Proteomics International
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PromarkerD latest results published in peer reviewed journal

Highlights

- **Latest PromarkerD clinical validation results published in the *Journal of Diabetes and its Complications***
- **PromarkerD is the first test globally capable of predicting the onset of diabetic kidney disease**
- **In the 447 patient study, PromarkerD correctly predicted 86% of those who went on to develop chronic kidney disease (CKD) within four years**
- **The latest results also show PromarkerD has an excellent negative predictive value, or "rule-out" capability, of 98% for four-year risk of developing diabetic kidney disease (DKD)**
- **Globally 1 in 3 adults with diabetes have CKD - diabetes-associated CKD is the 16th leading cause of death in the US, accounting for 40,000 deaths per year**
- **PromarkerD could aid clinical decision-making by identifying at-risk individuals for earlier targeted personalised intervention**
- **PromarkerD could also benefit future clinical trials of new drugs for DKD through selective enrolment of high-risk patients, allowing smaller and shorter trials**
- **Proteomics International is in discussions with tier-1 diagnostics and pharmaceutical companies, targeting global markets to expand the reach of PromarkerD**

Medical technology company Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) announces the publication of the latest PromarkerD clinical validation study results in the *Journal of Diabetes and its Complications*.

The peer-reviewed work was conducted in collaboration with the University of Western Australia Medical School and the article, titled "Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II", is available online (doi.org/10.1016/j.jdiacomp.2019.07.003) prior to formal publication. The initial study results were presented at the American Diabetes Association's 77th Annual Scientific Sessions [ASX: 13 June 2017].

Peer reviewed publications form an important part of Proteomics International's on-going engagement strategy with multi-national diagnostics and pharmaceutical companies and global Key Opinions Leaders.

According to the Centers for Disease Control and Prevention an estimated 1 in 3 adults with diabetes have chronic kidney disease (CKD) and diabetes-associated CKD is the 16th leading cause of death in the US, accounting for 40,000 deaths per year.

Conventional tests for assessing renal function, namely the urinary albumin-to-creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR), have limited accuracy in predicting CKD progression.

The primary aim of the present study was to validate the utility of PromarkerD for predicting rapid kidney decline (defined as an incidence of clinically defined CKD, or a significant decline (>30%) in kidney function) over a four-year follow-up period. The validation cohort contained 447 participants with type 2 diabetes who were followed for four years.

During the four years of follow-up, approximately 10% of patients experienced a rapid decline in kidney function. PromarkerD correctly predicted 86 per cent of previously disease-free patients who went on to develop chronic kidney disease (AUC = 0.88, sensitivity = 86%, specificity = 78%).

Proteomics International managing director Dr Richard Lipscombe said, “the latest results were particularly important because they showed PromarkerD has an excellent negative predictive value, or "rule-out" capability, of 98% for four-year risk of developing diabetic kidney disease. This can improve patient management and help to save healthcare systems billions of dollars.”

The published PromarkerD test system comprises three clinical variables (age, serum HDL-cholesterol and eGFR), which were chosen based on accessibility in routine diabetes care, combined with the three patented plasma proteins (ApoA4, CD5L and IGFBP3).

The validation of an accurate prognostic test such as PromarkerD could aid clinical decision-making by identifying at-risk individuals for earlier targeted personalised intervention and monitoring of disease progression. In high risk patients, the test could justify the early introduction of new therapeutic treatments that have kidney benefits such as the SGLT-2 inhibitor drugs empagliflozin (Boehringer Ingelheim/ Eli Lilly & Co.) and canagliflozin (Janssen Pharmaceuticals).

PromarkerD may also be useful for selective enrolment of high-risk patients into future clinical trials of interventions in DKD, allowing smaller and shorter trials.

Worldwide there were 425 million adults with diabetes in 2017, a global prevalence of 9.9% showing a dramatic rise from the 108 million adults with diabetes in 1980. Currently one in three adults with diabetes already have diabetic kidney disease, however, with early intervention it is possible to delay or prevent clinical symptoms of the disease.

Proteomics International is in discussions with tier-1 diagnostics and pharmaceutical companies, targeting the markets of Europe, Japan, India and US, to expand the global reach of PromarkerD.

Glossary

Sensitivity (true positive rate)	The ability of a test to correctly identify those with the disease.
Specificity (true negative rate)	The ability of the test to correctly identify those without the disease.
Negative Predictive Value (NPV)	The probability that people who get a negative test result truly do not have the disease. In other words, it’s the probability that a negative test result is accurate.
Positive Predictive Value (PPV)	The probability that a patient with a positive (abnormal) test result actually has the disease. When the occurance of a disease is low, the positive predictive value will also be low, even using a test with high sensitivity and specificity.
AUC	"Area Under the ROC Curve". A receiver operating characteristic curve, or ROC curve, is a graphical plot that illustrates the performance of a classifier system.
Interpreting AUC values	Conventionally the clinical significance of AUC is: > 0.7 acceptable discrimination > 0.8 excellent discrimination > 0.9 outstanding discrimination

PromarkerD algorithm	The power of the PromarkerD test system is that it can be adjusted to provide optimal results: • Maximise sensitivity or PPV to capture those at high risk of progressing towards dialysis or kidney transplant • Maximise specificity or NPV to rule-out those who are at low risk of progressing towards dialysis or kidney transplant

ENDS

About PromarkerD (www.PromarkerD.com)
The PromarkerD test system assesses the risk of diabetic kidney disease in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein 'fingerprint' to provide an early detection of the onset of disease. 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. PromarkerD has received patent protection in multiple jurisdictions including Europe, China, Japan and the USA.

Further information is available through the PromarkerD web portal.

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. The Company's business model uses its proprietary technology platform across three integrated areas of diagnostics, drug discovery and analytical services.

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