

Evaluation of the Diagnostic Performance of a Rapid Prostate-Specific Antigen Test for Prostate Cancer

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ABSTRACT

Background: Prostate cancer is one of the most common malignancies affecting men worldwide. Early detection through prostate-specific antigen (PSA) testing can improve clinical outcomes; however, conventional laboratory assays may not always be readily available in all healthcare settings. Rapid PSA tests have emerged as a convenient alternative for screening, offering faster results and easier implementation. Assessing the diagnostic performance of these rapid tests is essential before their widespread use in clinical practice.

Objective: This study aimed to evaluate the diagnostic accuracy of the Fortel rapid PSA test for prostate cancer screening by comparing its performance with the standard clinical PSA assay.

Methods: A cross-sectional study was conducted on 150 male participants aged over 50 years, or over 40 years with a family history of prostate cancer. All participants underwent medical history assessment, digital rectal examination, conventional serum PSA measurement, and Fortel rapid PSA testing. Diagnostic indices, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy, were calculated by comparing the rapid test with the clinical PSA results.

Results: The mean age of participants was 57.73 ± 4.90 years. Clinical PSA testing identified 72 (48.0%) positive and 78 (52.0%) negative cases, while the Fortel rapid PSA test showed 73 (48.7%) positive and 77 (51.3%) negative results. No significant association was found between age and Fortel PSA test results ($p = 0.975$). A highly significant agreement was observed between the rapid test and clinical PSA findings ($p < 0.001$). The Fortel PSA test demonstrated excellent diagnostic performance, with 97.2% sensitivity, 96.2% specificity, 95.9% PPV, 97.4% NPV, and an overall accuracy of 96.7%.

Conclusions: The Fortel rapid PSA test demonstrated high diagnostic accuracy and strong agreement with conventional serum PSA testing. Its excellent sensitivity and specificity suggest that it is a reliable, rapid, and practical screening tool for prostate cancer, particularly in primary healthcare and resource-limited settings. Further multicenter studies are recommended to validate these findings in larger and more diverse populations.

List of Abbreviations

PSA : Prostate-Specific Antigen
DRE : Digital Rectal Examination
PPV : Positive Predictive Value
NPV : Negative Predictive Value
TP : True Positive
TN : True Negative
FP : False Positive

FN : False Negative
SD : Standard Deviation
IQR : Interquartile Range
SPSS : Statistical Package for the Social Sciences
PC : Prostate Cancer

Keywords: Prostate Cancer, Prostate-Specific Antigen, PSA, Fortel Rapid PSA Test, Screening, Diagnostic Accuracy, Sensitivity, Specificity

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Introduction

Prostate cancer is one of the most frequently diagnosed malignancies among men and remains a leading cause of cancer-related morbidity and mortality worldwide. The disease predominantly affects older men, with its incidence increasing significantly after the age of 50 years. Early-stage prostate cancer is often asymptomatic, making timely detection crucial for improving treatment outcomes and reducing disease-specific mortality [1]. Screening strategies have therefore become an integral component of prostate cancer control programs, particularly among individuals with advanced age, a positive family history, or other recognized risk factors [2].

Prostate-specific antigen (PSA) is currently the most widely used biomarker for prostate cancer screening and early detection. Serum PSA testing, especially when combined with digital rectal examination (DRE), has substantially improved the identification of clinically significant prostate cancer before the onset of advanced disease. Nevertheless, conventional laboratory-based PSA assays require specialized equipment, trained personnel, and laboratory infrastructure, which may limit their accessibility in primary healthcare facilities, rural settings, and resource-limited regions. In addition, delays in obtaining laboratory results may postpone clinical decision-making and patient referral [2].

Rapid point-of-care PSA tests have emerged as a promising alternative to conventional laboratory assays by providing qualitative or semi-quantitative results within a short period while requiring minimal laboratory resources. Such tests have the potential to facilitate early clinical assessment, improve patient compliance, and expand screening opportunities in outpatient clinics and community-based healthcare settings. However, before these rapid diagnostic tools can be incorporated into routine clinical practice, their diagnostic performance must be rigorously evaluated against established laboratory PSA measurements [3].

