ASX Release
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PromarkerD outperforms standard of care tests in predicting kidney decline in type 2 diabetes - results published in peer-reviewed journal

- **Landmark results published in a special edition of the journal *Diagnostics* demonstrate PromarkerD significantly outperforms conventional tests in identifying the risk of diabetes-related chronic kidney disease (DKD)**
- **PromarkerD has been previously validated for predicting renal decline up to four years in advance in type 2 diabetes**
- **Commercial Expansion in the US & Australia – Proteomics International has launched a Reference Laboratory in California and is preparing to introduce PromarkerD in Australia**
- **Global health impact: Potential to improve outcomes for over 537 million people worldwide with diabetes and at risk of DKD by enabling earlier intervention, improving care and reducing healthcare costs**

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Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce the publication of results of its landmark study demonstrating the PromarkerD test significantly outperforms the current standard of care tests in predicting future kidney function decline in individuals with type 2 diabetes (DKD).

The findings highlight the potential for PromarkerD to revolutionise diabetic kidney disease risk assessment and management, ultimately improving patient outcomes and reducing healthcare costs. These results are an important extension of data first presented at the American Society of Nephrology Kidney Week Conference [ASX: 5 November 2021].

The results were published overnight in the peer-reviewed journal *Diagnostics* as part of the Special Issue 'Current Issues on Kidney Diseases Diagnosis and Management 2025' in a paper titled *"PromarkerD Versus Standard of Care Biochemical Measures for Assessing Future Renal Function Decline in Type 2 Diabetes"*[1].

Proteomics International Managing Director Dr Richard Lipscombe said, *"this peer-reviewed comparison against standard of care is critical in proving the power of PromarkerD to the medical community. As we acknowledge Kidney Health month in the US, we want to provide healthcare professionals with the best tools available to combat this debilitating disease."*

According to the American Society of Nephrology many patients suffer silently at first because chronic kidney disease is largely asymptomatic at the beginning. This lack of early detection can be fatal as kidney dysfunction that lasts longer than three months most often is irreparable[2].

Diabetes affects over 537 million people worldwide, and chronic kidney disease is a major complication,

[1] doi.org/10.3390/diagnostics15060662 (www.mdpi.com/2075-4418/15/6/662#:~:text=PromarkerD%20demonstrated%20significantly%20higher%20predictive,Figure%203)

[2] www.asn-online.org/nationalkidneymonth/

leading to severe health outcomes and increased mortality. 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].

Summary of Study

Chronic kidney disease affects up to 50 percent of people with type 2 diabetes, leading to severe health complications and increased healthcare costs. The current standard of care for the definition, classification, and prognosis of chronic kidney disease, defined by the Kidney Disease Improving Global Outcomes (KDIGO) guidelines - the estimated glomerular filtration rate (eGFR) and urinary albumin:creatinine ratio (uACR) - have severe limitations in accurately predicting disease progression.

The community-based study followed 857 adults with type 2 diabetes over four years and found that PromarkerD delivered significantly improved predictive accuracy, with an area under the receiver operating characteristic curve (AUC) of 0.88 compared to conventional tests, which ranged between 0.63 and 0.82 ($p<0.001$).

Participants classified as high risk of kidney decline by PromarkerD had significantly higher odds of experiencing the primary study endpoint[4] compared to those at low risk (Odds ratio (OR) 21.34), whereas KDIGO risk categories showed only modest degrees of association with the OR for high risk versus low risk at 1.28 ($p<0.001$).

Critical for patient management, PromarkerD identified 84 percent of individuals with normal kidney function at baseline who later developed significant kidney decline, cases that would have been missed by standard classification methods.

PromarkerD also exhibited an excellent "rule-out" rate (Negative Predictive Value [NPV] >96%), for categorising patients at low risk of developing DKD, and demonstrated considerably less false positives compared to standard of care testing.

Proteomics International recently announced the opening of its Clinical Laboratory Improvement Amendment (CLIA) certified Reference Laboratory in California to service the US market [ASX: 28 February] and is also preparing to launch PromarkerD in Australia. The test will initially be available through a direct-to-consumer (DTC) go-to-market route as a prelude to out-licensing to major industry players in the diagnostics sector.

Glossary

Sensitivity (Sn) (true positive rate)	The ability of a test to correctly identify those with the disease. E.g. sensitivity of 80% means that for every 100 people with disease, the test correctly diagnosed 80 with the condition.
Specificity (Sp) (true negative rate)	The ability of the test to correctly identify those without the disease. E.g. specificity of 75% means that for every 100 people without disease, a test correctly identifies 75 as not having the condition.
Odds Ration (OR)	A measure of the strength of association between two events, E.g. an odds ratio of 1.2 means the chances of having a disease are 20% more likely than the odds of not having the disease, whereas an OR of 10, means you are 10 times more likely. to have 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 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.

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

[4] Primary endpoint was defined as: eGFR < 60 mL/min/1.73 m^2) or eGFR decline ≥ 30% over four years

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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[5]:

- 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)
Diabetes-related chronic 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 blood test to detect a unique 'fingerprint' of the early onset of the disease. The multivariate test measures a select panel of protein and clinical biomarkers, before 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 precision 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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[5] pubmed.ncbi.nlm.nih.gov/15998892/

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