

March 8, 2021



Bio-Techne Announces ExoTRU Kidney Transplant Rejection Assay Data Publication

MINNEAPOLIS, March 8, 2021 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) today announced that Exosome Diagnostics, a Bio-Techne brand, has published preliminary data on its kidney transplant rejection test, ExoTRU™ (Exosome Transplant Rejection Urine), a non-invasive multigene urine-based exosomal mRNA assay. ExoTRU was developed in collaboration with the Azzi laboratory at the Transplantation Research Center at Brigham and Women's Hospital, Harvard Medical School. The ExoTRU test will be the first ever commercially available test capable of discriminating between types of kidney rejection, providing critical information to assist clinician decision making and optimize patient care. The ExoTRU test is expected to launch in calendar 2021 and will be performed in Exosome Diagnostics' CLIA-certified, CAP-accredited laboratory in Waltham, Massachusetts.

The paper entitled, "[Discovery and Validation of a Urinary Exosome mRNA Signature for the Diagnosis of Human Kidney Transplant Rejection](#)," was published this month in the peer-reviewed publication, Journal of the American Society of Nephrology by Dr. Jamil Azzi, Associate Professor of Medicine at Harvard Medical School and a physician scientist at the Brigham and Women's Transplantation Research Center. The study demonstrated high stability of urinary exosomes and reliability in monitoring patients for allograft rejection. The assay discriminates between "any-cause rejection vs. no rejection" with a negative predictive value (NPV) of 93.3% and positive predictive value (PPV) of 86.2% and differentiates between "T-cell mediated rejection (TCMR) vs. antibody mediated rejection (ABMR)" with a NPV of 90.6% and PPV of 77.8%. The assay's ability to discriminate between TCMR and ABMR is critical to improving patient management and outcomes. The current standard of care relies on measuring changes in serum creatinine levels, which has poor sensitivity and specificity for detecting kidney transplant rejection, and can rise and fall due to numerous factors, leading to challenges making therapeutic decisions in a timely manner. Utilization of needle biopsy procedure and histology is more accurate; however, this method introduces additional risks and potential complications, leading to higher costs and increased morbidity.

According to Dr. Azzi, "Kidney transplant providers currently have sub-optimal tools to care for transplant patients and need more reliable tools to ensure post-operative success of kidney transplants, particularly for those patients that are far from academic centers." He continued, "There is increased risk for non-compliance in patients after one year as most cannot continue check-ups due to logistical or resource constraints. Non-compliance after the first year can lead to subclinical rejections, kidney fibrosis, and mortality, as well as increased costs to the healthcare system. I expect the non-invasive urine-based ExoTRU test will be well-received among transplant care providers as patients can easily provide a urine sample from the comfort and convenience of their home, enabling improved allograft monitoring."

"ExoTRU is an important test to improve the management and care of kidney transplant patients," said Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "With ExoDx Prostate (EPI) already commercially available, ExoTRU will be the second innovative liquid biopsy test launched by the Exosome Diagnostics team. We look forward to continued development and commercialization of our rich pipeline of diagnostic tests leveraging the power of exosomes."

See press release from Brigham and Women's Hospital [here](#).

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

Contact: David Clair, Senior Director, Investor Relations & Corporate Development
david.clair@bio-techne.com
612-656-4416

View original content to download multimedia: <http://www.prnewswire.com/news-releases/bio-techne-announces-exotru-kidney-transplant-rejection-assay-data-publication-301241689.html>

SOURCE Bio-Techne Corporation