

# MiCheck<sup>®</sup> Prostate

## For Clinically Significant Prostate Cancer



### Benefits and Challenges of PSA Screening

PSA screening has meaningfully reduced prostate cancer mortality — recent data shows reductions of up to 35%.<sup>1</sup>

However, PSA is non-specific: frequently elevated in benign conditions, leading to unnecessary biopsies and detection of low-grade cancers that would have remained asymptomatic. Biopsy complications result in ~1% of patients requiring hospitalisation.<sup>2</sup>

### Which Patients Require Prostate Biopsy?

Of men with PSA 4–10 ng/mL, only ~18% have a positive biopsy.<sup>3</sup> PSA cannot distinguish clinically significant cancers (csPCa, Grade Group (GG)  $\geq 2$ ) from indolent disease (GG1).

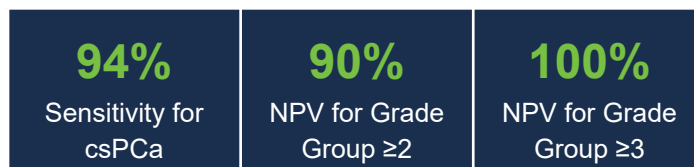
In Australia, elevated PSA often triggers Multiparametric Magnetic Resonance Imaging (mpMRI), generating a PIRADS score of 1–5. While PIRADS 4–5 patients generally proceed to biopsy, the decision is less clear for PIRADS 1–3 patients —

approximately 15% of whom harbour csPCa but don't typically undergo biopsy. Even in PIRADS 4–5 patients with a negative biopsy, MiCheck<sup>®</sup> Prostate may assist with subsequent clinical decisions.

### What is the MiCheck<sup>®</sup> Prostate test?

MiCheck<sup>®</sup> Prostate assists urologists in determining the likelihood of csPCa (GG  $\geq 2$ ) in patients being considered for biopsy.

The test combines three Abbott ARCHITECT<sup>™</sup> immunoassays (**PSA, free PSA, HE4**) with **patient age** and **mpMRI prostate volume** to generate a Percentage Risk Score and Risk Classification.



In PIRADS 1–3 patient subset: sensitivity **92%** and NPV **96%** for csPCa.<sup>4</sup>

*There is a clear clinical need for a test that assists the urologist's decision as to whether to proceed to prostate biopsy.*

### Value of MiCheck<sup>®</sup> Prostate

MiCheck<sup>®</sup> is a clinical decision support tool — not a replacement for clinical judgement. The risk score is combined with other clinical factors when the urologist and patient are jointly deciding whether to proceed to biopsy. Each urologist will continue to make their own decision to perform a biopsy based on their experience and clinical judgement.

Example: Patients A, B and C all presented with elevated PSA and normal DRE. MiCheck<sup>®</sup> correctly classified A and C as Low Risk (1% and 4%), and B as Increased Risk (40%) — see Table 1.

### How to Order MiCheck<sup>®</sup> Prostate

Available through the Sonic Healthcare Australia pathology network (e.g. DHM in NSW, Melbourne Pathology in VIC, Sullivan Nicolaides in QLD). Biomarker testing and reporting are performed at Douglass Hanly Moir (DHM) Pathology Central Laboratory, Macquarie Park (see example report in Figure 1).

<b>1</b> <b>Request</b> Fill out a pre-printed DHM "MiCheck Prostate" request form for the patient	<b>2</b> <b>Record</b> Record Prostate Volume (if available) on the request form	<b>3</b> <b>Direct</b> Send patient to any Sonic Healthcare blood collection centre	<b>4</b> <b>Receive</b> Physician's report via Sonic Dx or usual reporting channel
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**Table 1. Clinical characteristics of three patients tested using MiCheck<sup>®</sup> Prostate**

Patient	Total PSA (ng/mL)	Suspicious DRE?	MiCheck <sup>®</sup> Classification	MiCheck <sup>®</sup> % Risk of csPCa	Grade Group
A	4.3	No	Low risk	1%	No Cancer
B	4.3	No	Increased risk	40%	GG3
C	4.4	No	Low risk	4%	GG1

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### Conclusion

- Simple blood test with very high sensitivity and NPV for clinically significant prostate cancer
- Particularly valuable in PIRADS 1–3 patients where the biopsy decision is least clear
- Complements clinical judgement — not a replacement for it
- Available through the Sonic Healthcare network across Australia

### MiCheck<sup>®</sup> Prostate at a Glance

#### Simple inputs

PSA, free PSA, HE4 (Abbott ARCHITECT™) plus patient age and/or mpMRI-derived prostate volume

#### Simple to request

Same workflow as a standard PSA — results via Sonic Dx or your usual reporting channel

#### Two clear outputs

A Percentage Risk Score and a Low Risk / Increased Risk classification at a 6% threshold

#### Validated locally

Clinical validation in 192 Australian patients<sup>4</sup>

Figure 1: Example MiCheck<sup>®</sup> Prostate physician's report generated by Douglass Hanly Moir Pathology.



#### MiCheck Prostate Algorithm

Determined % Risk of Clinically Significant Prostate Cancer (csCaP) is: **40 % INCREASED RISK (< 6% Low Risk)**

#### Prostate Specific Antigen and Volume

Total PSA	1.7	ug/L	(0.30-4.5)
Free PSA	0.31	ug/L	
% Free PSA	18	%	(10-60)
Prostate Volume (cc)	34	cc	

#### Comment

MiCheck Prostate is an algorithm that combines the testing results of three in vitro serum immunoassays (Total Prostate Specific Antigen (PSA), Free PSA and Human Epididymal Protein 4 (HE4)), with the patient's age, and/or a MRI derived Prostate Volume (PV) result. The MiCheck algorithm combines these results to yield a MiCheck Prostate Percentage Risk Score, which is intended to inform the likelihood of Clinically Significant Prostate Cancer (csCaP) and is called the %Risk of csCaP.

%Risk of csCaP represents the likelihood of Clinically Significant Prostate Cancer (Gleason score  $\geq 7$ ). MiCheck Prostate is indicated for use with otheration to aid in the decision to proceed to a prostate biopsy. Prostate biopsy is required for the diagnosis of cancer.

It is important for you to provide the prostate volume result from the MRI if it is available at the time of MiCheck test ordering. The test is more sensitive if you have prostate volume data.

#### Disclaimer

The determination of Prostate Volume via MRI is performed as per standard clinical practice. The MiCheck Prostate Algorithm is performed by Minomic International Ltd. NATA/RCPA accreditation does not cover Prostate Volume via MRI or the MiCheck Prostate Algorithm. Use of the algorithm outside of the intended use has not been validated. Test results should be interpreted in conjunction with other laboratory and clinical data available to the physician and relevant guidelines on the decision for biopsy.

Surgery Use

Normal

No Action

Contact Patient

See Patient

See File

1. Carlsson SV. Screening and Prevention of Prostate Cancer 2021 (Part 1). Grand Rounds in Urology, May 2021.
2. Fenton JJ et al. PSA-Based Screening for Prostate Cancer. JAMA. 2018;319(18):1914–1931.
3. NCCN Guidelines Version 2.2021 Prostate Cancer Early Detection.
4. Polikarpov et al., 2026 (submitted).