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Positive results for PromarkerD

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SAN DIEGO—June saw Proteomics International Laboratories Ltd. present findings from a clinical validation study—undertaken as a joint collaboration between Proteomics International and the University of Western Australia—at the American Diabetes Association's 77th Annual Scientific Sessions showing that its PromarkerD blood test can predict the onset of diabetic kidney disease (DKD) better than any currently available method.

These findings, presented by Prof. Tim Davis of the University of Western Australia Medical School, confirm results from an original development study, also completed in collaboration with Davis.

PromarkerD is a blood test that uses a protein "fingerprint" to measure kidney disease in patients with diabetes, and it can be used to both diagnose and predict DKD. 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: the ACR and eGFR tests.

This four-year prospective study, which evaluated the clinical utility of PromarkerD with 792 patients, is the largest prospective clinical study on diabetic kidney disease to date. Throughout the course of the study, the PromarkerD predicted 86 percent of previously disease-free patients who went on to develop chronic kidney disease. In comparison to the development study, the results from the larger validation study showed slightly lower levels of predictive ability; however, it achieved a 10-percent improvement in levels of false positives. Initial findings on the diagnostic performance of PromarkerD were published in the *European Journal of Proteomics* in March 2017.

In March, a Frost & Sullivan report titled "Biomarkers Enabling Diabetes and Obesity Management" identified PromarkerD as the world's leading test for diabetic kidney disease, and the new results confirm that PromarkerD predicts rapid decline in kidney function in type 2 diabetes, across clinically significant definitions of disease, independently of recognized clinical risk factors.

Proteomics International's DKD patents have been granted in the United States, Australia, Russia, Singapore and China, covering a potential market size of 153 million adult diabetics. Patents are pending in Brazil, Canada, Indonesia, India, Japan and Europe that, if granted, will cover an additional 151 million diabetics. In total, this represents 304 million of the world's estimated 415 million people with diabetes.

Currently there are no drugs specifically for DKD, but the pharmaceutical industry is trying to change this with more than 20 drugs in late-stage clinical trials right now. By monitoring diabetics using PromarkerD, high-risk patients could be put on these medications immediately before serious symptoms appear, and those with moderate risk could be more frequently monitored. In addition, low-risk patients could be managed for diabetes alone rather than being medicated as a precaution, which is a current practice due to the lack of sensitive diagnostic tests.

Further clinical studies are also being considered to apply PromarkerD to the prediction of any form of kidney disease and as an endpoint marker in clinical trials for any new drug, given that kidney toxicity is a common concern for investigational drugs. The Promarker platform is being used to develop diagnostics tests for other diseases such as endometriosis, mesothelioma and to detect the gastro-causing parasite *Giardia*.

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Lipscombe tells *DDNews* the next step is bringing the test to market through clinical pathology laboratories as an *in-vitro* diagnostic (IVD), as a laboratory-developed test and as a companion diagnostic. Proteomics is currently in discussion with pathology laboratories and diagnostic companies in the United States, Central America, China, Japan and Australia for the commercial use of PromarkerD as an IVD, with several entities in the United States and Europe for the rollout of PromarkerD in CLIA-certified clinical laboratories that are targeting new technology platforms for diagnostics and with various pharmaceutical companies for the use of PromarkerD as a companion diagnostic test used to aid patient stratification and potentially identify patients for whom a drug will or will not work.

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