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BIO-TECHNE ANNOUNCES PUBLICATION OF NEW DATA DEMONSTRATING EXODX PROSTATE TEST CORRELATION WITH POST-PROSTATECTOMY PATHOLOGY OUTCOMES

MINNEAPOLIS, Feb. 14, 2022 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced an important publication in World Journal of Urology, entitled [Pre-diagnosis urine exosomal RNA \(ExoDx EPI score\) is associated with post-prostatectomy pathology outcome](#). Principal investigator Dr. Alexander Kretschmer, urologist from Ludwig Maximilian University of Munich, Germany, and colleagues demonstrated utility of the ExoDx™ Prostate test, or EPI, to address limitations related to prostate biopsy sampling error, prostate biopsy bias as well as multifocality of the disease, providing a more relevant assessment of low-risk men who could remain on active surveillance. The significance of this study is that in men with an EPI score below the cut-point of 15.6, the ExoDx Prostate test could prevent low-risk men from proceeding to radical prostatectomy.

According to the American Cancer Society, active surveillance is often used to monitor prostate cancer closely. Usually this includes a doctor visit with a prostate-specific antigen (PSA) blood test about every 6 months and a digital rectal exam at least once a year. Prostate biopsies and imaging tests may be done every 1 to 3 years. If test results change, the doctor would then discuss treatment options. Active surveillance is less invasive and a preferable option for men versus radical prostatectomy surgery that entails removal of the entire prostate gland and surrounding lymph nodes.

The study consisted of 2,066 subjects and explored the applicability of an exosome-based, non-invasive urine test for men with low-risk disease considering active surveillance. When EPI scores were evaluated for men with grade group 1 (GG1) on biopsy, those men who were upgraded to grade group 3 (≥GG3), had significantly higher scores compared to men that remained GG1 post radical prostatectomy. In contrast, neither PSA nor any of the standard multiparametric risk calculators provided any discrimination between these groups. Further, in this cohort, zero cases were upgraded to ≥GG3 when the EPI scores were below the cut-point of 15.6 resulting in a high NPV (100%) for ruling out ≥GG3.

The EPI test was previously validated in patients presenting for an initial biopsy as well as men with a prior negative biopsy. This study confirms that the ExoDx Prostate test also performs exceptionally well to predict which men will not be upgraded ≥GG3 at subsequent radical prostatectomy.

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 more than 248,000 newly diagnosed cases occurred in 2021. 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. 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. Alexander Kretschmer, urologist from Ludwig Maximilian University of Munich, Munich, Germany, stated, "From the clinical perspective, active surveillance (AS) is still underused in eligible patients with low-risk localized prostate cancer and more tools are necessary to inform AS decisions. This study demonstrated the EPI test accurately identified men with GG1 at biopsy who remained GG1 post-radical prostatectomy (RP) compared to men upgraded to \geq GG3 post-RP ($p < 0.001$). Since the EPI test was associated with low-risk pathology post-RP, and can be a valuable tool for urologists informing AS decisions."

"This study has important implications for up to 75% of men who would be eligible for an active surveillance program and potentially avoid radical prostatectomy," commented Chuck Kummeth, President and Chief Executive Officer of Bio-Techne Corporation. "Using ExoDx Prostate to predict which men can undergo active surveillance is an exciting and substantial advancement for men with a diagnosis of low-grade prostate cancer. The ExoDx Prostate Test provides the right intervention, for the right patient, at the right time."

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

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