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PromarkerD demonstrates predictive value for diabetic kidney disease in Aboriginal Australians

- PromarkerD shows acceptable and clinically meaningful predictive accuracy for diabetes-related chronic kidney disease (DKD) in Aboriginal people with diabetes
- Peer-reviewed study published overnight in the Internal Medicine Journal shows no statistically significant difference in test performance between Aboriginal and non-Aboriginal participants
- High negative predictive value (>85%) supports PromarkerD as a powerful tool for ruling out medium-term kidney decline and optimising healthcare resources
- National health impact: the overall burden from DKD is over 7 times higher for Aboriginal people than for non-Indigenous people
- Next-Gen PromarkerD test is now available to type-2 diabetes patients in Australia via multiple health channels

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics, is pleased to announce new clinical findings showing that its PromarkerD predictive blood test demonstrates promising prognostic accuracy for diabetic kidney disease (DKD) in Aboriginal people, one of the highest-risk populations for kidney failure globally.

The results are derived from an analysis of 1,081 adults with diabetes, including 71 Aboriginal participants, drawn from the Fremantle Diabetes Study Phase II and the Aboriginal Diabetes Sub-study. The study assessed the PromarkerD test for its ability to predict incident DKD or rapid decline in kidney function over four years.

These findings highlight PromarkerD's potential to enhance early identification of kidney disease risk, support more targeted intervention strategies, and strengthen health outcomes among Aboriginal people, who have one of the highest rates of diabetes and chronic kidney disease globally. In Australia, the burden of DKD is approximately seven times higher for Aboriginal people compared to non-Indigenous people¹.

Proteomics International Managing Director Dr Richard Lipscombe said, "Aboriginal people bear a disproportionately high burden of diabetes and DKD, often with earlier onset and faster progression - raising both the need and the potential benefit for better prognostic tests validated in these communities."

In Aboriginal participants, the next-gen version of PromarkerD achieved acceptable predictive performance, with area under the ROC curve (AUC) values of 0.71. This result was not statistically different from those observed in the non-Aboriginal cohort (AUC 0.89). Importantly, the test delivered high negative predictive values (also known as 'rule-out' rate) of >85%, indicating that a low PromarkerD score reliably identifies individuals unlikely to experience kidney function decline in the near term.

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¹ dio: 10.3389/fmed.2025.1561566

Professor Tim Davis, consultant physician and endocrinologist at Fremantle Hospital and a Professor of Medicine at The University of Western Australia said, "these findings show that PromarkerD has potential to support earlier, more accurate identification of kidney disease risk in Aboriginal people with type 2 diabetes. Early prediction is critical in this population, and a reliable test such as PromarkerD can help clinicians focus preventive care where it is needed most - it offers a significant opportunity to improve chronic disease management in remote and regional Aboriginal communities."

The publication, titled 'The prognostic value of a plasma protein-based biomarker test for chronic kidney disease complicating diabetes in Aboriginal Australians', is available from the Internal Medicine Journal (IMJ), the region's leading internal medicine publication, publishing original medical research from all over the world. The journal also plays a major role in continuing medical education through review articles relevant to physician education.

PromarkerD is a validated blood test that can predict DKD up to four years before clinical symptoms appear, supporting doctors in making earlier, informed treatment decisions to improve outcomes for patients with 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. 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.
Probability (P)	The P 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).

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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

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² doi.org/10.1111/imj.70275

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

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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