Although several studies have investigated point-of-care PSA testing, the available evidence remains inconsistent regarding their diagnostic accuracy across different populations and healthcare settings. Most published studies have evaluated laboratory-based assays or were conducted in developed countries with well-established healthcare systems. Furthermore, relatively few studies have assessed the diagnostic performance of the Fortel rapid PSA test, particularly in populations at increased risk for prostate cancer [4-6]. Limited local evidence regarding its sensitivity, specificity, predictive values, and overall diagnostic accuracy represents an important gap in the current literature [5].

The novelty of the present study lies in providing a comprehensive clinical evaluation of the Fortel rapid PSA test by directly comparing its performance with the conventional clinical PSA assay in a well-defined screening population. In addition to assessing the agreement between the two methods, this study determines key diagnostic performance indicators, including sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. These findings provide valuable evidence regarding the suitability of this rapid assay as a practical screening tool in routine clinical practice,

particularly in settings where access to laboratory facilities is limited [7].

Given the increasing burden of prostate cancer and the growing need for accessible, rapid, and reliable screening methods, evaluating the diagnostic performance of rapid PSA tests is of considerable clinical importance. Demonstrating high diagnostic accuracy could support their implementation in primary healthcare centers, community screening programs, and resource-constrained environments, thereby facilitating earlier diagnosis and appropriate patient referral [8].

The present study aimed to evaluate the diagnostic performance of the Fortel rapid prostate-specific antigen (PSA) test for prostate cancer screening by comparing its results with those of the conventional clinical PSA assay and determining its sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy among men at increased risk for prostate cancer.

Patients and Methods

After obtaining written informed consent was obtained from all participants before enrollment in the study, this prospective cohort clinical study was conducted at Alnoor Specialist Hospital, Makkah, Kingdom of Saudi Arabia, during the period from January 2022 to June 2023. The study included 150 male participants who were recruited consecutively and evaluated for prostate cancer screening.

All procedures were performed in accordance with the ethical principles of the Declaration of Helsinki.

Inclusion and Exclusion Criteria

Participants were included if they were male patients aged above 50 years, or above 40 years with a positive family history of prostate cancer, who attended the outpatient clinic for prostate cancer screening. All eligible participants underwent detailed history taking and clinical evaluation. Patients who did not meet the age criteria, declined participation, or had incomplete clinical or laboratory data were excluded from the study.

Study Procedures

All enrolled participants were subjected to the following procedures

History Taking

A comprehensive medical history was obtained from each participant, with particular emphasis on urological history. Information regarding age, lower urinary tract symptoms (including urinary frequency, urgency, nocturia, weak urinary stream, hesitancy, and incomplete bladder emptying), previous urinary tract infections, history of prostatitis, previous urological interventions or surgeries, medication history, smoking status, and family history of prostate cancer was recorded. Participants were also questioned about previous PSA testing and any prior diagnosis or treatment for prostate diseases.

Clinical Examination

A complete general physical examination was performed for all participants. Subsequently, a focused urological examination was conducted, including digital rectal examination (DRE) to

evaluate the prostate gland. The prostate was assessed for size, consistency, symmetry, surface characteristics, and the presence of any suspicious nodules, induration, or irregularities suggestive of malignancy. The findings of the DRE were documented before laboratory investigations and rapid PSA testing.

Conventional Laboratory PSA Measurement

Approximately 5 mL of venous blood was collected from each participant under aseptic conditions before performing the rapid PSA test. Blood samples were sent immediately to the clinical laboratory for quantitative measurement of total serum prostate-specific antigen (PSA) using the standard laboratory immunoassay. The laboratory PSA result served as the reference standard against which the diagnostic performance of the Fortel rapid PSA test was evaluated. According to the study protocol, a PSA value of ≥ 4 ng/mL was considered positive, whereas a value < 4 ng/mL was considered negative.

