# PromarkerD results for predicting kidney decline in type 1 diabetes published in peer-reviewed journal

- **Breakthrough results published in the journal of *Clinical Diabetes and Endocrinology* show PromarkerD demonstrated high accuracy 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 the publication of groundbreaking results showing the PromarkerD predictive test can predict renal decline in type 1 diabetes. These findings were first presented at the Australasian Diabetes Conference in Perth, Australia, in August [ASX: 23 August].

The results were published overnight in the peer-reviewed journal of *Clinical Diabetes and Endocrinology* in a paper titled "*Application of a validated prognostic plasma protein biomarker test for renal decline in type 2 diabetes to type 1 diabetes: The Fremantle Diabetes Study Phase II*"[1].

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. Utilising the PromarkerD test, originally developed and validated for predicting renal decline in type 2 diabetes, the study of 92 community-based individuals demonstrated outstanding performance in predicting CKD risk and kidney function decline (Area under the receiver operating characteristic curve (AUC) 0.93; optimal sensitivity, specificity, positive and negative predictive values were 78%, 90%, 47%, and 97%, respectively).

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[2]. Diabetes has emerged as the largest single cause of end-stage renal disease (leading to dialysis or kidney transplant) in developed and developing countries[3]. 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.

Proteomics International is currently focused on launching PromarkerD in the USA in H1 CY25 and in Australia in Q1 CY25 through a hybrid approach of traditional licensing and direct-to-consumer/patient (DTC/DTP) go-to-market approaches [PIQ Annual Report and ASX: 19 September].

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[1] doi.org/10.1186/s40842-024-00191-8

[2] International Diabetes Federation 2021

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

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**Glossary**

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| 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. |
| 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 |

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[4]:

- 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).

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**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.

**For further information please contact:**

| | |
|---|---|
| Dirk van Dissel | Lisa Barnes |
| Investor Relations | Public Relations |
| Candour Advisory | Profile Media |
| T: +61 408 326 367 | T: +61 416 583 672 |
| E: dirk@candouradvisory.com.au | E: lisab@profilemedia.com.au |

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

**Proteomics International Laboratories Ltd**
ABN 78 169 979 971
Box 3008, Broadway, Nedlands, WA 6009, Australia
T: +61 8 9389 1992 | E: enquiries@proteomicsinternational.com | W: www.proteomicsinternational.com
2/3                                    Part of the PILL Group

Dr Richard Lipscombe
Managing Director
Proteomics International Laboratories Ltd
T: +61 8 9389 1992
E: enquiries@proteomicsinternational.com

Proteomics International (Europe)
Plesmanweg 9, 7602 PD Almelo
The Netherlands
T: +31 85 40 11 173
E: Europe@PromarkerD.eu

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