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MiCheck® Prostate

A simple blood test to optimize biopsy decisions

Abstract

Prostate cancer (PCa) remains the most common malignancy in men and one of the leading causes of cancer-related mortality. Current diagnostic pathways, which typically combine PSA testing with digital rectal examination (DRE), are widely used and valued by many urology professionals, yet they still lack specificity for clinically significant disease and can lead to unnecessary biopsies. Clinically significant prostate cancer is generally defined as Gleason 3+4 or higher, also known as Grade Group 2 or higher.

MiCheck Prostate is a blood-based risk stratification tool that incorporates three FDA-approved serum biomarkers on either Roche or Abbott immunoassay analyzers: PSA, free PSA, and HE4, together with the patient's age, to produce a risk score that provides strong discriminatory power with an AUC of 0.85. A multi-center validation study across 12 sites utilizing an Abbott immunoassay analyzer demonstrates high sensitivity of 95% and high specificity of 62% with age as the only additional clinical factor in the algorithm. The test provides an easy-to-interpret report that can support shared decision-making between clinicians and patients.

Introduction

More than 1 million prostate biopsies are performed annually in the United States, with up to 70% yielding negative or clinically insignificant results [1]. These unnecessary procedures expose patients to risks of infection, bleeding, and anxiety, while burdening healthcare systems [2].

PSA testing remains the cornerstone of prostate cancer early detection, but has limited specificity for clinically significant prostate cancer (csPCa). Clinically significant disease is defined as Gleason 3+4 or higher, corresponding to Grade Group 2 or higher, which carries a greater risk of progression and mortality. PSA levels may be influenced by benign conditions, including hyperplasia and inflammation [3]. Furthermore, age strongly influences prostate cancer risk [4].

DRE, historically combined with PSA for risk assessment, has shown poor sensitivity, low specificity, and high operator variability [5,6]. Recent guidelines in the U.S. and Europe no longer recommend routine DRE for prostate cancer screening [7,8], and patient acceptance remains low.

The MiCheck Prostate algorithm

MiCheck Prostate combines PSA, free PSA, and HE4 with age to generate a risk score for clinically significant prostate cancer (Gleason ≥3+4; Grade Group ≥2). Using age as a clinical factor supporting the algorithm in place of DRE or other clinical factors increases ease of use, eliminates variability, improves reproducibility and patient compliance. The test was developed by Minomic International Ltd. (Sydney, Australia) and is commercially available in the United States through Doc Lab Inc. (Hillsboro, OR). Minomic and Doc Lab currently offer MiCheck Prostate as a laboratory-developed test, with plans to implement the test directly within physician-operated laboratories in the near future.

Patient characteristics

The MiCheck-01 study [9], led by Dr. Neal Shore, Professor Dan Chan (Johns Hopkins University), Professor Mark Emberton (University College London) and Professor David Gillatt (Macquarie University), was designed to reflect a representative population of men undergoing prostate biopsy across the United States.

Conducted at 12 LUGPA centers, the trial enrolled men scheduled for prostate biopsy based on elevated, age-adjusted PSA thresholds (≥1 ng/mL for ages 40–50, ≥2 ng/mL for 50–60, and ≥3 ng/mL for ≥60).

Overall, 72% of participants were biopsy-naïve and 28% were undergoing repeat biopsy, with all biopsy results centrally scored. Patients were excluded if they had undergone prostate manipulation within six weeks or were receiving 5-alpha-reductase inhibitors (5-ARIs). Among the 361 participants, 186 had no prostate cancer and 175 had confirmed PCa, including 62 with Gleason 3+3 and 113 with Gleason ≥3+4 disease. Mean PSA levels were 5.2 ng/mL in men without PCa and 8.1 ng/mL among those with PCa.

The performance of MiCheck Prostate has been evaluated in 361 subjects from the MiCheck-01 clinical trial using both Roche Cobas and Abbott ARCHITECT immunoassay analyzers, along with the associated biomarker immunoassay reagents for PSA, free PSA, and HE4 [10,11].

In both cases, algorithms incorporating age outperformed those including DRE, with the Abbott platform yielding the highest specificity. (See Table 1.)

