

Bio-Techne Announces ExoDx Prostate Test Data Publication in the Journal of Prostate Cancer and Prostatic Diseases

MINNEAPOLIS, Oct. 13, 2021 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced that Exosome Diagnostics, a Bio-Techne brand, has published important clinical research in the journal *Prostate Cancer and Prostatic Diseases*, entitled [Predicting high-grade prostate cancer at initial biopsy: clinical performance of the ExoDx \(EPI\) Prostate Intelliscore test in three independent prospective studies](#). In this pooled analysis from three independent prospective-validation studies and more than 1200 subjects, principal investigator Dr. Erik Margolis, Chief of Urology at Englewood Hospital and Medical Center, and colleagues demonstrated the ExoDx Prostate test, or EPI, can discriminate high-grade (\geq GG2) from low-grade (GG1) cancer and benign disease. In the pooled cohort, the validated cut-off of 15.6 would avoid 23% of all prostate biopsies and 30% of "unnecessary" (benign or Gleason 6/GG1) biopsies, with a negative predictive value (NPV) of 90%.

The EPI test was previously independently validated in two prospective multi-site studies and the control arm of a clinical utility study that evaluated EPI in the biopsy decision process between physician and patient. This pooled analysis study consistently confirms that the ExoDx Prostate test effectively guides the biopsy-decision process independent of PSA and other standard of care factors.

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 249,000 newly diagnosed cases and 34,000 deaths will occur in 2021. 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, "Both the National Comprehensive Cancer Network (NCCN) and United States Preventive Task Force (USPSTF) updated guidelines support shared decision making between men and their physician for PSA screening to reduce overdiagnosis and overtreatment of indolent prostate cancer." He continued, "The NCCN guidelines included the EPI test for early detection of prostate cancer as another datapoint independent of PSA to enable patients and their physicians to make more informed decisions regarding prostate biopsies."

"This study provides additional data supporting the power of the EPI test as a tool for men

with indeterminate PSA scores to utilize to potentially avoid an unnecessary prostate biopsy procedure," said Chuck Kummeth, Bio-Techne's President and Chief Executive Officer. "We look forward to continuing to empower men with the EPI test in the future."

[About Bio-Techne Corporation](#) (NASDAQ: TECH)

Contact: David Clair, Senior Director, Investor Relations & Corporate Development

david.clair@bio-techne.com

612-656-4416

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