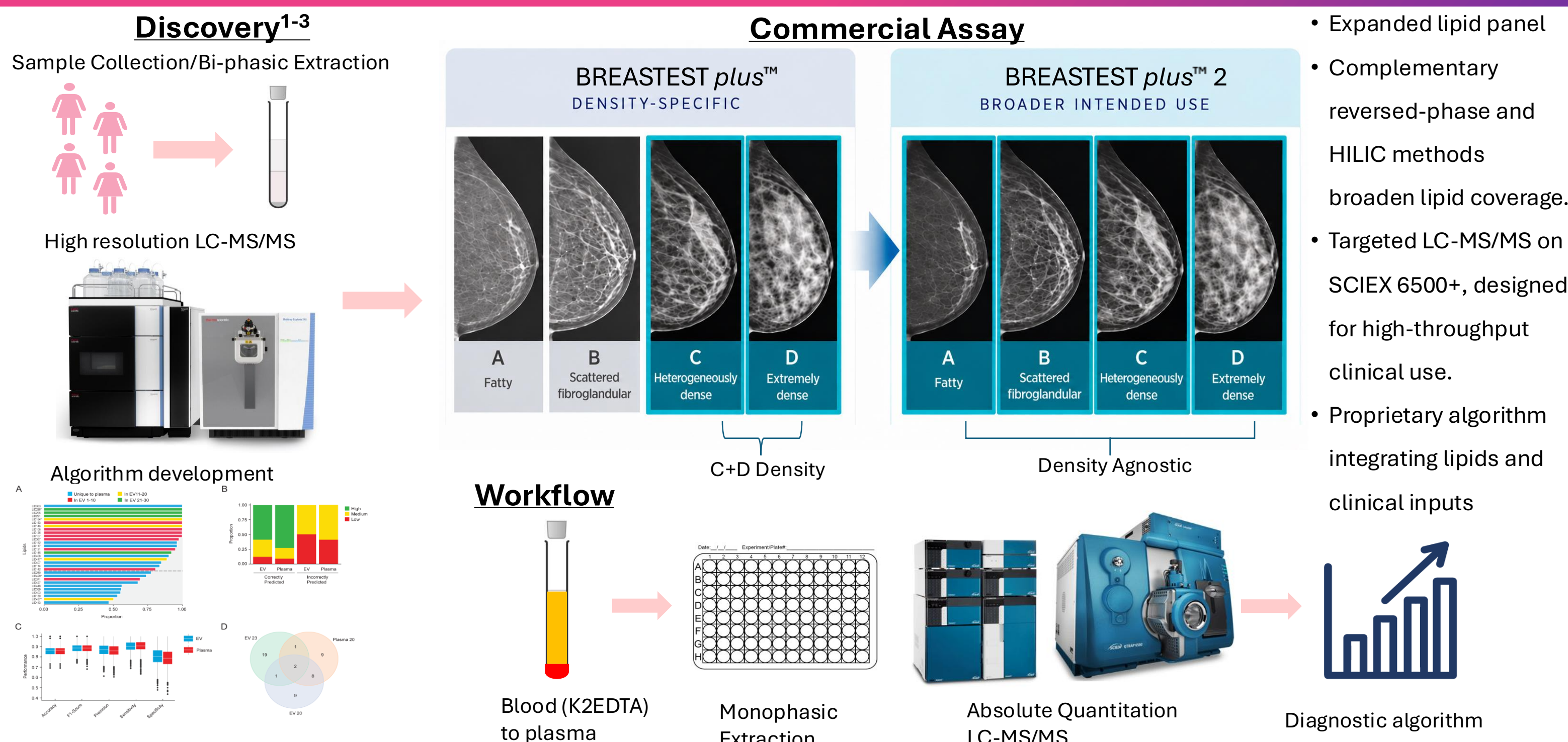
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