

ASX Release 30 October 2023

ASX code: PIQ

Investor Presentation

Proteomics International Laboratories Ltd (Proteomics International; the Company; ASX: PIQ) is pleased to release a copy of its latest investor presentation for a non-deal roadshow to institutional investors.

Authorised by Dr Richard Lipscombe (Managing Director) and Mr Neville Gardiner (Non-Executive Chairman) on behalf of the Board of PIQ.

ENDS

About Proteomics International Laboratories (PILL) (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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Proteomics International Laboratories Ltd



A medical technology company at the forefront of precision medicine and predictive diagnostics

Three key focus tests driven by a proprietary platform technology:



Diabetic Kidney Disease

COMMERCIALISATION



Endometriosis

DEVELOPMENT



Esophageal Cancer

DEVELOPMENT

- Proven predictive test for early detection of diabetic kidney disease (DKD)
- Being commercialised & launched in the US by Sonic Healthcare USA
- US\$390 indicative test price & PIQ receives royalty for each test sold
- Test in development to diagnose Endometriosis
- Affects 1 in 9 women and costs Australia alone over AU\$10 billion a year
- Prototype test identified up to 90% of patients with the disease
- Test in development to diagnose Esophageal Cancer
- 1 in 20 cancer deaths worldwide due to oesophageal cancer
- Prototype test identified up to 90% of patients with the disease

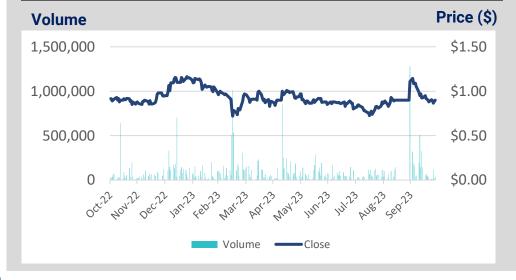
Corporate Overview



Corporate Snapshot	
ASX code	PIQ
Market Capitalisation	A\$110m
Cash (30 Sept '23 + ~\$1.8m R&D tax incentive due Q4 CY23)	\$4.9m

Share Price	A\$0.90
Shares on issue (+1.4m options)	122m

Revenue & other income – FY23	A\$3.3m
Average Quarterly cash burn – FY23	A\$1.55m



Financial and Corporate

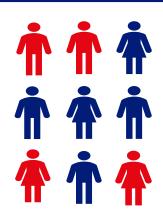
- Top 40 Shareholders hold 49%
- Directors are highly aligned with shareholders holding 18%
- Multiple institutional & family office shareholders on the register
- State-of-the-art laboratories
 - Accredited (ISO 17025 and ISO 13485) cutting-edge facility
 - Specialist proteomics technology platform
 - Analytical services pharmacokinetic (PK) testing & biosimilars
 - Headquartered on QEII Medical Campus, Perth, WA
- Revenue generating
 - Bioanalytical service business helps offset cash burn
 - Current revenue does not include any major sales of PromarkerD

Promarker - Platform Technology





PromarkerTM is a platform technology that can identify unique protein biomarkers 'fingerprints'

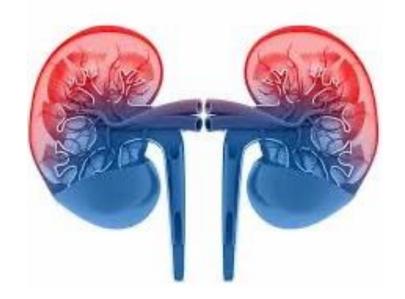


The platform identifies and links the unique protein biomarkers to specific diseases, enabling Proteomics International to create novel diagnostic tests

Promarker D

PROACTIVELY CHANGING RENAL HEALTHCARE

A simple blood test for predicting diabetic kidney disease



Problem and Solution - Diabetic Kidney Disease





The Problem

- 537 million adults with diabetes globally
- 1-in-3 with diabetes have chronic kidney disease
- Kidney disease is a silent killer kidney function can fall below 15-20% with no symptoms
- Damage to kidneys is irreversible, therefore early detection is paramount
- Diabetic kidney disease leads to renal failure which requires dialysis (US\$72,000 p.a.) or kidney transplant
- Total cost of diabetic kidney disease = US\$130 Bn per year in USA alone



