



INVESTOR ROADSHOW PRESENTATION OCTOBER 2022

MiCheck[®] Prostate for **Detection of Aggressive Prostate Cancer**

Dr Brad Walsh, CEO



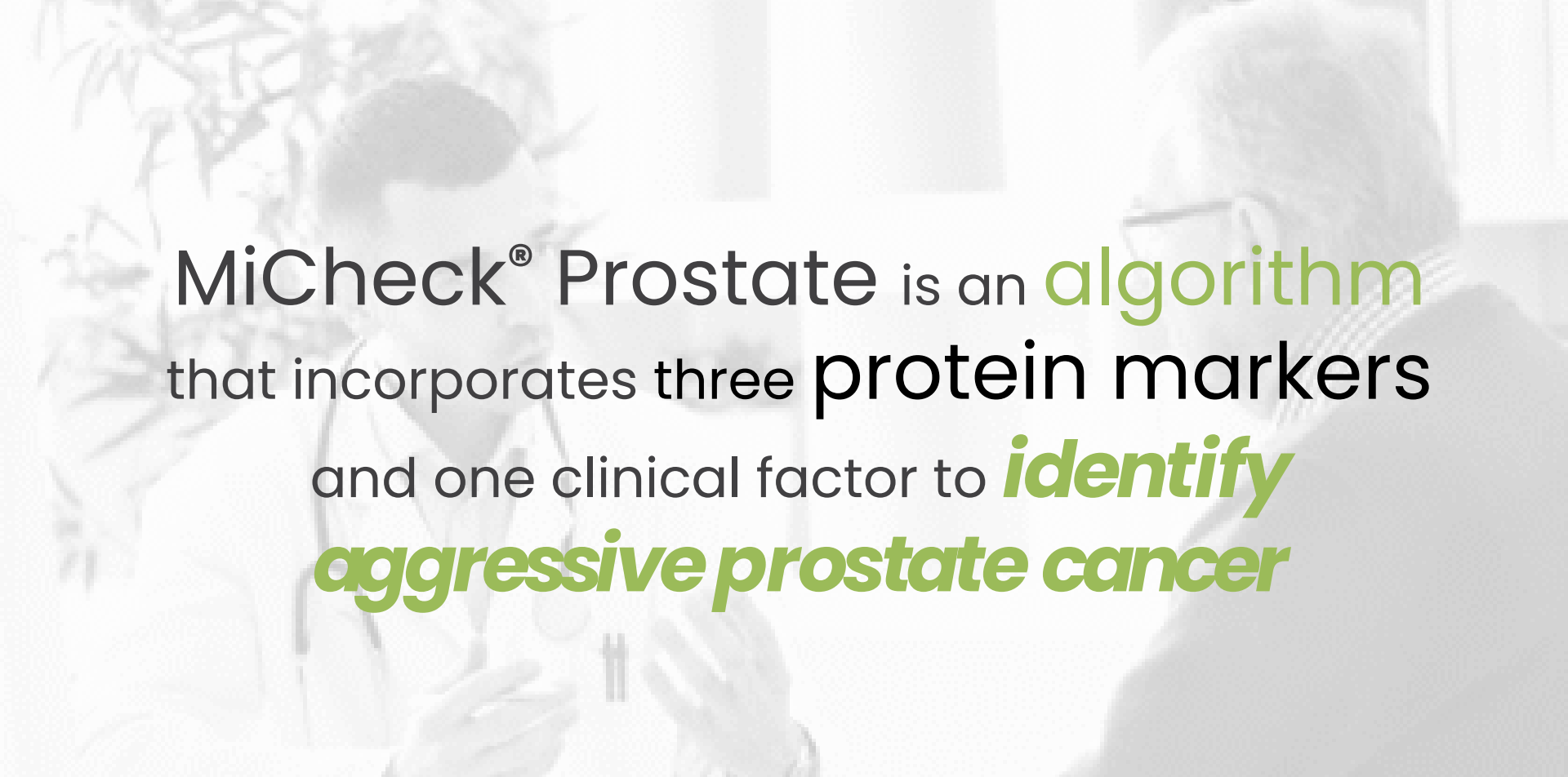
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MiCheck[®] Prostate is an **algorithm** that incorporates three **protein markers** and one clinical factor to **identify aggressive prostate cancer**

