MiCheck® Prostate
Reliably Detects Aggressive Prostate Cancer

Benefits and Challenges of PSA Screening

Early detection of prostate cancer via PSA screening has a clear impact on reducing prostate cancer mortality, with recent data demonstrating reductions of up to 35% following PSA screening[1].

However, PSA is not specific to prostate cancer, and it is frequently elevated in patients with benign conditions, leading to unnecessary biopsies due to the detection of low-grade cancers that would have otherwise remained asymptomatic. Complications such as pain and infection, can result from prostate biopsies with approximately 1% of patients requiring hospitalization following the procedure[2].

Which Patients Require Prostate Biopsy?

Most men with elevated PSA do not have prostate cancer detected following biopsy, with an estimated 18% having a positive biopsy in the PSA 4-10 ng/ml range[3].Furthermore, PSA does not distinguish between patients with high grade, aggressive cancers (Gleason score 3+4 or higher) versus indolent cancers (Gleason score 3+3).

MRI often follows an elevated PSA generating a PIRADS score between 1 and 5. While PIRADS 4 and 5 patients will typically proceed to biopsy, decision to proceed to biopsy in PIRADS 1 to 3 patients remains challenging. Approximately 15% of PIRADS 1 to 2 patients harbour aggressive prostate cancer but do not typically undergo biopsy.

Additionally, in PIRADS 4 and 5 patients who have a negative biopsy, tests such as MiCheck® Prostate may assist with subsequent clinical decisions.

There is a clear need for a test to identify those patients with aggressive prostate cancer who would benefit from a prostate biopsy.

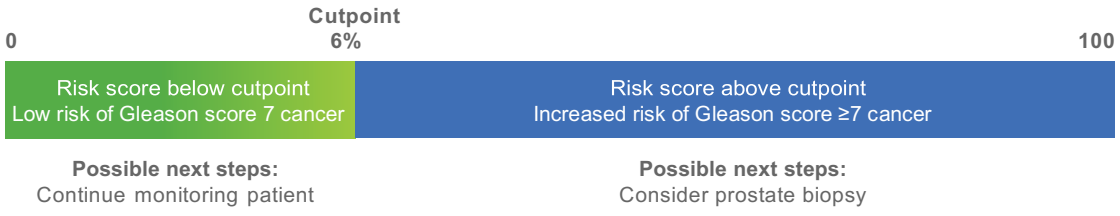
MiCheck® Prostate

MiCheck® Prostate was developed to assist urologists in determining which patients are likely to have aggressive prostate cancer (Gleason 3+4 or higher) and would therefore benefit from a prostate biopsy.

MiCheck® Prostate has **94% sensitivity** for the detection of aggressive prostate cancers, with a **negative predictive value** of 90% for Gleason ≥3+4 and 100% for Gleason ≥4+3 prostate cancers.

MiCheck® Prostate combines blood test results measured from three commercially available tumour biomarker IVD tests with the Prostate Volume and/or DRE status of the patient, in a proprietary algorithm to assess the risk of aggressive prostate cancer.
The algorithm produces a percent risk of aggressive prostate cancer stratified into “Low Risk” or “Increased Risk” classifications based on a threshold of 6%. An “Increased Risk” patient may be considered for biopsy and a “Low Risk” patient may enter/remain in active surveillance.

Figure 1



1 Carlsson, Sigrid V. “Screening and Prevention of Prostate Cancer 2021 (Part 1): Evidence for PSA Screening” May 2021. Accessed Sep 2021. https://grandroundsinurology.com/screening-and-prevention-of-prostate-cancer-2021-part-1-evidence-for-psa-screening/

2 Fenton JJ, Weyrich MS, Durbin S, Liu Y, Bang H, Melnikow J. Prostate-Specific Antigen-Based Screening for Prostate Cancer: Evidence Report and Systematic Review *for the US Preventive Services Task Force. JAMA. 2018 May 8;319(18):1914-1931. doi: 10.1001/jama.2018.3712. PMID: 29801018.*

3 NCCN Guidelines Version 2.2021 Prostate Cancer Early Detection

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Value of MiCheck® Prostate

MiCheck® Prostate is designed to be used by the urologist to assist in making a joint decision with the patient on PSA and/or abnormal MRI or DRE result.

An example of how MiCheck® Prostate can assist in clinical decision making is provided below in Table 1.

Patients A, B and C all presented with equivalent clinical features: increased PSA and normal DRE. All patients underwent biopsy due to elevated PSA.

Prostate biopsy showed that patient A did not have prostate cancer, patient B had aggressive Gleason 4+3 cancer, while patient C had indolent Gleason 3+3 cancer.

Table 1. *Clinical characteristics of three patients tested using MiCheck® Prostate*

Patient	Total PSA (ng/mL)	Suspicious DRE?	MiCheck® Classification	MiCheck® % risk of AgCaP	Gleason score
A	4.3	No	Low risk	1%	No Cancer
B	4.3	No	Increased risk	40%	4+3
C	4.4	No	Low risk	4%	3+3

Use of MiCheck® Prostate for these patients would have provided additional information to guide the decision to proceed to biopsy. MiCheck® Prostate correctly classified patients A and C as low risk of aggressive CaP (1% and 4% respectively), while patient B was correctly classified as increased risk (40%).

How to Use MiCheck® Prostate

MiCheck® Prostate is available at Sonic Healthcare Australia Pathology's Douglass Hanly Moir Pathology (DHM) laboratory. It is similar to ordering a standard PSA test, simply request 'MiCheck' and record the Prostate Volume and/or DRE outcome on a standard pathology request form and direct your patient to any DHM collection centre. It requires a standard serum sample and a Prostate Volume and/or DRE result. MiCheck® Prostate results are reported to you via your usual reporting channel.

MiCheck® Prostate can provide vital information to increase confidence in the decision to perform a biopsy. In turn, by reducing unnecessary biopsies, the patient experience and quality-of-life is enhanced.

Conclusion

MiCheck® Prostate is a new, simple to use blood test that has very high sensitivity in detecting aggressive prostate cancer

It assists urologists and patients by identifying men who are at increased risk of aggressive prostate cancer that would benefit from a prostate biopsy

By identifying appropriate patients for biopsy, MiCheck® Prostate assists in helping urologists determine the best treatment pathway for their patients.

1 **MiCheck® Order**

2 **Sample Processing**

3 **MiCheck® Web Portal**

4 **MiCheck® Report**

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