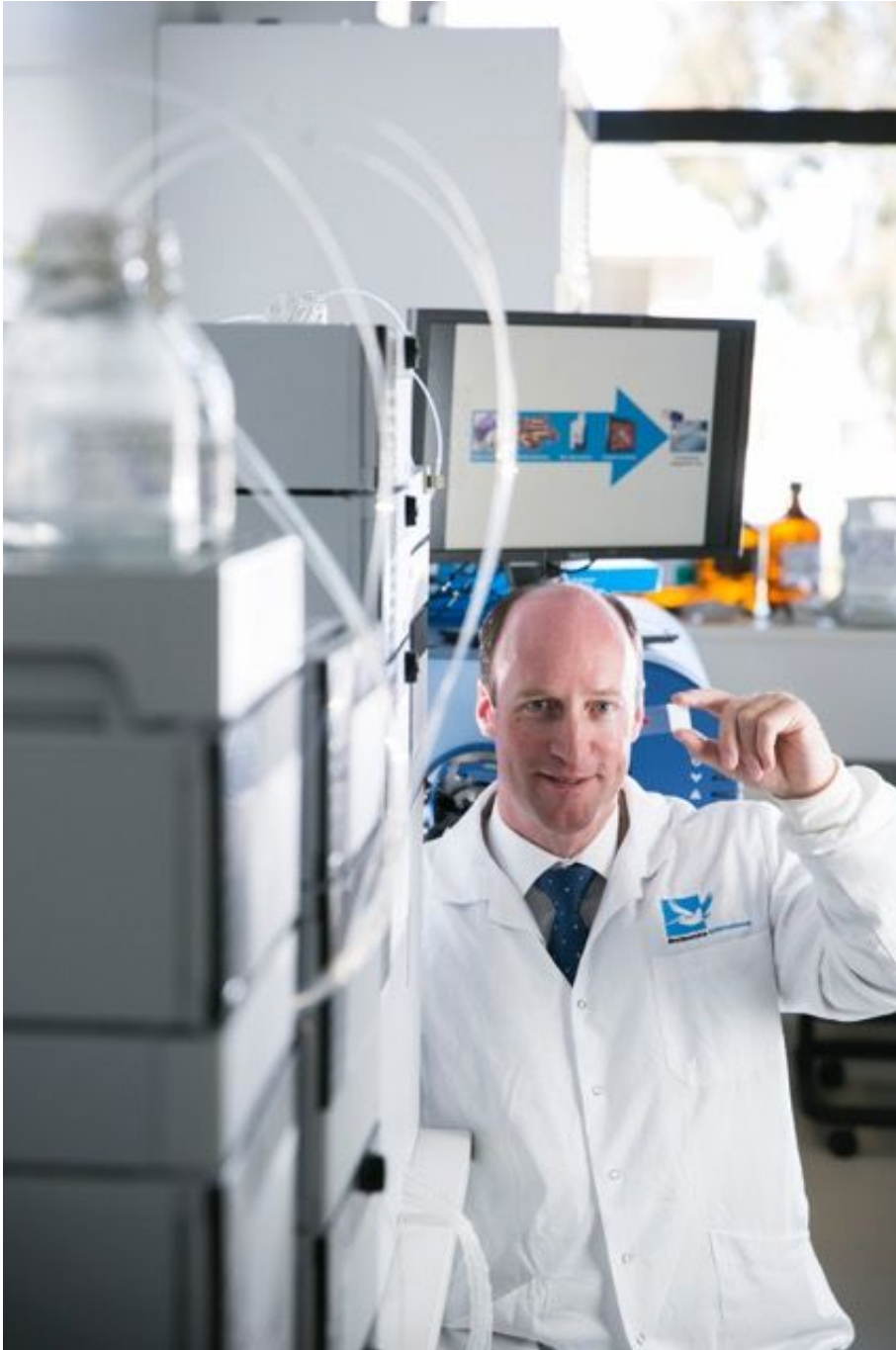# Clinical validation results confirm PromarkerD can predict diabetic kidney disease better than any current measure

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Managing Director Dr Richard Lipscombe in PILL Laboratories, Harry Perkins Institute of Medical Research, Perth, Western Australia. Credit: Proteomics International Laboratories

Proteomics International Laboratories Ltd. has announced results from the clinical validation study showing that its PromarkerD blood test can predict the onset of diabetic kidney disease (DKD) better than any current measure.