Executive Summary

Brief Company Overview

- Minomic International is a cancer-focused diagnostics company commercialising MiCheck Prostate®, a next-generation test for the detection of prostate cancer
- **MiCheck® Prostate is in revenue generation phase in the US and will be available in Australia imminently**
- MiCheck® Prostate can identify up to 95% aggressive cancers resulting in reduction of up to 50% of biopsies
- MiCheck® Prostate is simple to implement and integrates seamlessly to current diagnostic pathways
- **An Australian distribution partnership with Sonic Healthcare (World #3 in pathology) is already in place**

Pathway to commercialisation

- **MiCheck® Prostate is “Market Ready” – now available in the US & Australia**
- Targeting a huge total available market of 2.3 million patients in the US annually
- Commercial sales in US commenced, AU revenue commencing Q4, 2022
- Further studies underway to enhance uptake
- Licensing discussions underway with European and Middle East channel partners

Reimbursement

- US reimbursement pathway established – CPT Code USD760/test with significant potential to broaden US payer coverage
- AU – out of pocket AUD250/test with 18-month trajectory to reimbursement

Addressable market p.a.

- **USD 2B – US, Australia and EU**

Future growth opportunities

- Expansion into European, Asian and Middle Eastern markets
- Partnership with global pathology providers (Sonic, Quest) or global diagnostics co. (Abbott, Roche)
- Pipeline product development in other cancers – bladder, pancreas and point of care for prostate

Market Overview

	US	AU	EU
Total PSA Testing Market	26.9M ¹	1.5M ²	24M ³
MiCheck Prostate Addressable Market ⁴	2.3M	125K	1.6M
Price in Country	USD 760	AUD 250	EU 300
Market Value	USD 1.4B	AUD 31.3M	EU 480M
Total Market Value		USD 2.0B ⁵	

1. US Census data, Hall et al. Preventing Chronic Disease

2. Medicare 2019 PSA testing

3. The PSA Testing Market: US, Europe, Japan Test Volume, Sales Forecasts and Suppliers Shares by Country. VPG Market Report 2016

4. 6.5% of total market in grey zone of 4 to 10 ng/mL PSA (Catalona et al. NEJM) and men with cancer choosing active surveillance (Mahal et al JAMA)

5. Exchange Rates used USD1.00 = AUD 1.47, EU 1.00

- **Addressable market over USD 2 Billion**
- Prostate Cancer is the number one male cancer
- MiCheck® Prostate has a substantial market opportunity following an elevated PSA test result or after cancer diagnosis for what is termed “active surveillance”
- MiCheck® Prostate is a diagnostic test with a therapeutic market sized opportunity

MiCheck® Prostate

Detects Aggressive Prostate Cancer

The Unmet Need

- Currently **PSA tests** lead to false positive results due to **poor specificity**
- Urologists want a triage test with enhanced specificity and high negative predictive value to **biopsy the right patients**

The Minomic Solution

- MiCheck® Prostate is a blood test that gives a risk score for **aggressive prostate cancer**
- It is a triage test following an elevated PSA to identify **patients who would benefit** from prostate biopsy
- Superior accuracy adds certainty to biopsy decisions, allowing a **50% reduction in biopsies** in comparison to its only competitor
- **Biopsy of the right patients** reduces overall patient anxiety, pain and risk of drug-resistant infections