Current standard-of-care diagnostics

- Existing tests (known as eGFR and ACR) can only detect chronic kidney disease once it is already present
- Current standard-of-care tests cannot predict the onset of diabetic kidney disease
- If unchecked, patients ultimately require dialysis and/or a kidney transplant



Diseased Kidney



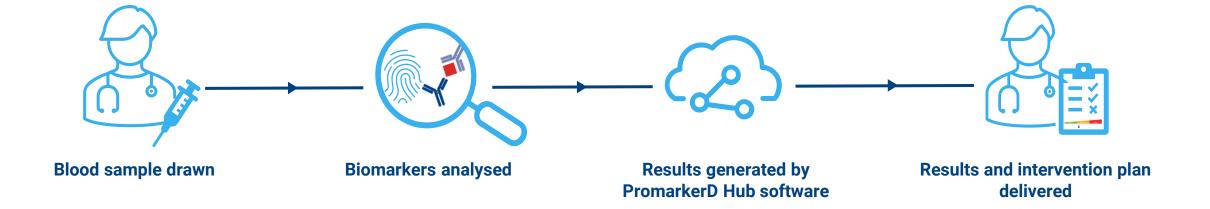
Promarker D

- PromarkerD can predict the onset of disease before clinical symptoms appear (up to four years prior)
- Doctors can then prescribe an early therapeutic treatment to slow or stop the onset of disease
- Kidneys remain healthier for longer, saving healthcare systems billions of dollars and improving quality of life for patients



PromarkerD - Simple Integration & Use





Sample is drawn at clinic or pathology laboratory

Laboratory uses a standard technology platform

Advanced rapid immunoassay measures three plasma proteins -

combined with three simple clinical factors (age, cholesterol, eGFR)

CE Mark registered

Manufactured to ISO 13485 standard in Europe

Cloud based algorithm, the "PromarkerD Hub" calculates the patient's kidney disease risk score

Employs a traffic light system for optimal performance, classifies patients as:

- low risk
- moderate risk
- high risk

Clinician delivers results to patient

Depending on results, intervention may include:

- · change of lifestyle; and/or
- therapeutic drugs
 - > SGLT2-inhibitor
 - ➤ GLP-1 angonist

PromarkerD in the Clinic





Peer Reviewed



Physician Support



Outperforms Standard of Care

PromarkerD tested on **over 5,000 patients** in 4-year clinical studies

10+ Peer Reviewed Publications

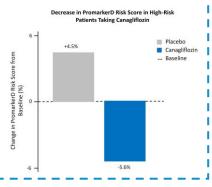
World leading results: Janssen

- Global clinical study 3,568 participants from completed CANVAS clinical trial
- PromarkerD predicted 'incident DKD' highrisk patients **13.5 times more likely** than lowrisk to develop DKD (P = $1.3x10^{-104}$)

[J. Clin. Med. (2020)]

PromarkerD
 high-risk
 patients show
 greatest benefit
 from early use of
 SGLT2-inhibitor

[J. Clin. Med. (2023)]

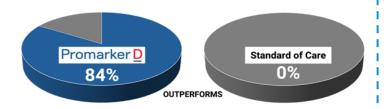


Survey of 400 Endocrinologists & Primary Care Physicians (US based)

- 96% of physicians were likely to use PromarkerD test scores for clinical decision-making
- PromarkerD consistently ranked as one of the top 2 factors driving physician decision-making:
 - monitoring frequency
 - use of anti-inflammatories
 - prescribing SGLT2s
 - ACE inhibitor dosing

[AMCP Nexus (2021)]

- 857 community based patients tested for existing DKD at baseline: 497 had normal kidney function
- 9% of patients developed DKD within 4 years:
 - PromarkerD accurately predicted 84% (N=38)
 - All were missed by Standard of care tests [ASN (2021)]