The findings were presented by Professor Tim Davis, from The University of Western Australia Medical School, at the American Diabetes Association's 77th Annual Scientific Sessions (ADA), 9-13th June, in San Diego, California. (ADA Abstract #2017-LB-7091-Diabetes)

The study, undertaken as a joint collaboration between Proteomics International and The University of Western Australia, is the largest prospective clinical study on diabetic kidney disease in the community and evaluated the clinical utility of PromarkerD with 792 patients.

In March, Frost & Sullivan identified PromarkerD as the world's leading test for diabetic kidney disease, and the new results confirm PromarkerD predicts rapid decline in kidney function in type 2 diabetes, across clinically significant definitions of disease, independently of recognised clinical risk factors.

According to the International Diabetes Federation, 415 million adults had diabetes in 2015. The US Center for Disease Control states that one in three adult diabetics have chronic kidney disease, or 138 million people today. Once detected, chronic kidney disease can be treated through medication and lifestyle changes to slow down the disease progression, and to prevent or delay the onset of kidney failure.

The International Diabetes Federation further predicts the number of diabetics will rise to 642 million by 2040, which, if unchecked, will increase the number of adults with chronic kidney disease by 76 million to 214 million. The current cost of dialysis is estimated at $100,000 per

person per year.

The validation study (assessing the performance of the prediction model in an independent population) confirms results from the original development study, also completed in collaboration with Professor Davis. Initial findings on the diagnostic performance of PromarkerD were published in the *European Journal of Proteomics* in March 2017.

In the four-year prospective study, the three protein marker (biomarker) blood test (PromarkerD) predicted 86 percent of previously disease-free patients who went on to develop chronic kidney disease (Sensitivity 86 percent, Specificity 78 percent, AUC 0.88). In comparison to the development study, the results from the larger validation study showed slightly lower levels of predictive ability (development 95 percent), however, it achieved a 10 percent improvement in levels of false positives.

Professor Davis concluded, "The data support the use of the protein biomarker panel in conjunction with eGFR (estimated glomerular filtration rate) in patients with type 2 diabetes to monitor and predict their decline in kidney function."

"This large clinical study validates the important role of the PromarkerD test to effectively monitor patients with diabetes," said Dr Richard Lipscombe, Managing Director of Proteomics International. "Although patients may appear to be adequately controlled for the complications of diabetes, current tests do not reveal early symptoms of kidney disease, which can result in the need for dialysis or kidney transplant."

The annual ADA Scientific Sessions are the world's largest and most prominent meeting of diabetes experts, attracting more than 13,000 delegates. The results were reported in the Late-breaking Abstracts section of the conference, titled "Novel Circulating Biomarkers

Predicting Rapidly Declining Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study." PILL's head of business development Chuck Morrison is also attending the event.

PromarkerD - a predictive diagnostic test for diabetic kidney disease

PromarkerD is a breakthrough [blood test](#) that uses a protein 'fingerprint' to measure kidney disease in patients with [diabetes](#). This ground-breaking test can both diagnose and predict disease. A published study in a peer-reviewed journal has shown that for diabetic patients already suffering from chronic kidney disease PromarkerD can diagnose the presence of disease that was missed by the current gold standard tests (known as the ACR and eGFR tests).

Critically, PromarkerD can also predict the onset of disease before clinical symptoms appear. In the current study 792 patients were followed in dual, four-year longitudinal clinical studies. PromarkerD correctly predicted 86 percent of the previously kidney [disease](#)-free diabetic [patients](#) who went on to develop [chronic kidney disease](#).

 More information: Biomarkers Enabling Diabetes and Obesity Management. www.proteomicsinternational.com/

Provided by Proteomics International Laboratories