Fortel Rapid PSA Test

The Fortel one-step PSA rapid test was performed according to the manufacturer's instructions under standardized conditions. The participant's fingertip was first cleaned with an alcohol swab and allowed to dry for approximately 30 seconds. A sterile disposable lancet was then used to obtain one or two drops of capillary blood. The collected blood sample was transferred into the sample well (marked "S") of the Fortel PSA test cassette using the disposable pipette supplied with the test kit.

After approximately 90 seconds, five drops of the buffer/wash solution were added to the diluent well (marked "D") to facilitate sample migration across the membrane. The test cassette was left undisturbed, and the result was interpreted 10 minutes after buffer application according to the manufacturer's instructions. The test generated a qualitative result, indicating positive (PSA ≥ 4 ng/mL) or negative (PSA < 4 ng/mL). All rapid tests were performed immediately after venous blood collection for the conventional PSA assay to minimize temporal variation between the two measurements.

Diagnostic Comparison

The results of the Fortel rapid PSA test were compared with those of the conventional quantitative serum PSA assay. Diagnostic concordance between both methods was evaluated by determining the numbers of true positives (TP), true negatives (TN), false positives (FP), and false negatives (FN). These data were subsequently used to calculate the diagnostic indices of the Fortel rapid PSA test, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy, using the conventional serum PSA assay as the reference standard.

Outcome Measures

The primary outcome was the diagnostic performance of the Fortel rapid PSA test compared with the conventional quantitative serum PSA assay.

Secondary outcomes included the agreement between the rapid PSA test and conventional PSA results and the relationship between test performance and patients' demographic characteristics.

Sample Size

The study included 150 male participants. The sample size had been calculated using PASS version 11.0, based on data reported by Ibrahim et al. [9] and Miano et al., [10] to provide sufficient power for evaluating the diagnostic accuracy of the Fortel rapid PSA test compared with the conventional quantitative PSA assay.

Sampling Method

A prospective consecutive sampling technique was used, whereby all eligible patients attending the Urology Outpatient Clinic during the study period who fulfilled the inclusion criteria and agreed to participate were consecutively enrolled until the required sample size was achieved.

Statistical Analysis

Data were recorded, coded, and analyzed using the Statistical Package for the Social Sciences (SPSS), version 23.0 (IBM Corp., Armonk, NY, USA). Quantitative variables were tested for normality using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Normally distributed continuous variables were presented as mean $\pm$ standard deviation (SD), whereas non-normally distributed data were expressed as median and interquartile range (IQR). Qualitative variables were presented as frequencies and percentages.

Comparisons between two independent groups for continuous variables were performed using the independent Student's t-test, while associations between categorical variables were analyzed using the Chi-square test or Fisher's exact test, when appropriate. The diagnostic performance of the Fortel rapid PSA test was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy using the conventional serum PSA assay as the reference standard. Statistical significance was considered at a 95% confidence interval, with $P < 0.05$ regarded as statistically significant and $P < 0.001$ considered highly statistically significant.

Results

Table 1: Demographic Characteristics of the Studied Patients

Table 1 shows that the study included 150 male participants with a mean age of 57.73 ± 4.90 years and an age range of 50–65 years.

Table 2: Distribution of Clinical PSA Results

Table 2 shows that the median PSA value was 3.8 ng/mL (IQR: 2.3–8 ng/mL), with values ranging from 0.3 to 390 ng/mL. Clinical PSA results were negative in 78 (52.0%) patients and positive in 72 (48.0%) patients.

Table 3: Distribution of Fortel Rapid PSA Test Results

Table 3 shows that the Fortel rapid PSA test was negative in 77 (51.3%) patients and positive in 73 (48.7%) patients.

Table 4: Comparison of Demographic Characteristics According to Fortel PSA Test Results

Table 4 shows that there was no statistically significant difference in mean age between patients with negative and positive Fortel PSA test results ($P = 0.975$).

Table 5: Relationship Between Clinical PSA and Fortel Rapid PSA Test Results

Table 5 shows that there was a highly statistically significant association between the clinical PSA results and the Fortel rapid PSA test results ($P < 0.001$). Among patients with negative clinical PSA results, 75 (96.2%) had negative Fortel PSA results, while 70 (97.2%) of patients with positive clinical PSA results had positive Fortel PSA results.