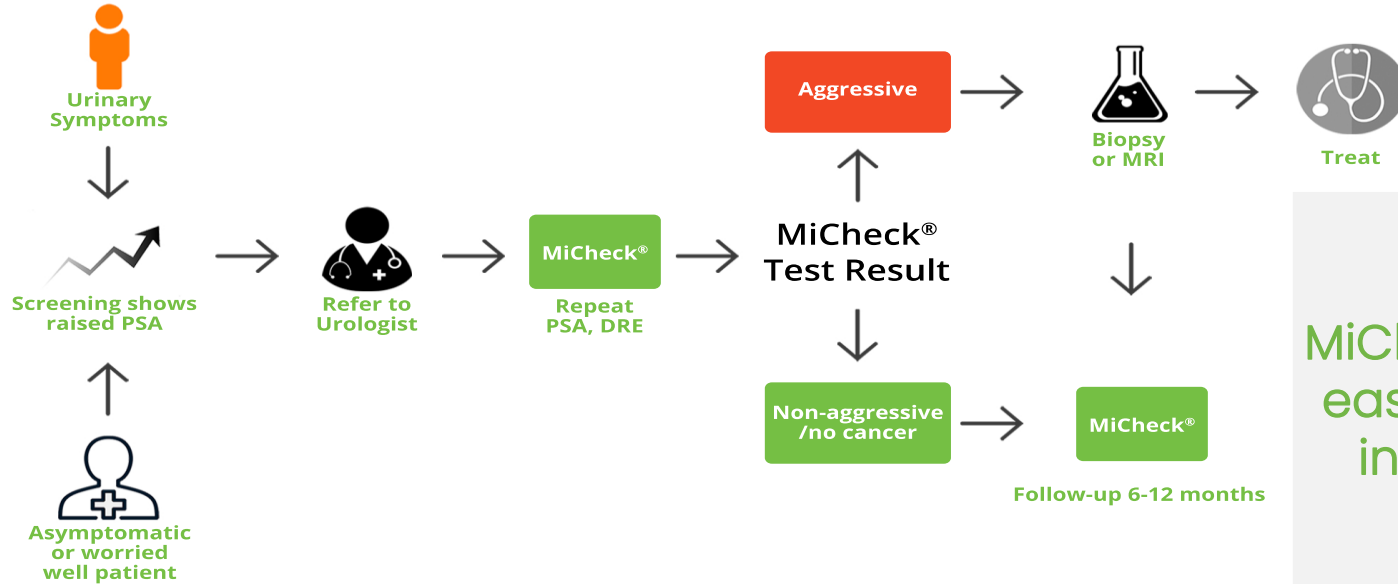
MiCheck® Prostate Performance

- Three studies demonstrate algorithm meets clinician expectations to reduce unnecessary biopsies but still detect largest number of aggressive cancers
- Algorithm applied to patients presenting with elevated PSA being sent to biopsy - showing how many would not be sent to biopsy if MiCheck® Prostate was used

	% Sensitivity/Specificity		Biopsy Reduction %
	PSA	MiCheck®	
Study 1 Shore <i>et al</i>	88/25	95/47	47
Study 2 Gillatt <i>et al</i>	66/37	93/43	43
Study 3 Unpublished	88/25	95/50	50

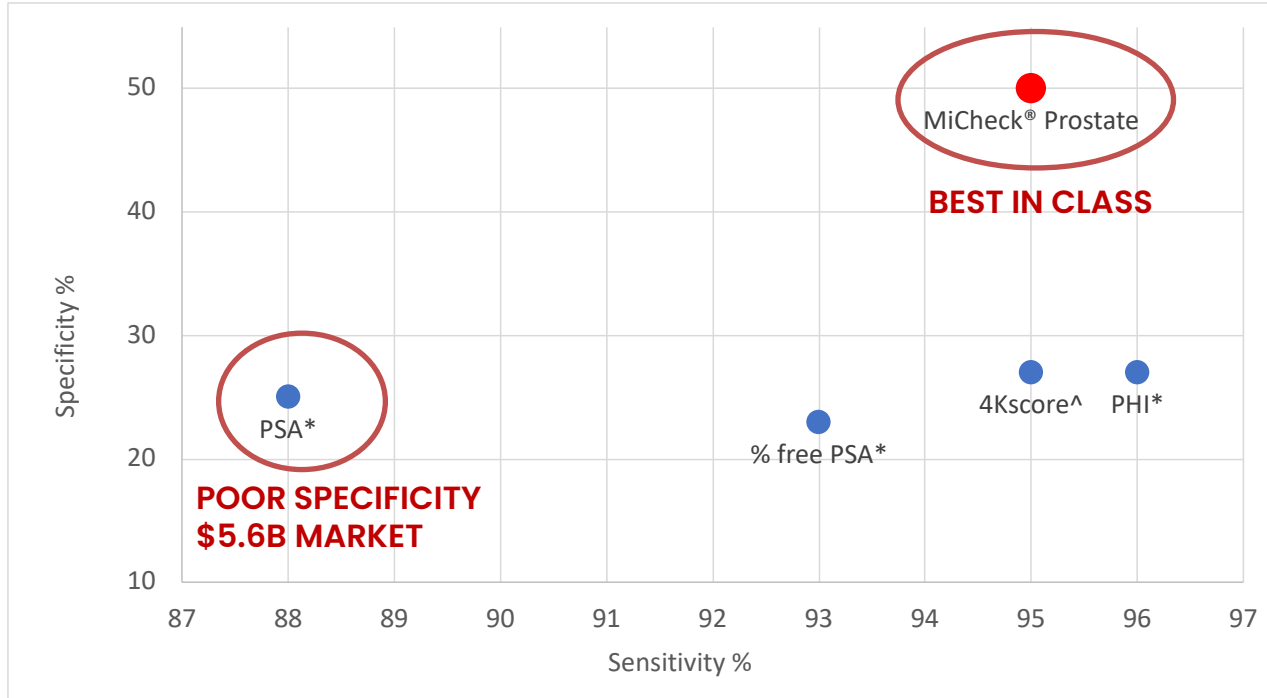
MiCheck® Prostate **Integrates Seamlessly** to Augment Current Diagnostic Pathways

