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BIO-TECHNE RECEIVES EUROPEAN IVDR CERTIFICATION FOR DIAGNOSTIC TEST TO MONITOR CHRONIC MYELOID LEUKEMIA

The QuantideX® qPCR BCR-ABL IS Kit is now compliant with the latest diagnostic regulations in Europe

MINNEAPOLIS, March 22, 2024 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) today announced that Asuragen, part of Bio-Techne's Molecular Diagnostics Division, has completed the Class C Certification under the new European Union In Vitro Diagnostic Regulation (IVDR) for its QuantideX® qPCR BCR-ABL IS Kit. Previously, the kit was CE-IVD marked for sale in the EU in compliance with the In Vitro Diagnostic Directive (IVDD), which has now been replaced by the IVDR.

The QuantideX qPCR BCR-ABL IS Kit gives labs a robust and reliable tool for monitoring chronic myeloid leukemia (CML) patients. The highly sensitive qPCR-based in vitro diagnostic test quantifies BCR-ABL1 and ABL1 transcripts in blood samples from patients with CML to determine their response to tyrosine kinase inhibitor (TKI) therapy. CML patients must undergo regular monitoring to ensure that they continue to receive the most appropriate treatment for their cancer. The QuantideX kit allows for direct reporting on the International Scale and further streamlines the workflow with easy-to-use analysis software. Clinical lab scientists can run up to 49 samples per plate for a scalable solution.

"Bio-Techne is dedicated to quality and compliance, and we applaud this new IVDR for strengthening the safety and performance requirements for diagnostic products," said Matt McManus, President of Bio-Techne's Diagnostics & Genomics Segment. "We are proud to achieve this new certification and will continue to provide the molecular diagnostic and liquid biopsy solutions that deliver world-class performance, scalability, and reliable results for the laboratory scientists, physicians, and patients who count on us."

About Bio-Techne:
Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities. Bio-Techne products assist scientific investigations into biological processes and the nature and progress of specific diseases. They aid in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With thousands of products in its portfolio, Bio-Techne generated over $1.1 billion in net sales in fiscal 2023 and has approximately 3,100 employees worldwide. For more information on Bio-Techne and its brands, please visit https://www.bio-techne.com or follow the Company on social media at: Facebook, LinkedIn, Twitter or YouTube.

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