## Applicability of the SelectMDx Test in Identifying Clinically Significant Prostate Cancer: Insights from an Eastern European Cohort

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## **Abstract**

*Background:* Prostate cancer is a major global health concern, and current diagnostic methods, including prostate-specific antigen testing, have significant limitations. SelectMDx is a urinary biomarker test used for risk stratification of clinically significant prostate cancer, with the potential to reduce unnecessary biopsies.

Methods: This retrospective study included 126 patients evaluated in a Romanian university hospital between January 2022 and December 2023. All patients had PSA >3 ng/mL and/or abnormal digital rectal examination findings and underwent the SelectMDx test followed by transrectal ultrasound-guided biopsy. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated, and diagnostic performance was assessed using ROC curves.

Results: SelectMDx demonstrated a sensitivity of 90.6%, specificity of 70.4%, and NPV of 94.3% in the cohort with PSA < 10 ng/mL. The test performed optimally in patients with negative DRE or PI-RADS  $\leq$  3 scores, reducing unnecessary biopsies.

Conclusions: SelectMDx has proven to be a valuable tool in the risk stratification of clinically significant prostate cancer, contributing to improved clinical decision-making and reducing unnecessary biopsies. However, further studies are needed to validate its performance across different populations.

**Keywords:** prostate cancer, SelectMDx, urinary biomarkers, non-invasive diagnosis, biopsy, PSA, risk stratification, PI-RADS

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