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FDA Grants Breakthrough Device Designation To Bio-Techne's ExoDx™ Prostate IntelliScore™ (EPI) Test

MINNEAPOLIS, June 17, 2019 /PRNewswire/ -- Bio-Techne today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to its ExoDx Prostate IntelliScore (EPI) test, making it the first exosome-based liquid biopsy test to receive a Breakthrough Device Designation. This designation not only validates the clinical importance of Bio-Techne's EPI test, it also marks a milestone in the advancement of the company's patented technology platform.

The Breakthrough Devices Program is intended to accelerate the regulatory review process for certain medical devices and device-led combination products that provide a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products that are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. The Breakthrough Device program is designed to expedite the development, assessment and review of these products through interactive and timely communication, pre/post-market balance of data collection, efficient and flexible study design, review team support, senior management engagement and priority review so that patients can have more timely access to these medical devices.

"By granting our EPI test Breakthrough Device Designation, the FDA is acknowledging that there is a need to avoid unnecessary prostate biopsies and that our test helps address this concern," said Charles R. Kummeth, President and Chief Executive Officer of Bio-Techne. "Additionally, the FDA is recognizing the benefit of our approach in analyzing exosomes to provide rapid, patient specific information to guide diagnosis and treatment decisions. Breakthrough Device Designation will accelerate our efforts to secure FDA clearance for our EPI test, which is part of our commitment to offer products that are supported by rigorous clinical data. This designation, combined with the recent updates to include the EPI test in the National Comprehensive Cancer Network (NCCN) guidelines and the draft Medicare Coverage Determination, is a collective recognition by the clinical community of the value of our test. We expect these actions will result in increased access to the EPI test for men faced with the difficult decision whether to proceed with an initial prostate biopsy."

About Bio-Techne Corporation (NASDAQ: TECH)

Contact:
David Clair
Investor Relations
ir@bio-techne.com
Phone: 646-277-1266

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