Table 1. Validation study data comparison

MiCheck Prostate	Roche	Abbott
NPV (%)	95% for GS ≥ 3+4 99% for GS ≥ 4+3	96% for GS ≥ 3+4 99% for GS ≥ 4+3
PPV (%)	46.5	53
Sensitivity (%)	95	95
Specificity (%)	50	62
AUC	0.85	0.85
Validation cohort	358	361
Intended use population	Men age 40+ with PSA>1 ng/mL	
Cut point	5%	

> Clinicians desire effective triage tools (biomarkers) for patients presenting with concerning PSA dynamics. We want to biopsy the right patients—those at risk for clinically significant disease—while avoiding an unnecessary prostate biopsy for patients with either indolent cancer or no cancer. A blood test like MiCheck Prostate, and its easy-to-interpret report, enables shared decision-making with patients regarding whether to proceed with a prostate biopsy.
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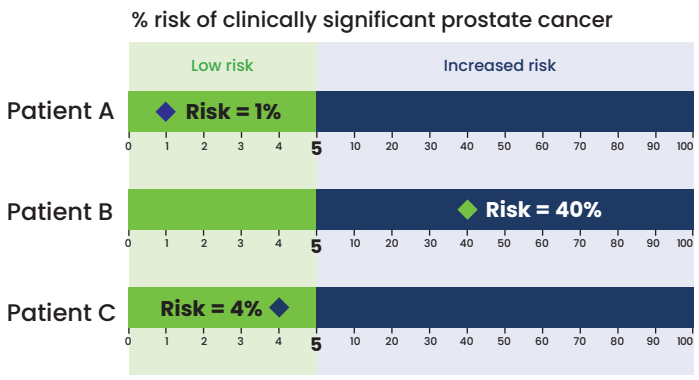
Representative characteristics for test patients A, B and C are shown in Table 2 and Figure 1.

Table 2. Clinical characteristics of three patients tested using MiCheck Prostate

	Total PSA (ng/mL)	Suspicious DRE?	MiCheck Classification	MiCheck risk of csPCa	Gleason Score
Patient A	4.3	No	Low Risk	1%	No cancer
Patient B	4.3	No	Increased Risk	40%	4 + 3
Patient C	4.4	No	Low Risk	4%	3 + 3

Figure 1. MiCheck Prostate patient reports for patients A, B and C



The following are data subsets for further analysis of MiCheck Prostate performance.

1. Repeat Biopsy and Prior Negative Biopsy data

In men with prior negative or repeat prostate biopsies, biomarker testing offers complementary information to standard clinical and imaging findings. These tests can help refine risk assessment and guide decisions about whether another biopsy is warranted.

A total number (N) of 96 patients from the MiCheck-01 clinical trial had a repeat biopsy. 33 patients (34%) are csPCa, 24 (25%) non csPCa, 39 (41%) No PCa.

	N	AUC	Sensitivity %	Specificity %
Repeat biopsy	96	0.82	97	46

2. Prior Negative Biopsy data

A total of 48 patients had prior negative biopsies. Repeat biopsies showed 13 (27%) were csPCa, 6 (13%) were non-csPCa and 29 (60%) were no PCa.

	N	AUC	Sensitivity %	Specificity %
Prior negative biopsy	48	0.83	100	46

3. MiCheck + MRI initial data

Multiparametric MRI has improved prostate cancer detection and risk stratification; however, its diagnostic performance is not perfect. Lesions scored as PI-RADS 1–2 are generally considered low likelihood for clinically significant cancer, yet a proportion of men in this category may still harbor disease that MRI does not detect. Optimal management of PI-RADS 3 patients remains challenging.

Minomic have reported the results of MiCheck Prostate in an Australian study of 192 patients in association with mp-MRI [12]. In this study, 78 (41%) were no PCa, 37 (19%) were non-csPCa and 77 (40%) were csPCa.

Two patients (1%) had PI-RADS 1, 16 (8%) had PI-RADS 2, 23 (12%) had PI-RADS 3, 88 (46%) had PI-RADS 4, 55 (29%) had PI-RADS 5 and 8 (4%) patients had no PI-RADS data (assigned to PI-RADS 1-3 group).

	N	AUC	Sensitivity %	Specificity %	NPV %
All PI-RADS	192	0.79	94	39	90
PI-RADS 1-3	49	0.8	92	65	96

Due to population differences between Australia and the US, and that MRI is used as standard of care in Australia, this study needs to be repeated in a US population to determine the optimum utilization of MiCheck Prostate and MRI. A number of different strategies have been proposed as to the scheduling and interpretation of biomarker tests and MRI: biomarkers pre-MRI, post-MRI or both. Optimum strategies for utilization of biomarkers and MRI are still being determined [13].

4. Patient Population Performance in Various Age Groups

Most available biomarker testing in prostate cancer is triggered by an elevated PSA in men. While PCa risk increases with age, PCa may also present in younger patients such as those below 55 years.