The adoption of MiCheck® Prostate is easily added to the management of a patient with elevated PSA, to assist in determining if a biopsy or further monitoring is warranted



MiCheck® Prostate is easy to implement in the clinician's workflow

Superior Performance of MiCheck® Prostate



- Current tests give high false positive rates so over 50% of men going to biopsy should not
- These tests do not meet urologists need to know risk of aggressive prostate cancer (defined as GS \geq 7)
- Comparison of MiCheck® Prostate against OPKO 4Kscore for aggressive prostate cancer risk shows MiCheck® Prostate's superior specificity resulting in halving of false positive rates

* Data from head-to-head study by Minomic
^ Opko 4Kscore performance data from Nordström et al. Eur. Urol. 68.1 (2015): 139
Opko 4Kscore unavailable in Australia, only US and selected EU countries

% free PSA = ratio free to bound PSA PHI = prostate health index

Note: Only blood tests have been considered as competition as the aim is to avoid unnecessary biopsies, other tests require a tissue sample obtained using biopsy

Key Opinion Leader Views



Dr Neal Shore
Chief Medical Officer Surgery/Urology
GenesisCare

“What’s really of note is that the ROC, sensitivity and negative predictive value [of MiCheck® Prostate] was remarkably strong”



Prof Mark Emberton
Dean, Faculty of Medical Sciences
University College London

“I think MiCheck® Prostate is a very good candidate to be that companion biomarker that will work very well before imaging or indeed with imaging”



Dr Vijay Goli
Principal
Las Vegas Urology

“I really like the test, I can make a decision whether to biopsy in seconds using the graph. The MiCheck® Prostate report is much easier than other tests which take more time to work out the pathway and are very complicated”

MiCheck® Prostate

Ready to Go and Easy to Implement

1

MiCheck® Order



Physician ▶

2

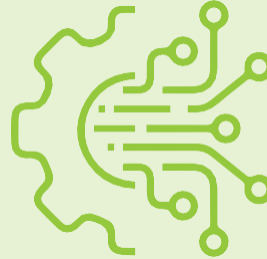
Sample Processing



Sonic ▶

3

MiCheck® Web Portal



Minomic Cloud Server ▶

4

MiCheck® Report



Sonic

- No new kits or technology required (low setup cost)
- Data simply sent to **cloud-based algorithm** that combines test results of 3 serum protein levels with a clinical factor
- **This** yields a percent risk of aggressive cancer score
- The score is calculated using a **logistic regression model** of the supplied test results
- In addition to percent risk, the report states that there is an 'INCREASED RISK' of Aggressive Prostate Cancer (**AgCaP**) if the % Risk is equal to or above 5%

Regulatory Approval in US

Regulatory Approval in US

- Two pathways for test – FDA OR Clinical Laboratory Improvement Amendments (CLIA) – regulated by CMS
- Minomic hold a CLIA licence for its lab in Maryland and is licensed to offer MiCheck® Prostate in the US as a Lab Developed Test (**LDT**)
- LDTs widely used in US – **in 2014 there were 11,000 different LDTs being offered by 2,000 laboratories in the US.**
- CLIA license enables a laboratory to offer LDTs – FDA approval is not required

