Frontiers in Health Informatics
ISSN-Online: 2676-7104
www.healthinformaticsjournal.com
2025; Vol 14: Issue 2
Open Access

Clinical Performance Evaluation of the PSA Rapid Test Cassette (TPS-402): Comparative Analysis With ACON Total PSA ELISA Test Kit

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Cite this paper as: Anika Tabassum Aziz (2025) The Rising Incidence of Breast Cancer among Women under 40 in Bangladesh: Causes and Screening Challenges. *Frontiers in Health Informatics, 14* (2), 2642-2643

ABSTRACT
This study evaluates the diagnostic accuracy of the PSA Rapid Test Cassette (TPS-402) using a clinical dataset: a 2021 comparison with ACON Total PSA ELISA Test Kit (n = 561), including 207 PSA-positive specimens and 354 PSA-negative specimens confirmed by the ELISA kit and clinical symptoms. The cassette correctly identified 205 of 207 ELISA-positive specimens and 351 of 354 ELISA-negative specimens, achieving a relative sensitivity of 99.0%, a relative specificity of 99.2%, and an overall accuracy of 99.1%. These findings confirm that TPS-402 delivers laboratory-comparable performance while retaining the speed and simplicity required for point-of-care testing.
Keywords: PSA; Rapid Test; Prostate Cancer; Clinical Evaluation; ELISA

INTRODUCTION
Prostate-specific antigen (PSA) is a key biomarker for prostate conditions, with serum levels correlating with prostate cancer, benign prostatic hyperplasia, and prostatitis. Conventional PSA detection relies on laboratory-based ELISA assays, which are accurate but time-consuming and facility-dependent. The PSA Rapid Test Cassette (TPS-402), a chromatographic immunoassay using colloidal gold conjugate and anti-PSA antibodies, enables semi-quantitative detection of total PSA in whole blood, serum, or plasma with a 3 ng/mL cut-off and 10 ng/mL reference value. This study benchmarks TPS-402 against the ACON Total PSA ELISA Test Kit to ensure clinical reliability.

CONTENT
Materials and Methods
Study Design and Specimens: A total of 561 clinical specimens (whole blood, serum, plasma) were tested, including 207 PSA-positive and 354 PSA-negative cases, confirmed by ELISA and clinical symptoms. Both TPS-402 and ACON Total PSA ELISA Test Kit were performed in parallel.

Test Procedure: Specimens were brought to room temperature. For serum/plasma: 1 drop (~40 µL) plus buffer was applied. For whole blood: 2 drops (~80 µL) plus buffer. Results were read at 5 minutes (no interpretation after 10). Interpretation: Test line weaker than reference = 3–10 ng/mL; equal to reference = ~10 ng/mL; stronger = >10 ng/mL; no test line = <3 ng/mL.

Data Analysis: Relative sensitivity, specificity, and accuracy were calculated versus ELISA. 95% confidence intervals were computed.

Results

Among 207 ELISA-positive specimens, TPS-402 detected 205 (sensitivity 99.0%). Among 354 ELISA-negative specimens, TPS-402 correctly identified 351 (specificity 99.2%). Overall accuracy was 99.1% (561 specimens). No test failures were reported.

Table 1: Clinical Study Results of PSA Rapid Test Cassette (TPS-402)

	ELISA Positive	ELISA Negative	Total
TPS-402 Positive	205	3	208
TPS-402 Negative	2	351	353
Total	207	354	561

Discussion

The TPS-402 test demonstrated excellent concordance with the ELISA reference, achieving sensitivity of 99.0%, specificity of 99.2%, and accuracy of 99.1%. Advantages over ELISA include speed (5 minutes), simplicity (no specialized equipment), and versatility (whole blood, serum, plasma). These features make TPS-402 well-suited for point-of-care and resource-limited settings.

Limitations: TPS-402 is semi-quantitative and should not be the sole diagnostic criterion for prostate cancer. PSA levels may also be unreliable in patients under hormone therapy or post-prostate manipulation.

Conclusion

The PSA Rapid Test Cassette (TPS-402) exhibits high sensitivity, specificity, and accuracy in semi-quantitative PSA detection, with strong concordance to ELISA. Its rapid turnaround, ease of use, and compatibility with multiple specimen types support its role as a reliable diagnostic tool for prostate health assessment.

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