

Medicare Issues Final Local Coverage Decision For Bio-Techne's ExoDx™ Prostate(IntelliScore) Test

MINNEAPOLIS, Oct. 10, 2019 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced that the Medicare Administrative Contractor (MAC) National Government Services, Inc. issued a final Local Coverage Decision (LCD) covering the ExoDx Prostate(IntelliScore) – EPI – test for men who are being considered for an initial prostate biopsy. The decision is effective for tests administered on or after December 1, 2019. Following the LCD finalization, more than 60 million Medicare beneficiaries will now be covered for the EPI test effective December 1, 2019.

The EPI test is a non-invasive, non-DRE requiring, urine-based, liquid biopsy test intended for men 50 years of age and older who have an elevated Prostate Specific Antigen (PSA) level between 2 – 10 ng/mL and who are being considered for a prostate biopsy. This liquid biopsy test recently received FDA Breakthrough Designation and is included in the NCCN guidelines for early detection in men for both initial and repeat biopsy. It is performed by Exosome Diagnostics, a Bio-Techne brand, in the CLIA, ISO, and NY certified laboratory located in Waltham, Massachusetts, which has processed over 30,000 patient tests to date. 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.

"It's been an extraordinary year for our ExosomeDx platform," commented Chuck Kummeth, Chief Executive Officer of Bio-Techne. "To achieve the NCCN guideline status after two remarkable patient studies was a great success for the ExosomeDx team and the company but attaining FDA breakthrough status was a testament to the strong promise this technology platform can bring to diagnosing cancer. Receiving a final LCD from National Government Services in record time, thus allowing Medicare reimbursement, signals the beginning of scaling this game-changing technology. I look forward to the many new indications to come in both urine and blood."

About Bio-Techne Corporation (NASDAQ: TECH)

Contact: David Clair

david.clair@bio-techne.com

612-656-4416

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