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Bio-Techne Announces Publication of ExoDx™ Prostate (IntelliScore) EPI Test Clinical Utility Study

MINNEAPOLIS, May 7, 2020 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced a major publication in the Journal of Prostate Cancer and Prostatic Diseases entitled, *Clinical Utility of the exosome based ExoDx™ Prostate (IntelliScore) EPI test in men presenting for initial Biopsy with a PSA 2-10ng/mL* (link available [here](#)). Principal investigators Dr. Ronald Tutrone, Medical Director of Chesapeake Urology, and Dr. James McKiernan, Professor of Urology at Columbia University, demonstrated the ExoDx Prostate test, or EPI, delivered improved patient outcomes over standard of care in a real-world clinical setting that included 72 urologists, 24 sites and more than 1000 patients. The study is the first ever prospective, multi-center, randomized prostate biomarker trial with a blinded control arm conducted in a clinical utility setting. The study was a collaboration between the largest urology practice in Maryland, Chesapeake Urology, and CareFirst Blue Cross Blue Shield of Maryland.

The EPI test is a urine-based genomic test that helps inform the prostate biopsy decision. This liquid biopsy test recently received coverage for the VA Healthcare system under the General Services Administration (GSA) award, received a positive coverage decision from Medicare, and is included in the National Comprehensive Cancer Network (NCCN) guidelines for early detection in men for both initial and repeat biopsy. It is performed by Exosome Diagnostics™, a Bio-Techne brand, in its CLIA, ISO, and NY certified and CAP-accredited laboratory located in Waltham, Massachusetts. The EPI test is a risk assessment tool that assists physicians and their patients with determining if a prostate biopsy is needed when presented with an ambiguous PSA test result, thereby reducing complications from unnecessary and invasive procedures.

Key findings from the study include:

- When implementing the ExoDx™ Prostate test in a real-world clinical setting, patients demonstrated improved compliance with the physician's recommendation to defer prostate biopsy when the test was negative and go through with a biopsy when the test was positive.
- Twenty-three percent of patients deferred a biopsy due to the EPI test based on the physician-patient shared decision questionnaire.
- In the standard of care setting, many high-grade prostate cancers are missed because not all high-risk men go through with a biopsy.
- Due to improved compliance to proceed to biopsy, physicians detected 30% more cases of clinically significant, or high-grade prostate cancer compared to the standard of care control arm.

These findings can have significant implications for both clinical and economic outcomes.

According to Dr. Ronald Tutrone, "From a clinical perspective, deferring biopsy can help a patient avoid the undesirable complications from a biopsy, such as pain, hematuria, infection and potentially hospitalization. Many patients are frightened to undergo biopsy procedure; however, introducing an EPI result not only improved compliance to proceed to biopsy, but detected more clinically significant cancers that might have been missed under the standard of care paradigm."

"This study has important implications from an economic perspective," commented Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "Avoiding unnecessary biopsy procedures represents an estimated savings to the healthcare system of \$1,400-\$4,000 per patient, in addition to added costs treating complications. There are economic consequences to missing high grade prostate cancer as well. Risk stratification tools such as the ExoDx Prostate test provide the right intervention for the right patient at the right time. Publication of this study in a leading urology journal confirms our convictions that the ExoDx Prostate test provides strong clinical utility and economic value to patients, the medical community and private payors."

A nationwide webinar is scheduled for May 21, 2020 to review the study findings in detail. More information can be found on the Exosome Diagnostics website at <http://www.exosomedx.com>.

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

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