Table 6: Diagnostic Performance of the Fortel Rapid PSA Test
Table 6 shows that the Fortel rapid PSA test demonstrated excellent diagnostic performance in screening for prostate cancer, with 70 true-positive, 75 true-negative, 3 false-positive, and 2 false-negative results. The test achieved an overall accuracy of 96.7%, sensitivity of 97.2%, specificity of 96.2%, positive predictive value (PPV) of 95.9%, and negative predictive value (NPV) of 97.4%, indicating high diagnostic reliability for prostate cancer screening.

Table 1: Descriptive for Demographic Data of the Studied Patients

		No. = 150
Age	Mean $\pm$ SD	57.73 $\pm$ 4.90
	Range	50 – 65
Gender	Male	150 (100.0%)

Table 2: Descriptive for PSA of the Studied Patients

		No. = 150
PSA value	Median (IQR)	3.8 (2.3 - 8)
	Range	0.3 – 390
PSA	Negative	78 (52.0%)
	Positive	72 (48.0%)

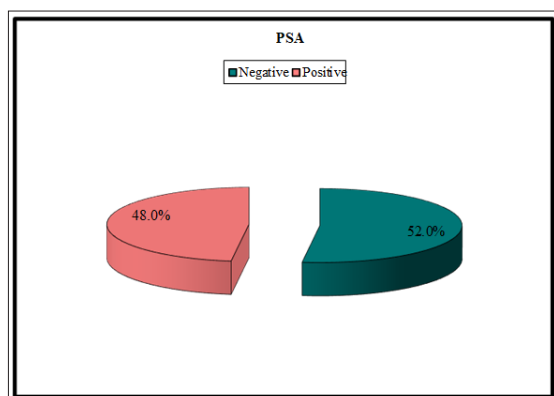


Figure 1: Descriptive for Psa of the Studied Patients.

Table 3: Descriptive for fortel PSA test of the Studied Patients

Fortel PSA test	No. (%)
Negative	77 (51.3%)
Positive	73 (48.7%)
Total	150 (100.0%)

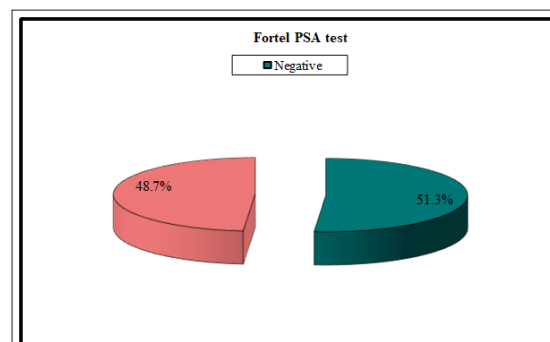


Figure 2: Descriptive for fortel PSA test of the studied patients.

Table 4: Comparison for Fortel PSA Test Regarding Demographic Data of the Studied Patients

		Fortel PSA test		Test value	P-value	Sig.
		Negative	Positive			
		No. = 77	No. = 73			
Age	Mean $\pm$ SD	57.71 $\pm$ 4.95	57.74 $\pm$ 4.88	-0.032	0.975	NS
	Range	50 – 65	50 – 65			
Gender	Male	77 (100.0%)	73 (100.0%)	NA	NA	NA

P-value > 0.05 : Non-significant (NS); P-value < 0.05 : Significant (S); P-value < 0.01 : highly significant (HS)

•: Independent t-test

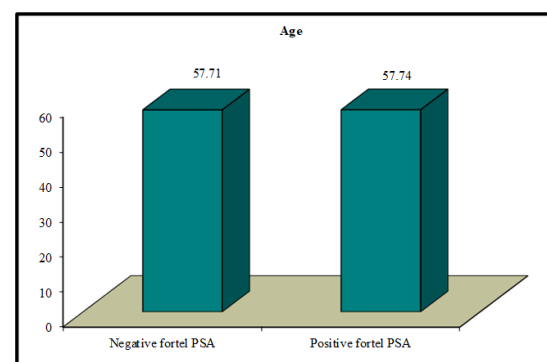


Figure 3: Comparison for fortel PSA test regarding mean age of the studied patients.