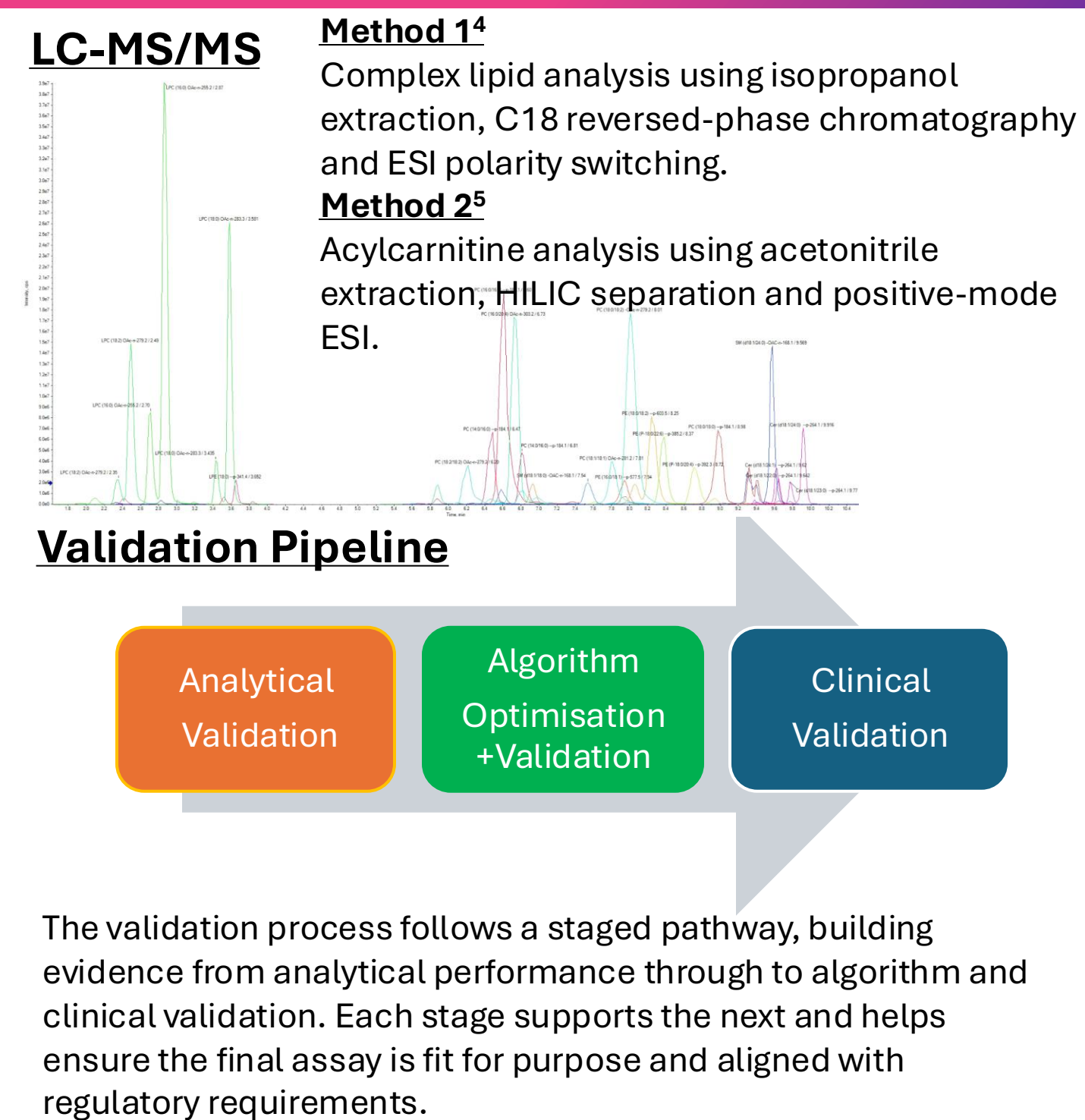
Introduction