PromarkerD compared to standard of care tests (eGFR and ACR) for predicting DKD

PromarkerD Patented in all Major Markets



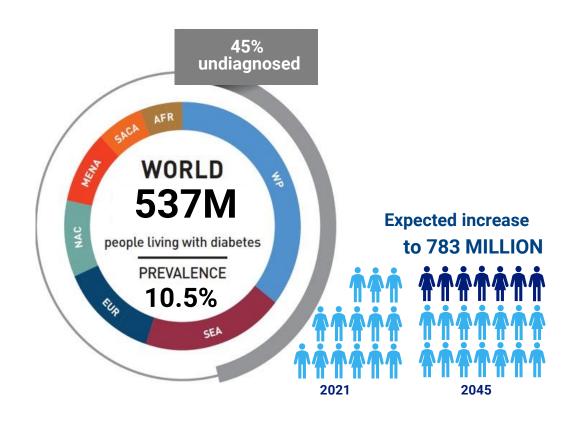
Diabetic Kidney Disease is becoming one of the largest burdens on healthcare systems globally

Patent family & Trademark covers 72% of world's diabetics¹

Country	Patent/Application No	Patent Status	No. Diabetics ¹
Australia	2011305050	Granted	1,491,800
Brazil	BR112013006740	Granted	15,733,600
Canada	2811654	Granted	2,974,000
China	ZL201180053583.9	Granted	140,869,600
Europe ^{2,3}	3151012	Granted	61,425,100
Hong Kong	18115912.3	Granted	686,000
India	3012/DELNP/2013	Granted	74,194,700
Indonesia	W00 2013 01585	Granted	19,465,100
Japan	2013-528474	Granted	11,005,000
Russia	2596486	Granted	7,392,100
Singapore	188527	Granted	711,800
USA ^{2,4}	US 9,146,243	Granted	32,215,300

~368 million Total

- 1. International Diabetes Federation (IDF) Atlas 10th Edition 2021 [Age group 20-79 years]
- 2. Australia, Europe, HK, USA patent family also covers testing for any form of kidney disease (Extra efficacy studies required)
- 3. Covers France, Germany, Italy, Spain, Turkey and the United Kingdom
- 4. USA patent further extended to cover method for identifying drugs for abnormal kidney function using one of the PromarkerD biomarkers (CD5L)



Market assumptions

- Test is performed once per year per patient on average
- Standard industry royalty rates range from 5-15%

United States: Commercialisation in Progress



Sonic Healthcare USA has the exclusive licence to commercialise PromarkerD in the world's largest healthcare market



Over 7,000 Employees
Over 300 Sales reps
Over 400 pathologists
Services over 20 million patients





Sonic is the <u>third</u> Largest laboratory medicine company in the US



Test listed on Sonic website & commercial launch expected in Q1 CY24



Sonic has labs spanning from Hawaii to Boston



Reimbursement Underway

Apr 2023



Proteomics International has been working with its partner Sonic Healthcare USA on reimbursement in the US

CMS is the federal agency in the United States that administers Medicare and Medicaid

Medicare and Medicaid collectively responsible for 42% of healthcare spending in the US

CMS has assigned a payment rate of US\$390.75 for PromarkerD

Jun 2023

Oct 2023

CMS is responsible for providing healthcare coverage to more than 100m Americans

Jan 2024

US Reimbursement Timeline Unique CPT Centers for Medicare and CMS proposed CMS Clinical Lab American Clinical Lab CMS pricing **Proprietary Laboratory** Medicaid Services (CMS) pricing of Association engaged by Fee Schedule effective for Analysis (PLA) code US\$390.75 for posts updated code list SHUSA to consider (CLFS) Annual **PromarkerD** approved PromarkerD Meeting to consider crosswalk or gapfill PLA code (0385U) for pricing pricing PromarkerD effective

May 2023

Jan 2023

Target Markets:





- Licence with Apacor Ltd for immunoassay test
- Test registered with Medicines & Healthcare products Regulatory Agency
- National Institute for Health & Care Excellence (NICE)
 Medtech Innovation Briefing "NICE Advice" published



- Licence with Omics Global Solutions for immunoassay (Innovatio ND2) in Puerto Rico & Dominican Republic
- Test registered with Ministry of Health
- First sales commenced



Israel

0.6m T2 diabetics

- Licence with Zotal Ltd for immunoassay test
- Product registration on-hold pending regulatory approval and first sales globally



Detailed market assessments completed

Next Steps

- Engagement with the NHS Supply Chain Tender
- PromarkerD inclusion in the NICE guidelines
- MIB are looked at by the broader healthcare industry and allow for positive engagement with private healthcare providers

Next Steps

- Securing public reimbursement
- Expanding uptake of the test through engagement with primary care physicians
- Exploring additional sales to neighbouring territories

Next Steps

Engaged with Zotal to initiate product registration and promote KOL awareness

Next Steps

Actively targeting potential partners in key jurisdictions

Pipeline of Precision Diagnostics

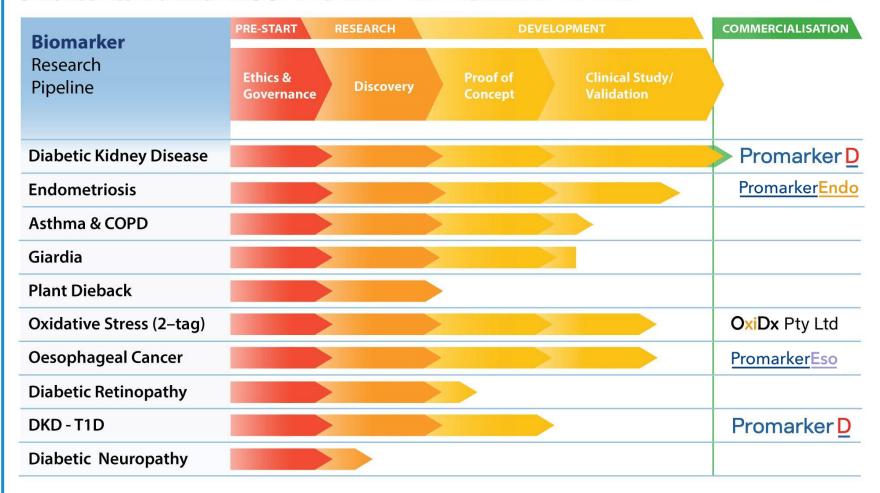


Platform technology drives deep pipeline of novel diagnostic tests

Further global potential in new markets

- Promarker[™] platform develops novel intellectual property
- Targeting new diagnostic tests in areas of significant unmet need
- Enormous markets and revenue potential

DIAGNOSTICS RESEARCH AND DEVELOPMENT – THE PROMARKER™ PIPELINE



Dx Pipeline: Endometriosis & Oesophageal Cancer



Proteomics International has two potential world-first blood tests in late-stage development

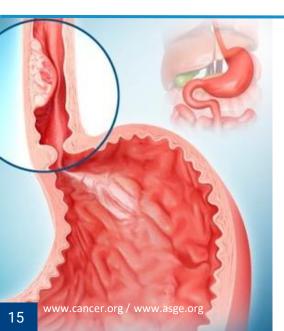
Impact of Endometriosis

- Endometriosis is a common and painful disease where uterus tissue grows into other organs
- Currently diagnosis takes an average of 7.5 years and requires invasive surgery (laparoscopy)
- Affects 1 in 9 women and costs Australia over AU\$10 billion a year – global opportunity significantly higher

Promarker[™] for Endometriosis

- Prototype test identified up to 90% of patients with the disease (World Endometriosis Conference, May '23)
- Collaboration with Royal Women's Hospital & University of Melbourne analysed 901 patients
- Biomarkers identified via the Promarker[™] platform offer a potential world-first blood test for endometriosis
- Next steps: confirm clinical performance and clinical utility in additional cohorts





