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MAURICE icIEF ESTABLISHED AS A GREEN METHOD FOR CHARACTERIZATION OF AAV IDENTITY AND STABILITY

MINNEAPOLIS, Aug. 25, 2022 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) announced the publication of a study in the *Green Analytical Chemistry* journal, titled *Establishment of a Platform Imaged Capillary Isoelectric Focusing (icIEF) Characterization Method for Adeno-Associated Virus (AAV) Capsid Proteins*. The study, led by Jiaqi Wu, Ph.D., and Chris Heger, Ph.D., describes an icIEF method on Maurice, the flagship CE (capillary electrophoresis) instrument by ProteinSimple (a Bio-Techne brand) for the development, platform suitability, and environmental friendliness (greenness) in evaluating the identity and stability of AAV samples for gene therapy development. This publication highlights not only Maurice's functionality and efficiency, but also its environmentally friendly impact.

The icIEF method described in this study used native fluorescence (NF) detection and was validated against the ICH Q6B guidelines to determine its precision, linearity, and limit of quantitation. It fared well on all three fronts. The precision was good for both percent peak area (relative standard deviation under 5%) and apparent p*I* (isoelectric point) values (standard deviation under 0.01 pH units). Linearity was sound, resulting in an excellent R^2 value of 0.998, and the LOQ was 2.6 x 10^{10} VP/mL. This validated method was then used to evaluate charge and stability profiles of different AAV serotypes. The resulting charge profiles were distinct, even between serotypes that differed only by six amino acids, and showed clear changes in charge profiles over time, thus rendering this method suitable for identity and stability of viral serotypes.

The greenness of the validated icIEF method was evaluated using the principles of *White Analytical Chemistry* (WAC), which is a three-pronged approach that assesses an analytical method for its efficiency, environmental friendliness and safety, and practicality. The reported icIEF method scored 88.8, 92.5, and 87.9 under the three criteria, respectively. The overall score of this method was 89.7, undeniably making it a sustainable one, which is a key requirement for being published in *Green Analytical Chemistry.*

The data presented in this publication shows that confirming the identity and stability of AAV samples can be a fast and efficient process with Maurice, unlike with other commonly used more laborious methods (SDS-PAGE, ion-exchange chromatography, etc.). Additionally, the Maurice icIEF method is environmentally friendly, owing to its NF detection capability, low sample/reagent volume requirement, and the cartridge design with its in-built waste reservoir.

"Maurice is already widely known in the biopharma industry for its unparalleled ease-of-use

and high-quality, reproducible data for CE analysis," said Will Geist, Bio-Techne's Protein Sciences Segment President. "Now, with this publication having demonstrated the greenness of this analytical method, scientists can have confidence not just in their data, but also in the low impact their work has on the environment."

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 approximately $1.1 billion in net sales in fiscal 2022 and has approximately 3,000 employees worldwide. For more information on Bio-Techne and its brands, please visit http://www.bio-techne.com

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