Table 5: Relation Between Clinical Psa Value and Fortel Psa Value of the Studied Patients

		Total no.	PSA		Test value*	P-value	Sig.
			Negative	Positive			
			No. = 78	No. = 72			
Fortel PSA test	Negative	77	75 (96.2%)	2 (2.8%)	130.670	0.000	HS
	Positive	73	3 (3.8%)	70 (97.2%)			

P-value > 0.05 : Non-significant (NS); P-value < 0.05 : Significant (S); P-value < 0.01 : highly significant (HS)*:Chi-square test

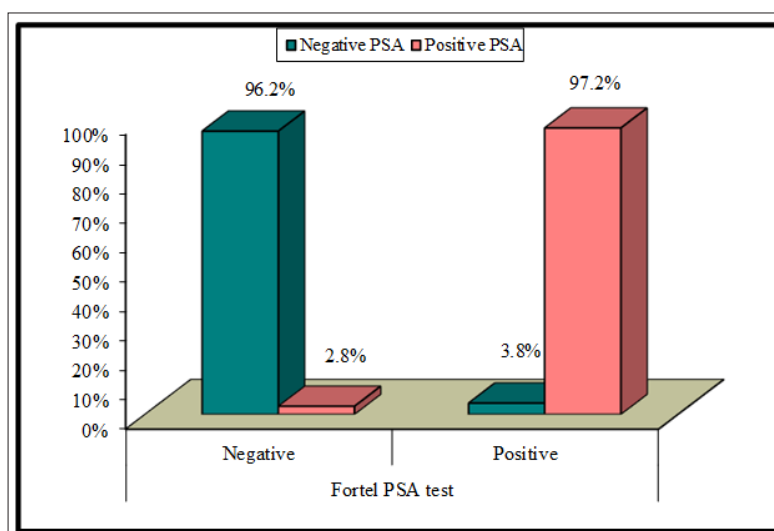


Figure 4: Relation between clinical PSA value and fortel PSA value of the studied patients.

Table 6: Diagnostic characteristics of Fortel PSA test in screening of prostatic cancer

Parameter	TP	TN	FP	FN	Accuracy	Sensitivity	Specificity	PPV	NPV
Fortel PSA test	70	75	3	2	96.7%	97.2%	96.2%	95.9%	97.4%
				PSA					
				Negative			Positive		
Fortel PSA test	Negative			TN			FN		
	Positive			FP			TP		

Sensitivity = TP, Specificity = TN, PPV = TP / Total positive (TP + FP), NPV = TN / Total Negative (TN + FN), Accuracy = (TP + TN) / Total no. of patients

Discussion

Prostate cancer is one of the most common cancers among men worldwide, and early detection is essential for improving patient outcomes. Although serum PSA testing is the standard screening method, its use may be limited by laboratory requirements, cost, and delayed results. Rapid point-of-care PSA tests offer a practical alternative by providing faster and more accessible screening, particularly in primary healthcare and resource-limited settings [11].

Despite the growing interest in rapid PSA assays, evidence regarding their diagnostic performance remains limited, especially for the Fortel rapid PSA test and in local screening populations. Therefore, further evaluation is needed to determine whether this test provides reliable results comparable to conventional laboratory PSA testing [12].

Since Screening for prostate cancer with serum prostate-specific antigen (PSA) represents major conflict and often may be associated with increased harms such as overdiagnosis and complications of treatment for indolent disease, investigating the efficacy and safety of prostate specific antigen (PSA) testing to screen for prostate cancer was highlighted as a main point of interest [13,14].

Nevertheless, screening for prostate cancer remains highly controversial because of limitations in randomized trials including contamination and under-representation of black men. Difficulty of shared, informed decision-making between patients and primary care providers about PSA screening may also contribute to practice variations [14].