In the MiCheck-01 study, 46 patients were age <55 years. 8 (17%) had csPCa, 9 (20%) had non-csPCa and 29 (63%) had no PCa. MiCheck Prostate showed high performance in the age group <55 years, showing potential utility in patients as early as 40 years of age. This could prove to be a valuable tool in identifying younger men at increased risk of csPCa.

	N	AUC	Sensitivity %	Specificity %
Age <55 years	46	0.97	100	87
Age <65 years	189	0.88	91	72
Age ≥65 years	172	0.82	97	48

Using age 65 as cut-off, MiCheck Prostate also shows high sensitivity and specificity in these patient age groups.

Data subsets for further analysis of MiCheck Prostate performance *(continued)*.

5. Higher risk groups

African American and Hispanic men, and men with a family history of prostate cancer are at higher risk of clinically significant prostate cancer.

For men who have an elevated risk of prostate cancer due to family history, race, or genetic predisposition, early PSA screening can play an important role in establishing a baseline and detecting potential disease earlier. When combined with biomarker testing, clinicians can better distinguish men who may benefit from closer follow-up or additional diagnostic workup.

In the MiCheck-01 study, a total of 127 high-risk men were biopsied. There were 43 (34%) csPCa, 31 (24%) non-csPCa and 53 (42%) no PCa subjects.

	N	AUC	Sensitivity %	Specificity %
High-risk men	127	0.78	91	46

6. PSA density

PSA density (PSAD) is calculated by dividing the PSA concentration (in ng/mL) by the volume of the prostate in mL. The volume of the prostate (PV) is determined via trans rectal ultrasound (TRUS), which takes 15–30 minutes, or if a patient has an MRI the PV can be obtained from the MRI.

A variety of cutoffs for PSAD are used: 0.10 and 0.15 are common cut points.

In the MiCheck-01 trial, 302 patients had prostate volume available for calculation of PSAD.

	N	AUC	Sensitivity %	Specificity %
PSA density 0.1	302	0.83	84	59
PSA density 0.15	302	0.83	70	83
PSA density @95% sensitivity	302	0.83	95	31
MiCheck Prostate	302	0.82	95	48

Note that the comparison for PSA density and MiCheck prostate with 95% sensitivity shows the benefit of MiCheck Prostate — an extra 17% specificity for the same sensitivity. If standard PSAD clinical cut points (e.g. 0.1 or 0.15) are used, there is a considerable loss of sensitivity compared to MiCheck Prostate.

7. PSA range 3-10 ng/mL

In the MiCheck-01 study, 246 samples have PSA between 3-10 ng/mL, 88 (36%) are csPCa, 49 (20%) are non-csPCa, 109 (44%) had no PCa.

	N	AUC	Sensitivity %	Specificity %
PSA 3-10 ng/mL	246	0.78	93	50

8. PSA ≤3 ng/mL

While PSA values below 3 ng/mL are often viewed as reassuring, PSA alone may not fully reflect an individual's true cancer risk. Biomarker testing can add complementary information to help distinguish men with a persistently elevated biological risk despite a low PSA.

A total of 81 samples had PSA ≤3 ng/mL in the MiCheck-01 trial, and showed 100% sensitivity, 95% specificity in this group although there were only 2 csPCa cases in total (one GS3+4 and one GS4+3).

Of these 81 samples, MiCheck Prostate showed 2 True Positives, 4 False Positives, 0 False Negatives and 75 True Negatives.

	N	AUC	Sensitivity %	Specificity %
PSA ≤3 ng/mL	81	0.97	100	95

Practice implications

MiCheck Prostate offers a simple, laboratory-deployable test validated on both Roche and Abbott analyzers, facilitating broad implementation. Its availability as a laboratory-developed test in the U.S. through Doc Lab allows clinicians immediate access. At the same time, the planned implementation within physician labs will further integrate testing into standard workflows. By improving specificity while maintaining very high sensitivity, MiCheck Prostate reduces unnecessary biopsies and aligns with value-based care models.

Conclusion

MiCheck Prostate represents an advance in prostate cancer diagnostics by combining multiple biomarkers with patient age, achieving reliable risk stratification for clinically significant prostate cancer without reliance on DRE. Developed by Minomic International Ltd and now offered in the U.S. through Doc Lab, the test provides a practical solution for reducing unnecessary biopsies, supporting shared decision-making, and enabling wider access to precision diagnostics.

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