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**EVOLIUCINĖ MEDICINA:
ŽMOGAUS RAIDOS PERSPEKTYVOS IR SVEIKATA
BESIKEIČIANČIOJE APLINKOJE**

**EVOLUTIONARY MEDICINE:
PERSPECTIVES ON HUMAN DEVELOPMENT AND HEALTH
CONSEQUENCES IN A CHANGING ENVIRONMENT**

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URINARY METABOLOME ANALYSIS FOR DETECTION OF CLINICALLY SIGNIFICANT PROSTATE CANCER: ACCURACY AND ACCEPTABILITY OF NOVEL BIOMARKER TEST

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Background and Aim: Population-level prostate cancer (PCa) screening, based on prostate-specific antigen (PSA) testing, has demonstrated the ability to diagnose PCa early and reduce PCa mortality. However, the limited specificity and sensitivity of PSA and other widely used biomarkers have led to an increased utilisation of invasive prostate biopsies, as well as the overdiagnosis and overtreatment of indolent PCa. The discovery of accurate and acceptable biomarker tests for detecting clinically significant PCa (csPCa) remains a major unmet clinical need, driving extensive research in the field. Urine passes through the prostatic urethra and collects metabolites from the prostate gland, making it a highly rational biofluid for the discovery of novel csPCa biomarkers, as well as a potentially more acceptable medium from the patient's perspective. We aim to develop a highly accurate, non-invasive diagnostic test for csPCa detection utilising urinary metabolomic fingerprinting. Our secondary objective is to evaluate and compare the acceptability of the novel urinary test against standard-of-care diagnostic modalities.

Materials and Methods: Pre-biopsy urine samples will be collected from a cohort of patients with elevated PSA levels and analysed via Gas Chromatography-Mass Spectrometry (GC-MS). Data preprocessing and machine learning techniques will be applied to identify distinct urinary metabolomic fingerprints differentiating patients with and without csPCa. Targeted prostate biopsies will be utilised as the diagnostic reference standard for the detection of csPCa. Patient-reported acceptability across the different diagnostic modalities will be systematically analysed and compared using structured questionnaires.

Results: Initial proof-of-concept data indicate that pairing routine PSA metrics with GC-MS spectral signatures provides excellent stratification of prostate cancer risk. Specifically, our baseline model separated csPCa (ISUP ≥ 2) from non-significant pathological findings with high precision (AUC = 0.842; 95% CI: 0.825–0.859).

Conclusions: Given this promising clinical performance, an additional study cohort is currently being recruited to further validate the diagnostic model and to formally evaluate patient acceptability.

Keywords: biomarker, clinically significant prostate cancer, test acceptability, urinary metabolome