Accordingly, this study aimed to evaluate the diagnostic performance of the Fortel rapid PSA test by comparing it with the standard clinical PSA assay and assessing its sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy for prostate cancer screening.

This Prospective cohort clinical study was conducted at tertiary care hospital at Urology Department, Outpatient clinic, Hospital. from January 2022 till June 2023 and performed on a total of 150 patients who were above 50 years old or above 40 years old with family history of prostate cancer.

During this study, 170 patients were assessed for eligibility and 150 patients were included in the study. Of all eligible patients, 12 patients were excluded from the study based on the inclusion criteria and 8 patients refused to participate in of the study. Ultimately, the analysis was based on the data of 150 patients who were above 50 years old or above 40 years old with family history of prostate cancer.

To enhance the convenience and reduce the cost of prostate cancer (PC) screening, a one-step prostate-specific antigen (PSA) test was evaluated in a large population. The PSA SPOT test kit enables rapid detection of human PSA in serum or plasma at or above a cutoff level of 4 ng/mL to aid in the diagnosis of PC [8].

The current study revealed that Median (IQR) of PSA value was 3.8 (2.3–8). The clinical PSA value was positive in 78 cases (52%) and negative in 72 cases (48%) and the fortel PSA test value was positive in 77 cases (51.3%) and negative in 73 cases (48.7%).

The current study results revealed that there was no statistically significant difference between negative and positive Fortel PSA test regarding mean age of the studied patients (p value= 0.975). The current study results revealed that there was highly statistically significant difference between negative and positive clinical PSA test regarding Fortel PSA value (p value= 0.000).

Among the 78 participants with a PSA value < 4 ng/mL, 75 (96.2%) were correctly interpreted as negative using the Fortel PSA test, whereas 3 were interpreted as positive, resulting in a test specificity of 96.2%. Consequently, our study results revealed that Fortel PSA test had high Sensitivity (97.2%), specificity (96.2%), positive predictive value (95.9%) and negative predictive value (97.4%) in accuracy of screening of prostatic cancer.

Different studies were done assessing accuracy, sensitivity, specificity of one-step PSA test in screening the PC, some of them agree and others differ from our results.

The results of the Fortel PSA test were comparable to those of other one-step PSA tests described in the previous literatures. Ashida et al., [8] conducted a study that enrolled 1429 men for PC screening using the PSA SPOT test to evaluate a rapid, one-step, qualitative PSA test, called the PSA SPOT test, as a possible way to enhance the convenience and reduce the cost of PC screening in a large population and revealed that the sensitivity, specificity, PPV, NPV, and accuracy of the test were 79.9, 93.0, 65.4, 96.6, and 91.2%, respectively.

In concordance with our results, Miano et al., [10] conducted a study that enrolled 188 men using one-step PSA Rapid Screen test for screening of PC to increase the acceptance rate and reduce the cost of the screening programme for prostate cancer and reported that Accuracy, negative and positive predictive values of PSA Rapid Screen test were 94, 98 and 89%, respectively. Among the 104 patients with PSA value ≥ 4 ng/mL, 94 were correctly interpreted as negative and 10 were positive with PSA Rapid Screen test, determining the specificity of the test ($94/104=90.4\%$).

This is consistent with the results conducted by Shigeno et al., [15] who reported sensitivity of 89.5% and specificity of 94.2%. Also, Dok et al., [16] reported sensitivity of 100% and specificity of 90% using One Step PSA screening test.

In a study by Berg et al., [17], a PSA one-step test (Uralen) showed a high acceptance rate due to a well-conducted publicity campaign and because it proved to be a fast, easy to perform and inexpensive test with sensitivity of 91% and specificity of 81%.

These findings are in line with the reported findings of Madersbacher et al., [18] who performed a study of 238 men using Oncoscreen one-step PSA screening test reporting sensitivity and specificity of 93% in screening PC.

The one-step PSA test we describe is very easy to administer and can be performed without costly additional equipment, although centrifuge is needed to separate serum from blood. The low cost and speed of the test make it useful and convenient as a tool for primary PC screening, even in general practitioner or urologist

office settings. The economic drawbacks to PSA mass screening could be overcome using this one-step PSA test [8].