- Breast cancer diagnosis remains predominantly reliant on imaging and tissue biopsy.
- Complementary blood-based biomarkers may support more accessible and scalable diagnostic pathways.
- BREASTEST plus™ 2 is a targeted lipidomic blood test combining LC-MS/MS lipid biomarkers with clinical variables and machine learning.
- The next-generation assay was developed to broaden the clinical use of the original Class 3 in-house IVD BREASTEST plus™ platform.
- This work describes the algorithm optimisation, analytical, algorithm and clinical validation, of the BREASTEST plus™ 2 platform.

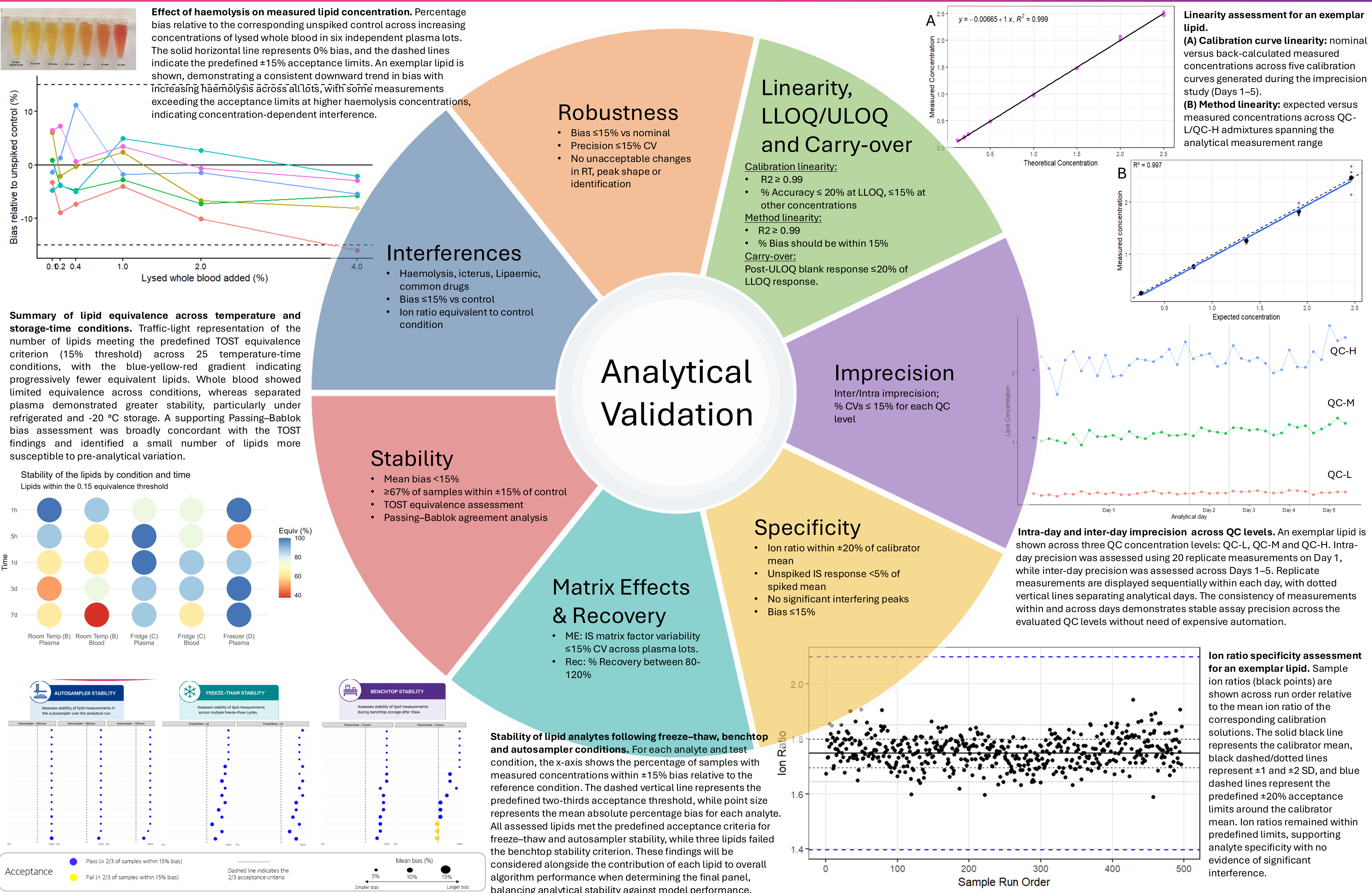
Lipidomics Discovery to Commercial Assay