Impact of Oesophageal Cancer

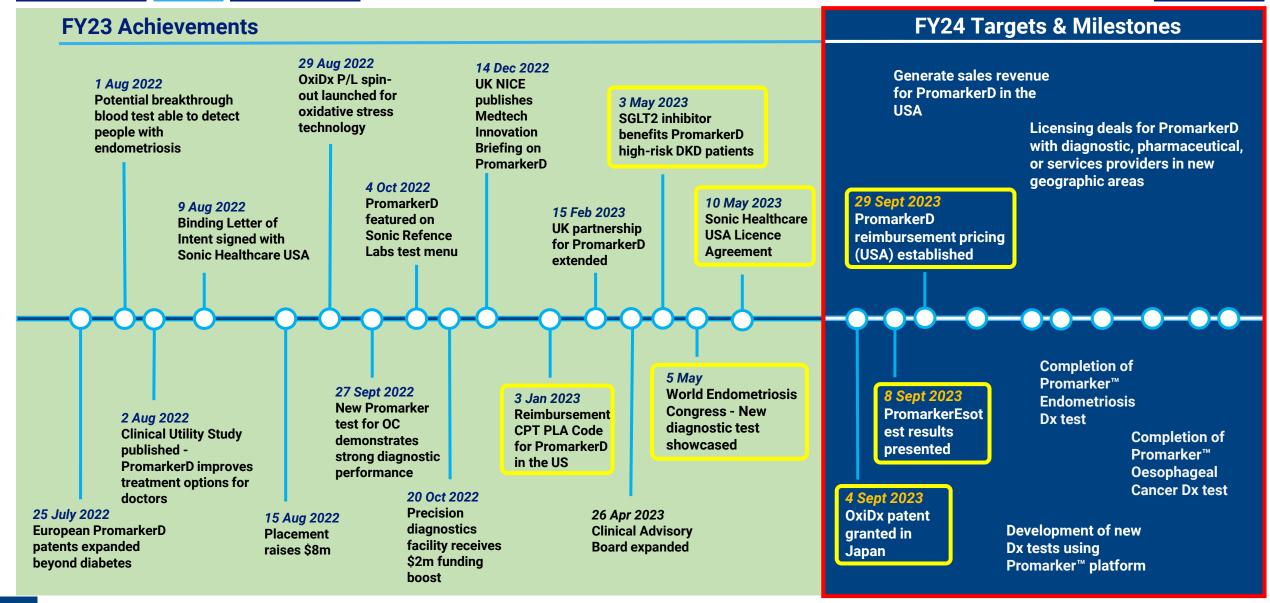
- 1 in 20 cancer deaths worldwide due to oesophageal cancer - 5 year survival rate < 20%
- Currently diagnosis requires a specialist endoscopy procedure; treating the disease cost \$2.9bn in USA in 2018
- Test targets oesophageal adenocarcinoma and Barrett's esophagus (pre-malignant) which affects 1-2% of adults and can arise from chronic acid reflux

Promarker[™] for Oesophageal Cancer and Barrett's esophagus

- Prototype test identified 90% of people with & without the disease (World Congress Esophageal Diseases, Sept '23)
- Collaboration with QIMR Berghofer Medical Research Institute analysed 302 samples;
- Results indicate a potential world-first blood test to screen for oesophageal cancer
- Next steps: confirm clinical performance and clinical utility in additional cohorts

Timeline & Milestones





Value Inflection Points



Exceptional Global Opportunity

- Disruptive, cutting-edge technology & proven in-house diagnostics platform
- PromarkerD test de-risked, patented, revenue ready
- Test rolling-out in easy-to-use, scalable, low cost format with high margins
- Whole of market appeal: pharma, clinical pathology labs, diagnostic platform developers, diabetes service providers, physicians and patients
- Deep pipeline of potential globally significant tests in development
- Vibrant corporate activity in the precision medicine, diagnostics and CRO (clinical trials) sectors

