



Proteomics International

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Performance of Next-Generation PromarkerD Test System published in The Journal of Applied Laboratory Medicine

- **PromarkerD is a blood test validated for predicting diabetes-related chronic kidney disease (DKD) up to four years before symptoms appear**
- **Simplified without compromising accuracy, the next-generation PromarkerD test system utilises a high-throughput immunoassay to generate a personalised DKD risk score**
- **Results published overnight in the peer-reviewed Journal of Applied Laboratory Medicine**
- **In a study of over 1,700 participants the next-generation PromarkerD test demonstrated:**
 - **excellent predictive discrimination, with patients predicted as high-risk by PromarkerD having 44-fold greater odds of kidney decline versus the low-risk group**
 - **exceptional predictive performance (AUC 0.88) and negative predictive value up to 97.4%, outperforming current standard of care tests**
 - **excellent analytical precision, reproducibility, and stability, meeting stringent international laboratory guidelines**
 - **matched previously published performance identifying 86% of individuals at risk of DKD, all missed by standard tests**
- **Major health impact: Potential to improve outcomes for 537 million adults globally with diabetes and at risk of DKD by enabling earlier intervention, improving care and reducing healthcare costs**
- **Next-Gen PromarkerD test is now available to Type-2 diabetes patients in both Australia & USA**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce the publication of results demonstrating the accuracy and performance of its next-generation PromarkerD test system, a simplified, immunoassay-based diagnostic that accurately predicts kidney function decline in adults with type 2 diabetes (T2D). The key results reported in the publication were first presented at the 85th Scientific Sessions of the American Diabetes Association (ADA) [ASX: 23 June].

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

Published overnight in the peer-reviewed Journal of Applied Laboratory Medicine¹, the study highlighted the test's strong predictive performance across diverse groups, and its high negative predictive value accurately rules out future kidney decline, enabling targeted care and better resource allocation.

Simplified without compromising accuracy, the next-generation PromarkerD test system utilises a high-throughput immunoassay that aligns with routine pathology workflows. The test now measures two plasma

¹ Journal of Applied Laboratory Medicine (2025); "Analytical and clinical performance of a novel immunoassay-based test system to predict diabetic kidney disease"; doi.org/10.1093/jalm/jfaf097

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protein biomarkers (ApoA4 and CD5L) alongside age and estimated glomerular filtration rate (eGFR) to generate a personalised DKD risk score.

In the 949-participant community based Fremantle Diabetes Study Phase II (FDS2), the test achieved exceptional predictive performance (AUC 0.88) and negative predictive value (NPV) of 97.4%, outperforming current standard of care tests eGFR and urinary albumin:creatinine ratio (uACR). External validation in the 757-participant CANagliflozin CardioVascular Assessment Study (CANVAS) cohort further confirmed robustness (AUC 0.78, NPV 95.1%).

Notably, patients predicted as high-risk by PromarkerD had a 44-fold greater odds of kidney decline versus the low-risk group. The next-generation version of the test matched previously published performance² [ASX: 11 March] by identifying 86% of individuals at-risk of DKD, all missed by current standard-of-care.

The next-gen PromarkerD test also demonstrates excellent analytical precision, reproducibility, and stability, meeting stringent international guidelines (Clinical & Laboratory Standards Institute (CLSI) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)).

This technology refinement builds upon PromarkerD's proven clinical utility and represents a key advancement towards large-scale clinical deployment in pathology laboratories globally, opening new pathways to transform diabetic care through precision medicine.

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. Also known as 'rule-out' rate, 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.
Odds Ratio (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 <i>P</i> value, or calculated <i>probability</i> , 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 is³:

- 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).

² Diagnostics (2025); doi.org/10.3390/diagnostics15060662

³ pubmed.ncbi.nlm.nih.gov/15998892/; JAMA. 2005 Jul 6;294(1):66-70; doi: 10.1001/jama.294.1.66

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About Promarker®D (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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