CLIA pathway widely adopted strategy, by large and small companies alike, to build value in US

Company	Test	Exchange	Market Cap
OPKO – BRL	Various incl. CaP	NASDAQ	USD 1.9B
Genomic Health	Ovarian, Breast, CaP	NASDAQ	USD 2.8B
Exact Sciences	Colorectal, breast	NASDAQ	USD 8.2B
Guardant Health	Colorectal cancer	NASDAQ	USD 4.9B

Regulatory Approval in Australia

- MiCheck® Prostate is exempt clinical decision support software (CDSS) that does not require inclusion on the Australian Register of Therapeutic Goods
- MiCheck® Prostate can thus be sold as a commercial product in Australia now

Pathway to Full Commercialisation

US Commercialisation Timeline for MiCheck® Prostate



Completed

- ✓ MiCheck® Prostate algorithm validated in our US-based CLIA licensed lab in MD
- ✓ Logistics infrastructure in place
- ✓ Reimbursement and billing infrastructure in place
- ✓ Sufficient scale for next 3 years (800 tests/week/machine)

Q4 CY22

- Revenue generation commenced
- Reimbursement pathway approved
- Customers sites requesting tests (6 with total of 120 doctors)
- Fall conference season - new lead generation by US marketing team

Q1 CY23

- Increase revenues via six more customer sites (these already in discussion with Minomic)
- Expansion of sales and marketing infrastructure

Q2/3 CY23

- Entry to NCCN guidelines to drive adoption and customer demand
- Expand customers to more of the top 48 Large Urology Group Practices

Establishment phase

Demand & Revenue Generation Phase

MiCheck® Prostate Available Through Sonic Pathology Australia Targeting Urologists Who Will Influence the Medical Community



Completed

- ✓ Lab process established
- ✓ Scale no problem as Sonic operates high throughput labs
- ✓ Simple blood draw at collection centres Australia wide

Establishment phase

Q4 CY22

- Revenue generation through urology practice at Macquarie Univ. Hospital and Westmead Hospital
- Expand to additional urologists in private practice
- Minomic and Sonic co-marketing **campaign to urologists** at key national and international meetings

Q1 CY23

- Rollout to VIC and QLD via Sonic network
- Expand sales and marketing infrastructure to increase testing revenues

Q2/3 CY23

- Commence further studies for entry to local guidelines to drive adoption, reimbursement
- Sonic/Minomic co-marketing campaign targeting GPs to generate awareness and revenue

Demand & Revenue Generation Phase

Well Credentialed Board and Management



**Dr Brad Walsh,
CEO and MD**

Founded Minomic in 2007 and led the scientific and business development, raising A\$29 million in equity funding. He has a PhD in protein chemistry and has worked in government agencies, universities and hospitals prior to founding two other startups



**David Burdis,
Chief Financial Officer /
Company Secretary**

A seasoned financial professional having worked in chemical, telecommunications and financial services industries. He has held various senior/board positions, for listed and unlisted companies, in Australia, UK and Hong Kong, including GFA International Limited, Swire Blanch Limited and OAMPS Limited.



**Dr Douglas Campbell,
Head of Research and
Development**

Leads Minomic's scientific team with nearly 20 years of experience in biomedical research. He has a PhD in cancer biology and since 2004 has worked for biotechnology startups in protein production, cancer therapies and clinical support software.



**Carl Stubbings,
Chief Commercialisation
Officer**

Carl is an experienced senior leader in the biotechnology and diagnostics industry. He has considerable experience commercialising diagnostic products, both locally and globally. Carl has Bachelor of Applied Science (Medical Technology) from Queensland University of Technology.



**Mr Raymore Millard,
Non-executive Director**

Holds extensive experience in providing strategic advice to both listed and unlisted companies in Australia and overseas. He has assisted various companies from raising seed capital, through to their ultimate listing. He is similarly assisting Minomic

Well Credentialed Board and Management



**Dr Yanling Lu,
CLIA Lab Lead**

Over 15 years' experience in the biotech and medtech industries specialising in product development and assay validation. Prior to joining Minomic she worked at Clinical Genomics, leading the analytical validation of InSureOne™. Yanling was involved in the technology transfer of the diagnostic test to their CLIA laboratory in Bridgewater (NJ).



