



Proteomics International

LABORATORIES LTD

ASX Release
5 November 2020
ASX code: PIQ

PromarkerD clinical assay performance results published in peer-reviewed journals

Highlights

- **PromarkerD clinical assay platforms successfully validated for reproducibility, robustness and stability**
- **High correlation between PromarkerD (MS)[#] and PromarkerD (IA)[#] technology platforms proves reliability of PromarkerD test system**
- **Multiple peer-reviewed publications demonstrate clinical and analytical validity of PromarkerD predictive test for diabetic kidney disease**
- **Publications drive engagement with Key Opinion Leaders and adoption of PromarkerD by the wider diabetes community**
- **Proteomics International continues to pioneer clinical diagnostic test development using Promarker™ technology**

Medical Technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics, announces the publication of two successful studies demonstrating the robust technical performance of the PromarkerD predictive test for diabetic kidney disease.

The results form an essential basis for regulatory approvals related to the PromarkerD test system and its adoption by pathology laboratories worldwide. Importantly, they also illustrate the potential for adoption of the Promarker™ diagnostics platform in future clinical practice.

The findings have been published online as early versions of internationally peer-reviewed academic journals, and also as an industry application note:

1. The journal *Clinical Proteomics*, article titled “A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease”¹, and *Agilent Technologies Clinical Research Application Note*, titled “From Nanoflow to Standard Flow LC/MS for Routine Quantitative Plasma Proteomics in Diabetic Kidney Disease Research”².

Article summary: The PromarkerD assay has already demonstrated clinical validity. This study refined the original research grade mass spectrometry assay to enable higher throughput and clinical application.

Independent analysis of the same set of samples across multiple laboratories proved the robustness of the protocol between different test sites (Proteomics International, the

¹ Clin Proteom (2020) 17:37; doi.org/10.1186/s12014-020-09302-w

² Agilent Technologies Publication Part Number: 5994-2381EN

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University of Sydney, and Atturos Ltd (Ireland)). The joint publication is one of the first validations of a proteomics derived multi-biomarker diagnostic test in a clinical setting.

2. The journal *Proteomes*, article titled “*The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease*”³.

Article summary: Reproducible protein measurement across technology platforms is an essential component of determining a specific disease state, such as diabetic kidney disease. This publication proved there was high correlation between the advanced mass spectrometry (IAMS) platform and the traditional immunoassay (ELISA - enzyme linked immunosorbant assay) platform, with >90% of the samples achieving PromarkerD risk scores within 5% of the other platform's score.

Both technology platforms were successfully validated for assay reproducibility, robustness and stability for the PromarkerD test system.

Preliminary results of both studies were first presented at the 18th Human Proteome Organization (HUPO) World Congress [ASX: 12 September 2019; 17 September 2019].

Proteomics International managing director Dr Richard Lipscombe said, “*This type of robust performance data is essential in achieving regulatory approvals for the PromarkerD test system. Not only do the results prove the test can be used reliably in today's clinical laboratories, but they also offer an insight into the use of the Promarker platform in clinical practice in the decades to come.*”

Peer-reviewed publications form an essential component of engaging with Key Opinion Leaders to drive PromarkerD's adoption by the wider diabetes community. PromarkerD scientific publications now include:

- 1. Cross-Platform Assay Validation Study**
(2020) The New and the Old: Platform Cross-Validation of Immunoaffinity Mass Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. *Proteomes* 8(4), 31
- 2. Multi-site Assay Validation Study**
(2020) A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease. *Clin Proteomics* 17:37
- 3. Global Multi-Centre Prognostic Validation Study**
(2020) PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). *Journal of Clinical Medicine* 9, 3212
- 4. Prognostic Validation Study**
(2019) Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II. *Journal of Diabetes and its Complications* 33 (12), 107406
- 5. Biomarker Clinical Utility**
(2019) Apoptosis inhibitor of macrophage (AIM/CD5L) and diabetic kidney disease. *Cellular & molecular immunology* 16(5):521.
- 6. Prognostic Development Study**
(2017) Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. *Diabetes Care* 40, 1548-1555.
- 7. Prognostic Development Study**
(2017) Novel circulating biomarkers predict rapidly declining renal function in type 2 diabetes: The Fremantle Diabetes Study. *Diabetes* 66 (Supplement 1).
- 8. Diagnostic Study**
(2017) Comprehensive mass spectrometry based biomarker discovery and validation platform as applied to diabetic kidney disease. *EuPA Open Proteomics* 14, 1-10.

Authorised by Terry Sweet (Chair) on behalf of the Board of PIQ.

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³ Proteomes (2020) 8(4), 31; doi.org/10.3390/proteomes8040031

About PromarkerD (www.PromarkerD.com)

PromarkerD is a predictive test for the early detection of chronic kidney disease (CKD) in patients with type-2 diabetes. CKD is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant.

The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of disease by measuring three serum proteins (ApoA4, CD5L and IGFBP3), combined with three routinely available conventional clinical variables (age, high-density lipoprotein (HDL)-cholesterol and estimated glomerular filtration rate (eGFR)).

In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Definitions:

"Promarker" - the proprietary technology used to discover and evaluate proteins for use as diagnostics

"PromarkerD/PromarkerD test system" - the patented predictive diagnostic test for Diabetic Kidney Disease

"PromarkerD (MS)" - the predictive diagnostic test for Diabetic Kidney Disease using Mass Spectrometry

"PromarkerD (IA)" - the predictive diagnostic test for Diabetic Kidney Disease using ImmunoAssay

"PromarkerD Hub" - the proprietary software tool used to calculate the risk of Diabetic Kidney Disease in diabetes patients

Further information is available through the PromarkerD web portal.

To visit the PromarkerD ADA virtual booth please see: www.PromarkerD.com/product

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of predictive diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. It received the world's first ISO 17025 laboratory accreditation for proteomics services, and operates from state-of-the-art facilities located on Perth's QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the Company's world-leading test for diabetic kidney disease, PromarkerD. The Company offsets the cash burn from R&D and product development through provision of specialist analytical services, whilst using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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