ASX Release
23 June 2025

ASX code: PIQ

Release of Next-Generation PromarkerD Test System for Predicting Diabetic Kidney Disease

- **PromarkerD is a blood test validated for predicting diabetes-related chronic kidney disease (DKD) up to four years before symptoms appear**
- **The next-generation PromarkerD utilises a high-throughput immunoassay to measure two plasma protein biomarkers alongside two clinical factors to generate a personalised DKD risk score**
- **Results presented over the weekend at the 85th Scientific Sessions of the American Diabetes Association in Chicago, Illinois, the largest gathering of diabetes professionals in the world**
- **Simplified without compromising accuracy, the next-gen PromarkerD matched previously published performance identifying 86% of at-risk individuals, all missed by standard tests**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce the successful development and release of the next-generation of the PromarkerD test system, a simplified, immunoassay-based diagnostic that accurately predicts kidney function decline in adults with type 2 diabetes (T2D).

In results presented over the weekend at the 85th Scientific Sessions of the American Diabetes Association (ADA) in Chicago, Illinois, this technology builds upon PromarkerD's proven clinical utility and represents a key advancement toward large-scale clinical deployment in pathology laboratories globally.

Diabetes-related chronic kidney disease (DKD), is a major global health burden. The PromarkerD test addresses a critical unmet need by the identification of individuals at risk of DKD up to four years before clinical symptoms appear. This early identification enables targeted, preventative care to reduce progression to costly and life-threatening end-stage renal disease requiring dialysis or kidney transplant.

The next-generation PromarkerD utilises a high-throughput immunoassay that aligns with routine pathology workflows. The test now measures two plasma protein biomarkers (ApoA4 and CD5L) alongside age and estimated glomerular filtration rate (eGFR) to generate a personalised DKD risk score.

Simplified without compromising accuracy, the next-gen PromarkerD matched previously published performance[1] [ASX: 11 March], and identified 86% of at-risk individuals, all missed by current standard-of-care eGFR and urinary albumin:creatinine ratio (uACR) tests.

In a 948 participant clinical study, the test retained its excellent predictive discrimination, with the high-risk PromarkerD group demonstrating 44-fold greater odds of kidney decline vs the low-risk group. The key clinical validation data was presented as a Late Breaking Abstract, a program for the inclusion of noteworthy and timely research advances, titled "*Next-Generation PromarkerD vs Standard of Care for Assessing Kidney Function Decline in Type 2 Diabetes*" [Copy of presentation attached].

PromarkerD is now positioned for global commercialisation and regulatory expansion, opening new pathways to transform diabetic care through precision medicine.

[1] Diagnostics (2025); doi.org/10.3390/diagnostics15060662

Glossary

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.
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.
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[2]:

- 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. Country specific use of this product is subject to the relevant regulatory approvals.

Proteomics International recommends that patients concerned about DKD seek advice from their doctors.
Further information on DKD is available through the www.mytest.health 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 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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[2] pubmed.ncbi.nlm.nih.gov/15998892/; JAMA. 2005 Jul 6;294(1):66-70; doi: 10.1001/jama.294.1.66

Next-Generation PromarkerD vs Standard of Care for Assessing Kidney Function Decline in Type 2 Diabetes

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Presented at the American Diabetes Association 85th Scientific Sessions June 20-23, 2025.

Booth: 3531

Introduction and Objective

- Diabetes-related chronic kidney disease (DKD) can progress to end-stage kidney disease, increasing morbidity and mortality. Standard assessments using estimated glomerular filtration rate (eGFR) and urinary albumin:creatinine ratio (uACR) have limited value for early risk prediction.
- **Promarker®D is a validated blood test that predicts DKD in people with type 2 diabetes (T2D) up to 4 years before clinical symptoms[1,2]**. An earlier version used three protein biomarkers and three clinical factors to predict DKD or ≥30% decline in eGFR[1], and outperformed eGFR and uACR in risk prediction[3].
- The next-generation PromarkerD test simplifies inputs while maintaining similar performance[2].
- **Objective:** To compare the performance of this next-generation test to eGFR and uACR for predicting kidney function decline in T2D.

