Proteomics International unveils groundbreaking study on type 1 diabetes and kidney health

- **Breakthrough study is the first application of the PromarkerD test for predicting renal decline in type 1 diabetes**

- **Results show PromarkerD demonstrated high accuracy (area under the curve (AUC) of 0.93) in predicting chronic kidney disease in patients with type 1 diabetes**

- **PromarkerD has been previously validated for predicting renal decline up to four years in advance in type 2 diabetes**

- **The additional application for type 1 diabetes patients with their unique clinical needs offers a new target market for PromarkerD**

- **Global health impact: addresses a critical health issue for over 537 million people worldwide who have diabetes, with type 1 diabetes representing 10% of all cases**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in predictive diagnostics is pleased to announce groundbreaking results showing the PromarkerD predictive test can predict renal decline in type 1 diabetes.

The results will be presented today in a study titled "*Application of a validated prognostic protein biomarker test for renal decline in type 2 diabetes to type 1 diabetes: The Fremantle Diabetes Study Phase II*" at the Australasian Diabetes Conference in Perth, Australia, held 21-23 August. The findings have also been accepted for publication in the journal of *Clinical Diabetes and Endocrinology*. This pioneering research marks the Company's first venture into the realm of type 1 diabetes.

The study addresses a significant gap in the medical field, focusing on the lack of prognostic biomarkers for chronic kidney disease (CKD) in individuals with type 1 diabetes. Utilizing the PromarkerD test, originally developed and validated for predicting renal decline in type 2 diabetes, researchers assessed its efficacy in a cohort of 92 individuals with type 1 diabetes from the Fremantle Diabetes Study Phase II.

The results are promising, with the PromarkerD test demonstrating strong predictive accuracy. The area under the receiver operating characteristic curve (AUC) was an impressive 0.93, indicating robust performance in predicting CKD risk and kidney function decline.

Proteomics International Managing Director Dr. Richard Lipscombe said, "*This significant advancement highlights the versatility and robustness of the PromarkerD test. We are excited about the potential impact this could have on managing kidney health in both type 1 and type 2 diabetes patients.*"

Professor Tim Davis, consultant physician and endocrinologist at Fremantle Hospital and Professor of Medicine, University of Western Australia, and lead author on the study, said, *"The early detection capabilities of PromarkerD are particularly beneficial for type 1 diabetes patients due to their unique clinical*

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needs. By identifying at-risk individuals years before traditional methods, we can intervene sooner, potentially preventing significant renal complications and improving overall patient outcomes."

Diabetes affects over 537 million people worldwide, and chronic kidney disease is a major complication, leading to severe health outcomes and increased mortality. Type 1 diabetes represents approximately 10% of all cases of diabetes and cannot be prevented[1]. Diabetes has emerged as the largest single cause of end-stage renal disease (leading to dialysis or kidney transplant) in developed and developing countries[2]. These preliminary findings suggest that the PromarkerD test is a highly effective prognostic tool for renal decline in both type 1 and type 2 diabetes, heralding a new era in diabetic kidney disease management.

PromarkerD has previously been validated as accurately predicting the onset of diabetic kidney disease (DKD) and future kidney function decline up to four years in advance in patients with type 2 diabetes.

<u>**Details:**</u> Australasian Diabetes Conference 2024, Oral presentation, titled:

Application of a validated prognostic protein biomarker test for renal decline in type 2 diabetes to type 1 diabetes: The Fremantle Diabetes Study Phase II

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Summary of the Study

Aim: To assess the performance of the PromarkerD predictive test, which has been validated to predict future kidney function decline in patients with type 2 diabetes, in patients with type 1 diabetes**.**

Method: The baseline PromarkerD test score was determined using the PromarkerD immunoassay in 92 community-based individuals with confirmed type 1 diabetes recruited to the longitudinal observational Fremantle Diabetes Study Phase II. Changes in a patient's kidney function were measured by estimated glomerular filtration rate (eGFR). The performance of PromarkerD in predicting the risk of incident CKD (eGFR <60 mL/min/1.73m² in people without CKD at baseline) or an eGFR decline of ≥30% over the next four years was determined.

Results: The area under the receiver operating characteristic curve (AUC) was 0.93 (95% confidence interval 0.87–0.99) for the composite renal endpoint, indicating excellent predictive accuracy. The optimal sensitivity, specificity, positive and negative predictive values were 78%, 90%, 47%, and 97%, respectively.

Conclusions: These preliminary data suggest that PromarkerD is at least as good a prognostic test for renal decline in type 1 as type 2 diabetes.

Glossary

Sensitivity (Sn) (true positive rate)	The ability of a test to correctly identify those <u>with</u> the disease. E.g. sensitivity of 80% means that for every 100 people with disease, the test correctly diagnosed 80 <u>with</u> the condition.
Specificity (Sp) (true negative rate)	The ability of the test to correctly identify those <u>without</u> the disease. E.g. specificity of 75% means that for every 100 people without disease, a test correctly identifies 75 as <u>not</u> having the condition.
Negative Predictive Value (NPV)	The probability that people who get a negative test result truly do not have the disease. In other words, it is 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.
Probability (P)	The *P* value, or calculated *probability*, that an observation is true. Most authors refer to statistically significant as P < 0.05 and statistically highly significant as P < 0.001 (less than one in a thousand chance of being wrong).
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.

[1] International Diabetes Federation 2021

[2] pubmed.ncbi.nlm.nih.gov/31767176/

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Interpreting AUC values	Conventionally the clinical significance of AUC is: > 0.7 acceptable discrimination > 0.8 excellent discrimination > 0.9 outstanding discrimination

For comparison, the statistical performance of the Prostate-Specific Antigen (PSA) diagnostic test (blood test measuring the concentration of the PSA protein) for the diagnosis of prostate cancer is[3]:

- Prostate cancer versus no cancer: AUC 0.68
- PSA cut-off threshold 3ng/ml: Sensitivity 32%, Specificity 87%

Authorised by the Board of Proteomics International Laboratories Ltd (ASX: PIQ).

ENDS

About PromarkerD (www.PromarkerD.com)
Diabetic kidney disease (DKD) is a serious complication arising from diabetes which if unchecked can lead to dialysis or kidney transplant. PromarkerD is a prognostic test that can predict future kidney function decline in patients with type 2 diabetes and no existing DKD. The patented PromarkerD test system uses a simple blood test to detect a unique 'fingerprint' of the early onset of the disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL cholesterol and estimated glomerular filtration rate (eGFR)). A cloud-based algorithm integrates the results into a patient risk report. In clinical studies published in leading journals PromarkerD correctly predicted up to 86% of otherwise healthy diabetics who went on to develop diabetic kidney disease within four years.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD 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. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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[3] pubmed.ncbi.nlm.nih.gov/15998892/

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