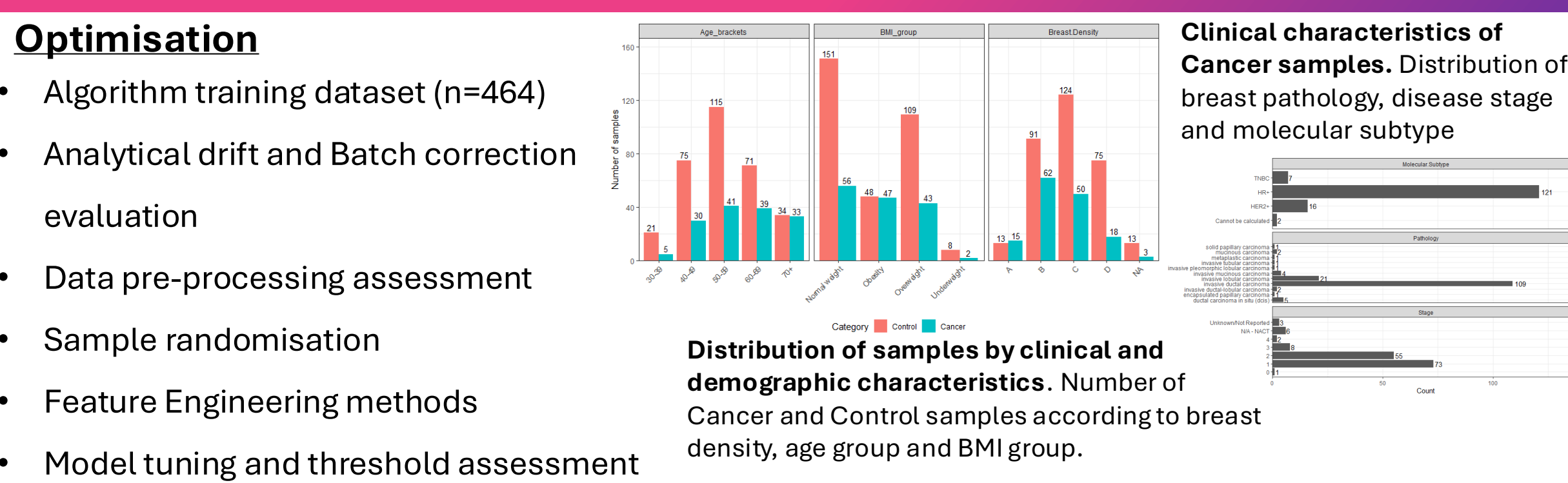
Methods



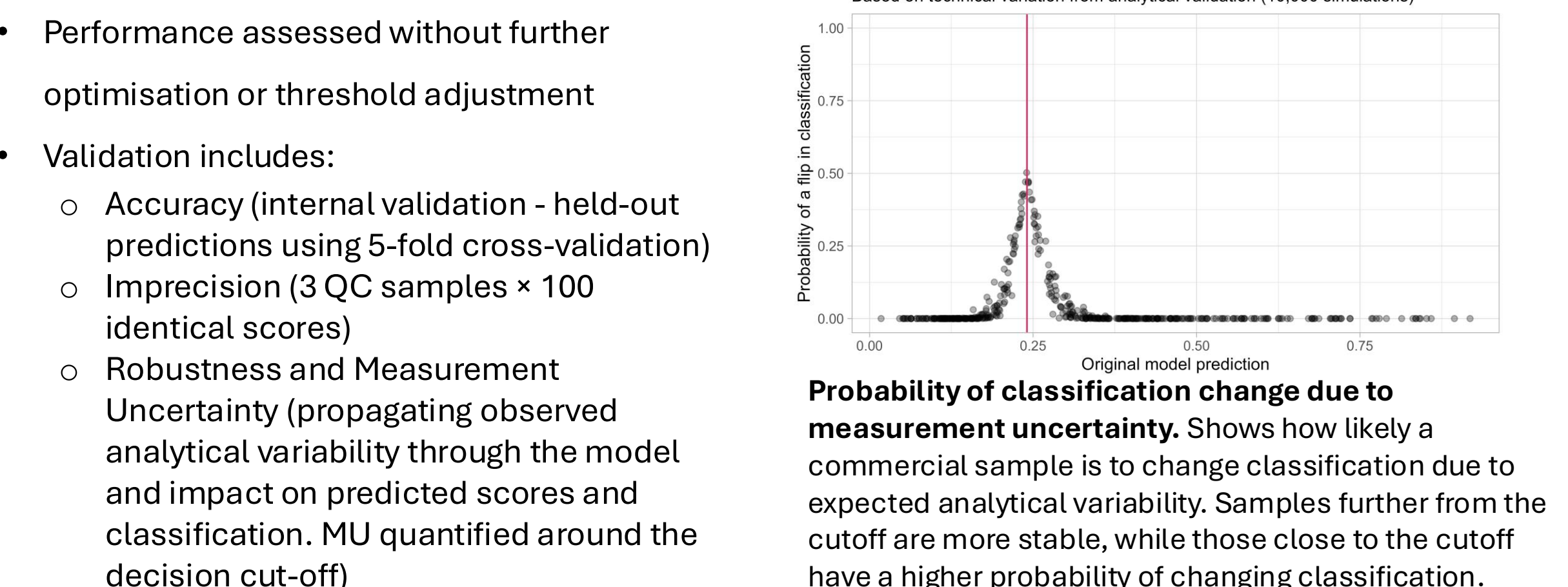
Analytical Validation



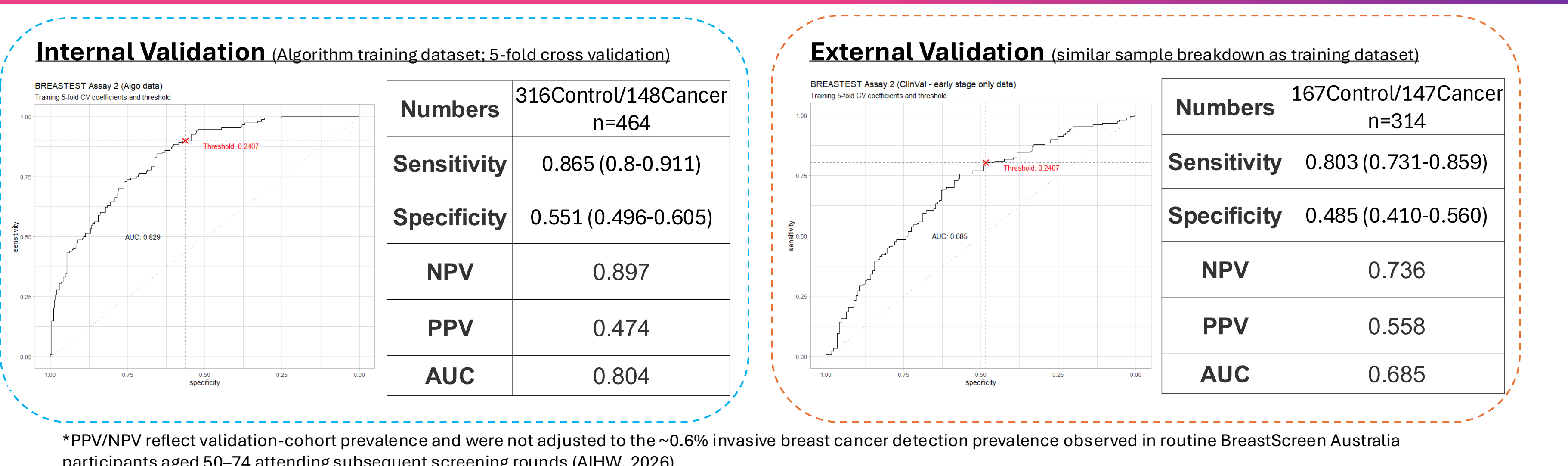
Algorithm Optimisation & Validation



Validation



Performance Results



Conclusion & Proposed Intended Use

The transition to BREASTEST plus™ 2, was supported by a complete validation pathway from analytical assay performance through algorithm optimisation and validation to independent clinical validation. The LC-MS/MS methods demonstrated suitable analytical performance for targeted plasma lipid measurement, while algorithm validation confirmed the locked model configuration and clinical validation assessed performance in previously unseen samples. Together, these studies provide an integrated evidence base supporting the improved BREASTEST plus™ 2 workflow to aid in the detection of early stage (0–2) breast cancer in women aged 30 years and over and with any breast density type. This body of work also provides the foundation for BREASTEST Monitor, with future development incorporating orthogonal biomarkers, including genomic markers, to further strengthen performance and expand the clinical utility of the platform.

References

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