Methods and Participants

- **Participants Studied:** Plasma and clinical data were analyzed from 948 participants in the longitudinal observational Fremantle Diabetes Study Phase II (FDS2)[4]. All underwent comprehensive clinical assessment at baseline (Table 1).
- **Next-Generation PromarkerD Test:** The latest version of the test combines two plasma biomarkers (Apolipoprotein A4 and CD5 antigen-like) measured by ELISA with Capt*Sure*™ technology, with age and eGFR to generate PromarkerD risk scores (0-100%). Patients are classified as low- (<10%), moderate- (10-35%), or high-risk (≥36%) for kidney outcomes within 4 years.
- **Primary Kidney Outcome:** i) incident DKD (eGFR <60 mL/min/1.73 m^2 at follow-up in those with eGFR ≥60 at baseline), or ii) ≥40% decline in eGFR over 4-years in those with baseline eGFR <60.
- **Statistical Analysis:** Logistic regression assessed the predictive performance of PromarkerD, eGFR, uACR, eGFR + uACR, and KDIGO risk categories[5]. Discrimination was measured using the area under the curve (ROC-AUC) and odds ratios (ORs) quantified associations with outcomes.

Table 1: Baseline characteristics of the 948 FDS2 participants.

Characteristic*	FDS2 (n=948)
Age (years)	65.3 ± 11.3
Gender, % male	54.3
BMI (kg/m^2)	30.7 ± 5.7
Diabetes duration (years)	7.9 ± 9.0
Fasting plasma glucose (mmol/L)	7.1 ± 1.7
HbA_{1c} (%)	6.8 ± 1.0
Serum total cholesterol (mmol/L)	4.2 ± 1.0
Serum triglycerides (mmol/L)	1.5 ± 0.7
Urinary ACR (mg/mmol)	2.1 ± 1.8
eGFR (mL/min/1.73m^2)	86.0 ± 16.5

*All values are proportions (%) or median ± median absolute deviation.

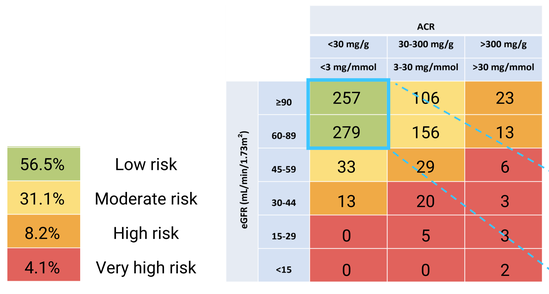

Figure 1: Number of participants by chronic kidney disease stage as defined by KDIGO (Kidney Disease Improving Global Outcomes) 2024 guidelines[5]. The proportion of participants by low-, moderate-, high- and very-high KDIGO risk categories is also shown.

Results

- **PromarkerD provided a significantly higher discriminative capability (AUC: 0.88)** compared to standard of care (AUC: 0.63-0.81) (all *P*<0.001) (Table 2, Figure 2).
- Higher PromarkerD scores were more strongly associated with outcomes (OR 3.14) than lower eGFR and higher uACR (OR 2.30 and 1.29, respectively), and remained independently predictive after adjusting for both (OR 2.88 (2.31-3.58) per 1 SD increase) (Table 2).
- **The high-risk PromarkerD group had 44-fold greater odds of kidney decline vs low-risk, while KDIGO categories showed only modest association (OR 3.91 and 1.30 for very high and high vs low, respectively) (Table 2, Figure 3).**

Table 2: Clinical performance of PromarkerD compared to standard of care.