Share Price Catalysts throughout FY24

Milestone	Qtr	Dec	Mar	Jun	Impact	
PromarkerD						
First Sales in USA					Initiate pathway to significant revenues	
CMS Reimbursement Pricing Set					Supports broad adoption of test	
Regulatory Submissions, Approvals Reimbursement RoW	&				Build user confidence in product & assist in global roll-out	
Licensing Deals in RoW					Drive global uptake and future revenue	
Promarker™	Promarker™					
Endometriosis Dx – update					New first-in-class diagnostic test	
Oesophageal Cancer Dx - update					New first-in-class diagnostic test	
Diagnostics Pipeline Updates					New IP (validation & proof of concept results)	
Analytical Services						
New Contracts					Engages potential future partners & enhances revenue profile	

Peer Comparison



		Stock Code	Company Focus	Market Capitalisation	Share Price	FY23 Revenue	FY23 Net Profit/Loss
Proteomics International LABORATORIES LTD	Proteomics International Laboratories	PIQ.ASX	Predictive blood test measuring novel protein biomarkers for DKD; simple, cost effective, commercial ready. Pipeline of novel diagnostic tests in development for chronic diseases.	A\$110m	A\$0.90	A\$0.7m	(-A\$6.2m)
INOVIQ	Innoviq Ltd	IIQ.ASX	Early stage in-licensed IP for various cancer diagnostics.	A\$55m	A\$0.60	A\$0.4m	(-A\$9.2m)
Lucid diagnostics	Lucid Diagnostics Inc	LUCD.US	Cancer prevention medical diagnostics company with a DNA test (via LDT) for oesophageal cancer.	A\$85m	USD\$1.29	A\$0.4m 31/12/22	(-A\$88m) 31/12/22
renal)tix al	Renalytix Al	RENX.LSE RNLX.US	DKD test based on AI and predictive blood-based biomarkers, genetic factors and electronic health records. Expensive (US\$950 p/test), non-mass market.	A \$75m	GBP£0.40	A\$5.4m	(-A\$72m)
RHYTHM BIOSCIENCES	Rhythm Biosciences	RHY.ASX	Pre-commercialisation proteomics derived diagnostic test for colon cancer licensed from CSIRO.	A\$40m	A\$0.18	Nil	(-A\$8.2m)
CLARITY PHARMACEUTICALS	Clarity Pharmaceuticals	CU6.ASX	Clinical stage radiopharmaceutical company focused on the diagnosis & treatment of serious disease.	A\$274m	A\$1.05	Nil	(-A\$24m)

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Supplemental



Board of Directors





Neville Gardiner BBus (Accounting and Business Law) (Curtin), Non-Executive Chair

Seasoned finance professional with over 30 years' experience providing corporate advice to Boards of public and private companies. He was Co-Founder and MD of Torridon Partners, an independent corporate advisory firm, which was acquired by Deloitte in 2016, where he became Partner in their M&A Advisory team.



Dr Richard Lipscombe PhD (London), MA (Oxon), Co-Founder & Managing Director

Led the Company from foundation through listing in 2015 to today. 30 years biotechnology experience in R&D and product commercialisation in academic and commercial entities. Technical expertise in chemistry, immunology, biomarker discovery & clinical proteomics.



Roger Moore R (Denmark), BPharm (U.Syd), Non-Executive Director

International pharmaceutical industry experience spanning 40 years, including almost 30 years as President of Novo Nordisk Japan. From 2000, he was appointed Novo Nordisk's Senior Vice President, Japan & Oceania Region. He has also served as a member of the Senior Management Board, Novo Nordisk A/S.



Paul House GAICD, BCommerce (UWA), Non-Executive Director

Over 25 years with multi-national corporations, CEO of Imdex (ASX:IMD), prior role as MD of SGS India for 8 years. Previously held CFO and COO roles, and was Senior Manager at a leading global management consultancy firm.



