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*Commentary*

# Reducing Unnecessary Prostate Biopsies Through Real-World Clinical use of the EpiSwitch PSE Blood Test

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## Description

Prostate cancer screening continues to be challenged by the limited specificity of prostate-specific antigen-based testing, resulting in substantial rates of unnecessary biopsy, patient anxiety, and downstream procedural morbidity. Although multiparametric MRI and adjunctive risk stratification tools have improved pre-biopsy assessment, clinically meaningful gaps remain in identifying patients who are most likely to benefit from invasive diagnostic evaluation. In this context, blood-based molecular assays capable of refining risk stratification in real-world clinical settings represent an important and timely advancement. The recent Cancers publication from Berghausen et al. (2025) elucidated how the EpiSwitch® PSE blood test is poised to improve prostate cancer diagnostics. This is not a theoretical model or abstract biomarker study, but a prospective, real-world clinical utility analysis of 187 men referred for prostate cancer workup. These findings reflect routine patient populations encountered in contemporary urologic practice. The implications are immediate, actionable, and long overdue. The author served as principal investigator and senior author of the referenced real-world clinical utility study.

The study showed that the PSE test, which combines epigenetic 3D genomic biomarkers with PSA, identified men at elevated risk of clinically significant prostate cancer with greater precision than PSA or MRI alone. Among 134 evaluable patients, more than 79% of unnecessary biopsies were safely avoided using this test. A more conservative approach still reduced biopsies in 67% of cases. For patients, this means fewer procedures, less anxiety, and more confidence in their care plans. For urologists, it means clarity and clinical efficiency in place of ambiguity and low-yield interventions. Importantly, biopsy avoidance was achieved without compromising the detection of clinically significant disease, underscoring the test's potential to recalibrate the balance between sensitivity and specificity that has historically constrained prostate cancer screening paradigms.

Its accuracy and reliability place it among the top-tier diagnostic tools currently available for prostate cancer risk stratification. The test achieved a 100% technical success rate, with an average turnaround time just over four days. In multivariate analysis, the PSE result was the strongest independent predictor of biopsy-confirmed cancer, outperforming PSA, PI-RADS scores, 4K Score, and family history. These findings highlight the incremental value of incorporating higher-order epigenetic information into screening workflows, beyond traditional clinical, biochemical, and imaging-based predictors.

PSE's value extends beyond performance. It changes the way we talk to patients. In men presenting with an elevated PSA, PSE functions as a pre-biopsy triage tool that facilitates more confident decisions regarding observation, further imaging, or biopsy. With a simple blood draw, clinicians can provide a clear, binary result indicating high or low likelihood and tailor subsequent management decisions within days. This is far easier to explain than complex risk percentages or probability scores, which often confuse or overwhelm patients. This clarity builds trust, improves adherence, and supports the kind of personalized high-value care we strive to deliver.

Operationally, PSE is just as compelling. Clinics are stretched thin. Imaging slots are often backlogged and biopsy suites overbooked. A test that avoids even a fraction of unnecessary interventions is not just helpful, it is essential. PSE requires only a 3 mL blood draw, is stable at room temperature, and does not need to be centrifuged, refrigerated, or frozen. It has no exclusion criteria based on PSA, DRE findings, or BPH status, making it more accessible than other tests with restrictive requirements. Such characteristics align closely with contemporary guideline recommendations emphasizing risk-adapted screening, reduction of low-yield interventions, and optimization of patient-centered outcomes.

## Conclusion

In summary, EpiSwitch PSE is a turning point for prostate cancer screening. It improves diagnostic precision, reduces harm, enhances clinic workflow, and restores clinical confidence. Taken together, these findings support broader clinical adoption of the EpiSwitch PSE blood test as a pragmatic tool to improve diagnostic precision and reduce unnecessary prostate biopsies in contemporary practice.

## Author contribution

GDP served as principal investigator and senior author of the referenced clinical utility study. He is also a paid clinical advisor for Oxford BioDynamics, Inc.

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