



# Proteomics International

LABORATORIES LTD

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## PromarkerD manufacturing tech-transfer completed - Successful production of components for over 50,000 tests

- **Specialist manufacturer Biotem produces key components for more than 50,000 PromarkerD tests**
- **Pilot batch is a significant milestone in transfer of technology needed for large-scale global distribution**
- **Increased production capacity will allow Proteomics International to meet anticipated demand for PromarkerD in the Northern Hemisphere**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) has successfully produced a pilot batch of PromarkerD test components with specialist immunoassay manufacturer Biotem. Working closely with Proteomics International, Biotem has completed the transfer of the manufacturing process and produced key components to assemble over 50,000 tests for predicting the onset of diabetic kidney disease.

Proteomics International managing director Dr Richard Lipscombe said the pilot production run was a significant step in demonstrating the technology transfer required for large-scale global distribution. *“Working with a specialist manufacturer like Biotem allows us to build our production capacity to meet the anticipated demand for PromarkerD in the Northern Hemisphere and worldwide,”* he said.

Proteomics International contracted Biotem to manufacture the immunoassay kit version of PromarkerD last year [ASX: 12 August 2021]. The test identifies a unique 'fingerprint' of protein biomarkers in the blood using specialist reagents (antibodies) developed by Proteomics International and produced by global life science company Abcam [ASX: 28 July 2021].

Both Proteomics International and Biotem have ISO 13485 certification—allowing Proteomics International to extend its regulatory approvals across additional jurisdictions. Prospective partners and licensees can also have confidence that PromarkerD can be manufactured in high volumes and to international regulatory standards. These 50,000 tests have been manufactured for quality control and regulatory testing but will form part of inventory for initial sales.

Dr Lipscombe said, *“Proteomics International was building a robust manufacturing framework that could be applied to the Company’s other diagnostics under development, including tests for endometriosis and asthma. This successful technology transfer will help accelerate the worldwide roll-out of PromarkerD, as well as the commercialisation of our pipeline of novel diagnostics.”*

Authorised by the Board of Proteomics International Laboratories Ltd (ASX.PIQ).

ENDS

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

Diabetic 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 simple blood test to detect a unique ‘fingerprint’ of the early onset of the disease by measuring three serum protein biomarkers, combined with three routinely available conventional clinical variables (age, HDL-cholesterol and estimated glomerular filtration rate (eGFR)). 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. The PromarkerD test is CE Mark registered in the European Union.

Further information is available through the PromarkerD web portal.

To visit the PromarkerD virtual booth please see: [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. 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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