

# Bio-Techne Announces Publication Of ExoDx Prostate Test Study In Patients With Prior Negative Prostate Biopsy

MINNEAPOLIS, Sept. 23, 2020 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced an important publication in BMC Urology, entitled *A urine-based Exosomal gene expression test stratifies risk of high-grade prostate Cancer in men with prior negative prostate biopsy undergoing repeat biopsy* (available [here](#)). Principal investigator Dr. James McKiernan, Professor of Urology at Columbia University, and colleagues demonstrated that using the ExoDx Prostate test, or EPI, resulted in good performance ruling out high-grade (Gleason 7 or higher) prostate cancer (HGPCa) in prior negative biopsy patients with the previously validated 15.6 cut point that was developed on an initial biopsy cohort. The EPI test yielded a negative predictive value (NPV) of 92% independent of other clinical features and would have avoided 27% of unnecessary prostate biopsies in men while missing only five patients with HGPCa (2.1%).

Initial prostate biopsy often fails to identify prostate cancer, resulting in patient anxiety especially when clinical features such as prostate specific antigen (PSA) remain elevated, and leading to the need for repeat biopsies. For example, in the landmark PROMIS trial study, results showed that a 12-core TRUS-biopsy failed to correctly identify high-grade prostate cancer (Gleason 7 and higher) 37% of the time when cancer was present. These concerns drive many men to undergo repeat biopsy. In fact, the Surveillance, Epidemiology, and End Results (SEER) data indicates that ~12% of men with a prior negative biopsy have a repeat biopsy within 1 year and 44% of men younger than 70 years old have a repeat biopsy.

The EPI test was previously validated in patients presenting for an initial biopsy, and previous data demonstrated that EPI would benefit men with a prior negative biopsy. This study confirms that the ExoDx Prostate test performs exceptionally well in a cohort of men with prior negative biopsies.

Prostate cancer (PCa) is a leading cause of cancer death among men in the United States, with more than 3.6 million men living with prostate cancer. It is estimated that 174,650 newly diagnosed cases occurred in 2019. Prostate needle biopsies are typically recommended for men with elevated serum PSA levels and/or a suspicious digital rectal exam (DRE) with added considerations based on family history, age, and race. The anxiety, pain, and potential complications associated with prostate biopsy are well documented. Furthermore, a large percentage of newly diagnosed prostate cancers are indolent, clinically insignificant, and with low metastatic potential. These cancers typically do not require definitive treatment and may be managed most effectively with Active Surveillance (AS). The low specificity of PSA which contributes to the high frequency of newly-diagnosed low-risk PCa suggests that 60–70% of men may be able to avoid biopsy.

Dr. Johan Skog, Chief Scientific Officer for Exosome Diagnostics, stated, "This study builds

upon the results of the original validation study evaluating men considering initial biopsy. Here we further demonstrated the clinical benefit for men with a prior negative biopsy to utilize the EPI test. A score below the validated cut-point of 15.6 indicates lower risk for finding high-grade prostate cancer on biopsy, with an NPV of 92% indicating a biopsy can be avoided with a high degree of confidence."

"This study has especially important implications for men who have had a prior negative biopsy but where clinical factors suggest a repeat biopsy may be necessary," commented Chuck Kummeth, President and Chief Executive Officer of Bio-Techne Corporation. "The ExoDx Prostate test use in the prior negative biopsy population can increase confidence in both the patient and the physician to determine if an additional biopsy is warranted or if it can be safely deferred. The ExoDx Prostate Test provides the information necessary for men to make more informed decisions about initial or repeat biopsies."

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