Therefore, the use of this test could spare a significant number of costly quantitative PSA determinations in screening populations due to the high percentage of negative PSA results in PC mass screening, although we could not show expected cost savings because the PSA SPOT test kit is not commercially available and not priced [8].

Clinical Implications

The findings of this study demonstrate that the Fortel rapid PSA test has excellent diagnostic performance, with high sensitivity (97.2%), specificity (96.2%), positive predictive value (95.9%), negative predictive value (97.4%), and overall diagnostic accuracy (96.7%) when compared with the conventional clinical PSA assay. These results suggest that the Fortel rapid PSA test can serve as a reliable point-of-care screening tool for identifying men at increased risk of prostate cancer. Its rapid turnaround time and ease of use may facilitate earlier clinical decision-making, prompt referral for confirmatory investigations, and timely initiation of appropriate management. Moreover, the test may be particularly valuable in primary healthcare centers, outpatient clinics, community screening programs, and resource-limited settings where access to standard laboratory testing is restricted. By expanding screening opportunities, the Fortel rapid PSA test has the potential to improve early detection rates and contribute to better patient outcomes.

Strengths of the Study

This study has several strengths. First, it included a relatively adequate sample of men belonging to the target population for prostate cancer screening, including individuals aged over 50 years or those over 40 years with a positive family history. Second, all participants underwent both conventional PSA testing and the Fortel rapid PSA test under the same clinical conditions, allowing direct comparison between the two methods. Third, the study comprehensively evaluated diagnostic performance using clinically relevant parameters, including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy. Finally, the findings provide valuable local evidence regarding the clinical utility of the Fortel rapid PSA test, which has been insufficiently investigated in previous studies.

Limitations

Despite its strengths, this study has several limitations. The study was conducted at a single center, which may limit the generalizability of the findings to broader populations. The sample size, although sufficient for the present analysis, remains relatively modest compared with large multicenter screening studies. In addition, the reference standard was the conventional clinical PSA assay rather than histopathological confirmation obtained through prostate biopsy, which remains the definitive diagnostic method for prostate cancer. Furthermore, the cross-sectional design did not allow assessment of long-term clinical outcomes, disease progression, or the impact of rapid PSA screening on patient survival. These limitations should be considered when interpreting the study findings.

Conclusion

The present study demonstrated that the Fortel rapid PSA test has excellent agreement with conventional clinical PSA testing and provides high diagnostic accuracy for prostate

cancer screening. The test exhibited outstanding sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy, indicating that it is a reliable and effective screening method.

Its rapid availability of results, simplicity of use, and minimal laboratory requirements make it a practical alternative for screening men at increased risk of prostate cancer, particularly in primary healthcare and resource-constrained settings. The findings support the clinical utility of the Fortel rapid PSA test as an effective point-of-care screening tool that may facilitate earlier detection and improve patient management.

Based on the findings of this study, the Fortel rapid PSA test may be considered for use as an initial screening tool in men at increased risk of prostate cancer, particularly in settings where conventional laboratory testing is not readily available. Larger multicenter studies involving more diverse populations are recommended to validate these findings and improve their generalizability. Future research should compare rapid PSA test results with histopathological findings to determine their diagnostic performance against the gold standard for prostate cancer diagnosis.

Ethical Considerations

The study was conducted after obtaining written informed consent from all participants before enrollment after explaining the study objectives, procedures, potential benefits, and possible risks. Participation was voluntary, and participants had the right to withdraw from the study at any time without affecting their medical care. All procedures were performed in accordance with the ethical principles of the Declaration of Helsinki.

Acknowledgment: none

Author Contributions

All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this study.

Confidentiality of Data

The confidentiality and privacy of all participants were strictly maintained throughout the study.

Personal identifiers were replaced with coded numbers, and all collected data were stored securely with access limited to the research team. The information obtained during the study was used exclusively for scientific research purposes and was not disclosed to any unauthorized individual or organization.

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