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Bio-Techne Announces Publication of Data Demonstrating Additional Clinical Validation of its EPI Test in European Urology Journal

MINNEAPOLIS, Sept. 18, 2018 /PRNewswire/ -- Bio-Techne today announced the online publication of its second prospective US clinical validation study of the Exosome Diagnostics-branded ExoDx® *Prostate(IntelliScore)* (EPI) in European Urology [McKiernan J, et al. A Prospective Adaptive Utility Trial to Validate Performance of a Novel Urine Exosome Gene Expression Assay to Predict High-grade Prostate Cancer in Patients with Prostate-specific Antigen 2–10 ng/ml at Initial Biopsy. Eur Urol (2018)], a high-impact international peer-reviewed urology journal. The published data confirm the findings of the first US prospective validation study presented in JAMA Oncology in 2016. The publication also discloses the consensus reached by the study's principal investigators on a care path integrating EPI into the decision about proceeding with an initial prostate biopsy.

"The strength of the results from this second prospective, real-world validation study has confirmed the clinical value of the EPI test," stated the study's lead investigator, James McKiernan, M.D., the John K. Lattimer Professor of Urology and chair of the Department of Urology of the College of Physicians and Surgeons at Columbia University and urologist-in-chief at NewYork-Presbyterian/Columbia. "That conclusion is further underscored by the publication of the study results in the highest impact urology journal in the world. As a practicing clinician, the decision about whether to biopsy a patient with a grey zone PSA (prostate specific antigen) result is challenging. The nature of the EPI test as a genomic biomarker provides a unique and valuable data point for consideration by both urologists and patients in reaching a shared decision about how to proceed," continued McKiernan.

While it is widely accepted that PSA screening has reduced prostate cancer mortality globally, slightly elevated levels of PSA are not specifically associated with prostate cancer. While prostate cancer often results in an elevated PSA, it is not the only condition that can cause a man's PSA levels to rise. Many other non-malignant conditions, including an enlarged prostate (benign prostatic hyperplasia) or inflammation of the prostate (prostatitis) can cause elevated PSA levels. In 2018, the US Preventative Services Task Force (USPSTF) reported that PSA screening leads to a significant number of

unnecessary biopsies, estimated in some studies to be as high as 75%, as well as the overtreatment of low-grade indolent prostate cancers that are non-life threatening. The EPI test is a non-invasive, urine-based, risk stratification test, designed to reduce the number of unnecessary prostate biopsies. Using a proprietary algorithm, the test examines the gene expression levels of three RNA markers associated with High-Grade Prostate Cancer (HGPCa); ERG, PCA3 and SPDEF. Unlike other prostate biomarkers, the EPI test is purely genomic and does not incorporate standard of care parameters or PSA and PSA isoforms into its algorithm, which allows for a completely independent data point for use in the USPSTF-recommended shared-decision making discussion prior to an initial prostate biopsy.

"Through the two independent published clinical validation studies we have demonstrated that EPI can help to avoid up to 30% of unnecessary initial prostate biopsies," stated Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "Combined with the results from our ongoing utility, decision impact, outcome and economic studies, it is clear that EPI helps avoid unnecessary procedures, complications and overtreatment, improves quality of life and eliminates unnecessary healthcare spending. That benefits patients, providers and payers," continued Kummeth.

About the EPI Test

ExoDx® *Prostate(IntelliScore)* (EPI) is the first exosomal urine-based liquid biopsy test, designed to risk stratify patients presenting for prostate biopsy. The test is a purely genomic test that examines the presence of three gene signatures known to be expressed in prostate cancer – SPDEF, ERG and PCA3. Visit epi.exosomedx.com to learn more.

About European Urology

European Urology is the premier specialist journal in the field of Urology and Nephrology. Publishing important, practice challenging manuscripts to educate readers and improve the care of patients. To keep up to date with the rapidly evolving world of medicine, the editorial team regularly review the journal's content, structure and mode of delivery. European Urology publishes peer-reviewed original articles, state of the art reviews and opinion piece editorials on a wide range of urological problems.

About Bio-Techne Corporation (NASDAQ: TECH)

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