**Megan Henken,
US Commercialisation Lead**

Is a global marketing and sales strategist with over 15 years of healthcare experience, spanning clinical diagnostics, LDTs, point-of-care medical devices, e-health, and distribution. At Focus Diagnostics, a subsidiary of Quest Diagnostics, she launched 3 FDA cleared assays, 8 CE kits and 20 ASRs. She established a consulting firm in 2014 building strong clinical relationships to drive early adoption and product roadmaps for commercialization.



**Lorne Havenhill,
US Sales Executive**

30+ years of pharmaceutical medical/lab leadership experience after beginning his career in academics and biomedical research. Lorne's executive background includes positions as VP & Director of Operations and Sales, National Sales Director, Regional & Area Director, Director of Key Customer Development and other leadership roles. Lorne has been involved in multiple company, field force, and product buildouts and launches. His interests also include corporate leadership and development where he holds certification in multiple leadership development platforms



**Dr. Chih-Ling Zao,
US Lab Director**

Is an American Board of Bioanalysis certified High-Complexity Lab Director and a Master of Healthcare Administration candidate. Dr. Zao has 14 years extensive clinical laboratory experience in CLIA, COLA, CAP and AATB compliance for the specialties of chemistry, immunology, infectious disease and molecular genetics. Additionally, she has more than 10 years experience in molecular-/antibody-based new assay development and validation for pathogen detection.

Internationally Renowned Clinical Advisory Panel



**Professor David Gillatt
(Chair)**

David was a leading UK prostate cancer surgeon who is now both Professor of Urological Oncology and Robotic Surgery and Director of Medical Services at Macquarie University Hospital. He is recognised as one of the world's foremost robotic surgeons in the treatment of both prostate and bladder cancers. He also has expertise in the discovery and optimisation of biomarkers for early prostate cancer.



Dr Neal Shore

Neal is an internationally recognised clinical researcher, working on innovative therapies for patients suffering prostate enlargement in the USA. His extensive research has included more than 350 clinical studies mainly focused on prostate and bladder disease. He is a past President of LUGPA and Director of Carolina Urologic Research Centre and CMO Surgery/Urology, Genesis Healthcare



Professor Daniel W. Chan

Daniel is the Director of The Center for Biomarker Discovery and Translation and Professor of Pathology, Oncology, Radiology and Urology at the Johns Hopkins University. He is also the Director of Clinical Chemistry Division and the Co-Director of Pathology Core Laboratory at the Johns Hopkins Hospital, Baltimore, USA



**Professor Mark Emberton,
OBE**

Mark is Dean of the Faculty of Medical Science at University College London. He leads a clinical innovation team that majors in experimental medicine by combining bio-engineering and nanotechnology with early phase trials in men with prostate cancer

Current Minomic Patent Estate

MiCheck® Prostate Patent Family	Stage of Development
Biomarker Combinations for Prostate Disease	PCT completed. Registered 6 countries. National Phase: AU, CA, KR
Biomarker Combinations for Determining Aggressive Prostate Cancer	PCT completed. National Phase starting: AU, CN, CA, EU, HK, US
Biomarker Combinations for Determining Aggressive Prostate Cancer II	PCT completed. National Phase commencing Dec 22
Pipeline Patent Family	Stage of Development
Cell Surface Prostate Cancer Antigen for Dx	PCT completed. Registered 20 countries. National Phase: CA
Monoclonal Anti-GPC-1 Ab and Uses Thereof	PCT completed. Registered 20 countries. National Phase: CA
Glypican Epitopes and Uses Thereof	PCT completed. Registered 18 countries. National Phase: CA, SG, US

Patented MiCheck® Prostate algorithm protects from competition
 Patent coverage min. 20-year period (range 2034/39)

Additional patents are in the pipeline for pancreatic and bladder cancer
 diagnostics
 IP counsel: Spruson & Ferguson (Dr S. Potter, Partner)

Countries of registration: AU, CA, CN, HK, JP, KR, SG, US, AT, BE, DK, FR, DE, IR, IT, NL, ES, SE, NO, CH, UK





Thank You !

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