Dr Robyn Elliott PhD Inorganic Chemistry (Monash), BSc(Hons) Chemistry (Monash), Non-Executive Director

Proven track record in product development, clinical trials, regulatory affairs, audits, quality management, project management and operational strategy. Dr Elliott is Executive Director, Strategic Fractionation Program Delivery at CSL Behring, a subsidiary of CSL Limited. She is also a non-executive director of PolyNovo Limited (ASX:PNV).

PromarkerD: World Class Advisory Board



Proteomics International is supported by an international, highly acclaimed advisory board

Professor Tim Davis MedSc, MB, W.Aust., DPhil Oxf., FRACP, MRCP (UK) – *Australia*

Consultant physician and endocrinologist, Fremantle Hospital, Professor of Medicine, University of Western Australia; WA Health Department's Diabetes & Endocrinology Clinical Network Co-lead



Dr Ele Ferrannini MD – *Italy*

Professor of medicine, The University of Pisa Adjunct Clinical Professor of Medicine, University of Texas Health Science Center: Senior research associate, National Research Council's Institute of Clinical Physiology



Ms Davida F. Kruger MSN, APN-BC, BC-ADM

- United States

Certified Nurse Practitioner, Henry Ford Health Past Chair of the American Diabetes Association's (ADA) Research Foundation; ADA Educator of the Year (2017)



Dr Joshua Neumiller PharmD, CDCES, FASCP, FADCES

- United States

Professor of Pharmacotherapy, Washington State University Recipient of Albert B. Prescott Pharmacy Leadership Award (2016) ADCES Diabetes Care & Education Specialist of the Year (2021)



Associate Professor Michael Shanik MD, FACP, FACE

- United States

Managing partner at Endocrine Associates of Long Island, PC Clinical Associate Professor, Stony Brook University Hospital, New York



Dr Neil Skolnik MD - United States

Professor of Family and Community Medicine, Sidney Kimmel Medical College, Thomas Jefferson University Associate Director, Family Medicine Residency Program Jefferson Health



Professor Merlin Thomas MBChB, PhD, FRACP,

FAAHMS - Australia

Nephrologist, scientist and program leader, the Department of Diabetes, Monash University Founder and Chief Scientific Officer, RAGE Biotech Ltd



Dr Alexander Turchin MD, MS – *United States*

Director of quality for the division of endocrinology, Brigham and Women's Hospital, Boston Associate Professor of Medicine, Harvard Medical School Fellow of the American College of Medical Informatics



Ms Hope Warshaw MMSc, RD, CDCES, BC-ADM,

FADCES - United States

Registered Dietician, Certified Diabetes Care and Education Specialist President of the ADCES 2016 & Chair of the Academy's Foundation 2022-2023



PromarkerD - Results & Intervention



How PromarkerD results are delivered LOW RISK MODERATE RISK HIGH RISK RISK SCORE % 0 10 20 100 Prognostic 16% indicates a moderate risk of decline in kidney function*

Risk Score	Intervention	Testing Regimen	
Low Risk	Standard diabetes management	Test Annually	
Moderate Risk	 More frequent monitoring Optimisation of lifestyle Review of glycemic targets and management Review non-glycemic risk factors Avoidance of potentially nephrotoxic drugs 	Test every 6 months	
High Risk	 Very close monitoring Intensive management strategies based on those for 'Moderate risk' above Utilisation of therapeutic drugs 	Test every 3 months	

^{*}as defined by incident diabetic kidney disease (eGFR <60ml/min/1.73m²) in the next four years. Note: if eGFR level at the time of the test is already <60ml/min/1.73m², then the risk of a further decline in kidney function is defined as an eGFR decline >30% in the next four years

New Treatments to Slow DKD



US\$7bn of sales in 2020 from the gliflozin class of type 2 diabetes drugs (SGLT2-inhibitors

PromarkerD has the potential to become a new standard of care and change clinical practice

Janssen collaboration assessed effect of SGLT2-inhibitor (gliflozin) vs placebo on PromarkerD risk scores

