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Bio-Techne's Exosome Diagnostics Laboratory Announces CE-IVD Certification For ExoDx Prostate Test

MINNEAPOLIS, March 23, 2021 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced that Exosome Diagnostics, a Bio-Techne brand, has completed its clinical validation of an in vitro diagnostic (IVD) version of the ExoDx™ Prostate test (EPI) kit enabling self-certification as CE-IVD as of March 22, 2021. The EPI-CE test will be performed immediately in our Munich ISO 15189 accredited clinical laboratory and be made available throughout Europe through various distribution channels.

Exosome Diagnostics is the world leader in developing exosomal liquid biopsy-based diagnostic assays. The EPI test is a non-invasive, urine-based genomic test that helps inform the prostate biopsy decision. This liquid biopsy test continues to expand its presence and usage among urologists and primary care physicians in the US. 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. The EPI-CE test demonstrated comparable results to the US ExoDx Prostate test with high sensitivity of 92% and high negative predictive value (NPV) of 89% for ruling out clinically significant prostate cancer.

These findings can have significant implications for both clinical and economic outcomes. According to Alexander Kretschmer, M.D., Assistant Professor of Urology at Ludwig-Maximilians-University Munich, "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 the biopsy procedure; however, introducing an EPI test can identify which patients should proceed to biopsy, and which patients can avoid biopsy, so it's really about performing the procedure for the right patient at the right time."

"The EPI test could have important implications from an economic perspective in Europe and the UK," commented Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "Avoiding unnecessary biopsy procedures represents an estimated savings to the healthcare system in Europe of more than €1,000 per patient, in addition to added costs for treating complications. There are economic consequences to missing high grade prostate cancer as well. Risk stratification tools such as the ExoDx Prostate test can help appropriately guide clinicians to treat the highest risk patients earlier. We look forward to enabling European men to make more informed decisions on whether to proceed with an invasive, and potentially dangerous, prostate biopsy."

For more information on how to order tests, please contact us at epi-emea@bio-techne.com.

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

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