



# Proteomics International

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## International study validates breakthrough predictive test for diabetic kidney disease

### Highlights

- Predictive test for diabetic kidney disease successfully validated in major clinical study
- PromarkerD is the world's first and only predictive test for diabetic kidney disease to receive European CE Mark registration
- Innovative test could save healthcare systems billions of dollars globally
- Results of analysis conducted on 3,000 patients from a completed multi-centre clinical trial (the CANVAS study) presented today at the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA)
- Data confirms previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance
- There are 463 million adults living globally with diabetes, with 1 in 3 having diabetic kidney disease

A global multi-centre study of 3,000 people has confirmed the effectiveness of an innovative predictive test for diabetic kidney disease – a breakthrough which could save healthcare systems billions of dollars by identifying at-risk individuals for earlier therapeutic intervention.

The findings were presented today at the world's leading diabetes conference, the 80<sup>th</sup> Scientific Sessions of the American Diabetes Association (ADA).

Perth/Australian-based Proteomics International Laboratories Ltd has developed a simple blood test that uses a unique protein 'fingerprint' to provide early detection of kidney disease in patients with type 2 diabetes.

The International Diabetes Federation estimates there are 463 million adults living with diabetes globally, with the annual cost of diabetic kidney disease estimated at USD50 billion per year in the United States of America alone.

Proteomics International Managing Director Dr Richard Lipscombe said that being able to correctly predict an early decline in kidney function meant that doctors and patients could take action to prevent patients going on to costly dialysis or eventually facing the prospect of kidney transplant.

"This technology has the ability to improve the lives of the 31 million Americans living with diabetes," Dr Lipscombe said.

"If patients know they're on the path to diabetic kidney disease, they can intervene sooner to treat the condition."

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The study applied the PromarkerD test system to patient samples from the CANVAS completed phase 3 clinical trial. The retrospective analysis of blood samples from the completed clinical trial showed that patients predicted by PromarkerD to be at high-risk of chronic kidney disease were 13.5 times more likely than the low-risk group to develop the disease, with the results showing high statistical significance ( $P = 1.3 \times 10^{-104}$ ).

Importantly, the current data confirms previous findings that PromarkerD is able to correctly predict a clinically significant decline in kidney function up to four years in advance.

Dr Lipscombe said the results were far-reaching for the commercial roll-out of the test because they substantiated the effectiveness of PromarkerD as a prognostic test for diabetic kidney disease in a globally recognised clinical cohort.

“These results show that PromarkerD works, it’s safe, and it can be run by accredited laboratories now as a laboratory developed test (LDT),” he said.

“This is really a green light for using this simple blood test globally.”

Proteomics International is now focused on partnering discussions with suitable organisations to bring PromarkerD to patients in the USA. The result also paves the way for future FDA approval of the test and complements the recent successful CE Mark registration of the new PromarkerD immunoassay in the European Union.

Further research is now being undertaken to determine whether patients display an improved prognosis after treatment, in the form of a lower PromarkerD risk score. This is a complex process, requiring extensive analysis of the large clinical data set.

The ADA’s 80<sup>th</sup> Scientific Sessions run from June 12 to 16. This year the conference has been restructured as a virtual experience.

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#### **About PromarkerD ([www.PromarkerD.com](http://www.PromarkerD.com))**

The PromarkerD test system assesses the risk of diabetic kidney disease (DKD) in patients with type 2 diabetes. Chronic kidney disease is one of the major complications arising from diabetes and if unchecked can lead to dialysis or kidney transplant. PromarkerD is a simple blood test that uses a unique protein ‘fingerprint’ to provide an early detection of the onset of disease. In clinical studies published in leading journals PromarkerD correctly predicted 86% of otherwise healthy diabetics who went on to develop chronic kidney disease within four years. The PromarkerD immunoassay, the PromarkerD mass spectrometry assay, and the PromarkerD software hub have each achieved CE Mark registration in the European Union.

Further information is available through the PromarkerD web portal.

[ADA poster presentation \(#1118-P\)](#) titled: ‘*Validation of the PromarkerD Test for Predicting Renal Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS)*’.

To visit the PromarkerD ADA virtual booth please click here: [www.PromarkerD.com/product](http://www.PromarkerD.com/product)

#### **About Proteomics International Laboratories (PILL) ([www.proteomicsinternational.com](http://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. It received the world’s first ISO 17025 laboratory accreditation for proteomics services and operates from state-of-the-art facilities located on Perth’s QEII Medical Campus.

Proteomics International's business model is centred on the commercialisation of the company's high-speed, low cost predictive test for diabetic kidney disease, PromarkerD. The company offsets

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the cash burn from R&D and product development through provision of specialist analytical services, while using its proprietary Promarker™ technology platform to create a pipeline of novel diagnostic tests.

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