Performance Metric	FDS2 (n=948)
AUC (95% CI):	
PromarkerD	**0.88 (0.85-0.91)**
eGFR	0.80 (0.77-0.84)*
uACR	0.63 (0.58-0.69)*
eGFR + uACR	0.81 (0.77-0.84)*
PromarkerD Odds Ratios (95% CI):	
Risk score (continuous)¥	3.14 (2.60-3.79)
Moderate vs Low	7.26 (3.95-13.35)
High vs Low	44.26 (23.48-83.35)
Standard of Care Odds Ratios (95% CI):	
eGFR (continuous)¥,#	2.30 (1.90-2.79)
uACR (continuous)¥	1.29 (1.12-1.49)
KDIGO Moderate vs Low	1.47 (0.94-2.30)
KDIGO High vs Low	1.30 (0.61-2.76)
KDIGO Very-high vs Low	3.91 (1.83-8.32)

* PromarkerD significantly higher AUC than eGFR and uACR (all *P*<0.001). ¥ Odds ratios are per 1 SD increase # eGFR odds ratio inverted for ease of comparison.

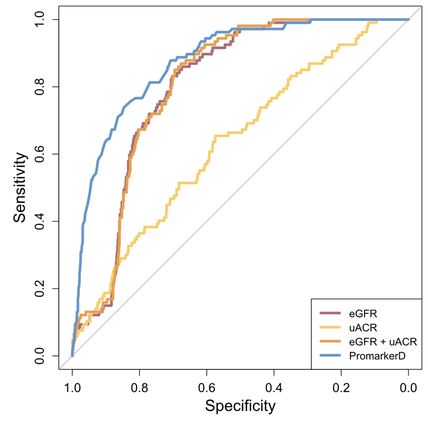

Figure 2: ROC-AUC comparing the discriminative ability of PromarkerD to standard of care tests for predicting kidney outcomes.

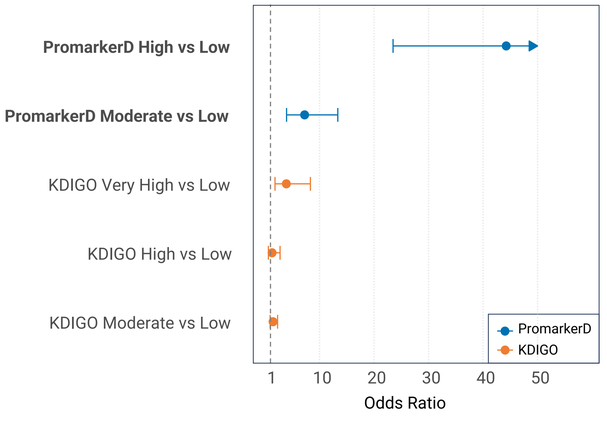

Figure 3: Odds Ratios with 95% CI for PromarkerD risk categories compared to KDIGO risk categories for predicting kidney outcomes.

Of the 536 people in the KDIGO "low-risk" category with normal kidney function, 49 (9.1%) developed DKD. PromarkerD correctly classified 86% of these people as moderate/high risk - all would have been missed by standard of care.

Results

- **During 4.2 ± 0.3 years follow-up, 107 (11.3%) participants developed the primary kidney outcome.**
- PromarkerD stratified participants into low (65.3%), moderate (24.2%), and high (11.0%) risk groups, with kidney outcomes observed in 2.6%, 16.2%, and 54.0% of each group, respectively.

Conclusions

This next-generation PromarkerD test provides superior performance to standard of care biochemical tests in predicting kidney function decline in T2D. It confirms the accuracy of the previous version while being simpler to perform. Importantly, PromarkerD identifies at-risk individuals missed by eGFR and uACR, enabling early preventative treatment strategies before irreversible kidney damage occurs.

Acknowledgements: FDS2 was supported by NHMRC grants #513781 and #1042231. The biomarker analyses were performed in part using NCRIS (National Collaborative Research Infrastructure Strategy)–enabled Bioplatforms Australia infrastructure at the Western Australian Proteomics Facility, located at the Harry Perkins Institute for Medical Research.

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