- Aim: Do 'at-risk' patients continue to decline, stabilize or recover?
- Method: Retrospective analysis of 2,008 patients from the CANVAS 4 year clinical trial:
- Results: Patients predicted at baseline by PromarkerD to be high-risk for developing DKD:
 - Treated with SGLT2i had significantly lower scores at Year 3 (Δ score: -5.6%; p<0.001)</p>
 - Patients on placebo remained high (Δ score: 4.5%; p=0.035) (Time*TRT p=0.002))
- Conclusion: SGLT2-inhibitors offer a potential treatment that can improve PromarkerD renal risk profile





Article

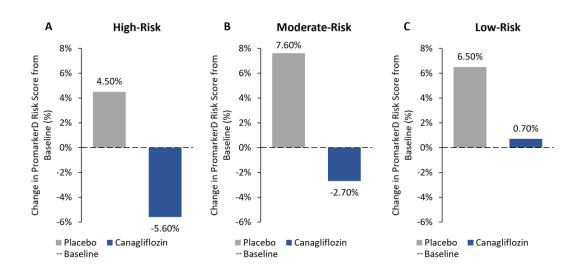
J. Clin. Med. 2023, 12, 3247. https://doi.org/10.3390/jcm12093247

Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Scores

Kirsten E. Peters ¹, Scott D. Bringans ¹, Ronan S. O'Neill ¹, Tasha S. C. Lumbantobing ¹, James K. C. Lui ¹, Timothy M. E. Davis ², ⁸, Michael K. Hansen ³ and Richard J. Lipscombe ¹

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(This article belongs to the Special Issue Editorial Board Member's Collection Series: Chronic Kidney Disease in Diabetes)



PromarkerD: Key Publications



PromarkerD Demonstrates Benefit of Early Treatment with SGLT2-inhibitors	Peters KE, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Score. J Clinical Medicine. <u>2023.</u>
Clinical Utility	Fusfeld L, et al. Evaluation of the clinical utility of the PromarkerD in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis. PLOS ONE. <u>2022.</u>
PromarkerD vs Standard of Care	Peters KE, et al. A Comparison of PromarkerD to Standard of Care Tests for Predicting Renal Decline in Type 2 Diabetes. Poster presented at ASN Kidney Week. <u>2021.</u>
Economic Health Benefit	Burchenal W, et al. Demonstrating the Economic Health Benefit of using the PromarkerD In Vitro Diagnostic Test in the Prediction of Diabetic Kidney Disease. Poster presented at the American Diabetes Association's 81st Scientific Sessions. 2021.
Global Multi-centre Validation	Peters KE, et al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Journal of Clinical Medicine. <u>2020.</u>
Predicts Late-stage Renal Function Decline	Peters KE, et al. PromarkerD Predicts Late-Stage Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). Poster presented at ADA. <u>2022.</u>
Prognostic Validation	Peters KE, et al. Validation of a Protein Biomarker Test for Predicting Renal Decline in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. J Diab Comp. <u>2019.</u>
Prognostic Development	Peters KE, et al. Identification of Novel Circulating Biomarkers Predicting Rapid Decline in Renal Function in Type 2 Diabetes: The Fremantle Diabetes Study Phase II. Diabetes Care. 2017.
Diagnostic Study	Bringans SD, et al. Comprehensive Mass Spectrometry Based Biomarker Discovery and Validation Platform as Applied to Diabetic Kidney Disease. EuPA Open Proteomics. <u>2017.</u>
Cross-platform Validation	Bringans SD, et al. The New and the Old: Platform Cross-Validation of Immunoaffinity MASS Spectrometry versus ELISA for PromarkerD, a Predictive Test for Diabetic Kidney Disease. Proteomes. <u>2020.</u>
Cross-over Validation	Bringans SD, et al. A Robust Multiplex Immunoaffinity Mass Spectrometry Assay (PromarkerD) for Clinical Prediction of Diabetic Kidney Disease. Clin Proteomics. <u>2020.</u>