



**Proteomics International**

LABORATORIES LTD

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## **Major milestone achieved as CPT PLA reimbursement code approved in the United States for PromarkerD**

- **American Medical Association (AMA) approves US reimbursement code (CPT® Proprietary Laboratory Analyses [PLA] code) for PromarkerD test for diabetic kidney disease**
- **Securing a new dedicated CPT PLA code is a major milestone and key to reimbursement coverage of the test by both Medicare and private health insurers in the US**
- **Approximately 32 million adults, or 11 per cent of the population, are living with diabetes in the United States**
- **Newly-approved dedicated CPT PLA code has been published by the AMA and will take effect from 1 April 2023**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ) is pleased to announce the achievement of a major milestone in the commercialisation of the PromarkerD predictive test for diabetic kidney disease with the approval of a new dedicated CPT® Proprietary Laboratory Analyses (PLA) code for the test in the United States.

The CPT PLA code—issued by the American Medical Association—is key to PromarkerD reimbursement being covered by both Medicare and private health insurers in the US, and hugely important for enabling affordable access and broad adoption of the test.

Proteomics International Managing Director Dr Richard Lipscombe said the approval of a distinct CPT PLA code for PromarkerD was extremely significant in the commercialisation of the test in the United States.

*“We’re delighted to announce this important step in the efforts to secure reimbursement for PromarkerD with our partner Sonic Healthcare USA [ASX: 9 August 2022]. It’s a substantial accomplishment that will minimise barriers to access and could enable millions more Americans with diabetes to have this potentially life-changing test.”*

In the United States an estimated 32 million people, or 11 per cent of the population, live with diabetes<sup>1</sup>. The total cost of diabetic kidney disease is USD 130 billion per year in the US alone<sup>2</sup>, according to the US Renal Data System.

The newly-approved code for PromarkerD (0385U) has been published and will be effective from 1 April 2023<sup>3</sup>. The PLA code was issued to Sonic Reference Laboratory, a CLIA certified, CAP and ISO 15189 accredited reference laboratory which is part of Sonic Healthcare USA (a division of Sonic Healthcare Limited; ASX: SHL).

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<sup>1</sup> International Diabetes Federation Diabetes Atlas 10th edition, 2021

<sup>2</sup> US Renal Data System 2020

<sup>3</sup> [www.ama-assn.org/practice-management/cpt/cpt-pla-codes](http://www.ama-assn.org/practice-management/cpt/cpt-pla-codes)

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CPT®, or Current Procedural Terminology, codes are widely used across the US to report medical procedures and services under public and private health insurance programs. The issuing of CPT PLA codes is done under a rigorous and open process that ensures codes that accurately reflect current clinical practice and innovation in medicine. A CPT PLA code uniquely identifies a test for the testing laboratory, enabling healthcare providers to order the test, facilitates a billing pathway for payers, and permits monitoring of test usage.

Early diagnosis of diabetic kidney disease using PromarkerD can help inform doctors' treatment decisions to improve clinical outcomes for patients [ASX: 2 August 2022], and could drive improved therapeutic interventions [ASX 16 July and 11 August 2021]. Reducing or delaying the progression of the disease and consequently the incidence of dialysis and kidney transplant would result in significant cost savings for health care systems [ASX: 2 July 2021].

Dr Lipscombe said the next step was to work with private payers and engage with the Centers for Medicare & Medicaid Services (CMS) to establish payment and include PromarkerD in their Clinical Lab Fee Schedule.

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

ENDS

#### **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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