

April 12, 2022



BIO-TECHNE AND CYGNUS TECHNOLOGIES, PART OF MARAVAI LIFESCIENCES, INTRODUCE NEW SIMPLE PLEX HEK 293 HCP 3G IMMUNOASSAY

MINNEAPOLIS, April 12, 2022 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) and Cygnus Technologies, part of Maravai LifeSciences (NASDAQ: MRVI), announced today the launch of the Simple Plex™ HEK 293 HCP 3G assay for automated process impurity testing on the Ella™ immunoassay platform.

Purification of viral particles to minimize host cell protein (HCP) contaminants is a crucial aspect of the viral production workflow in [cell and gene therapy](#) applications. Accurate quantitation across process steps is needed to ensure HCP impurity clearance is achieved in accordance with regulatory guidelines.

Utilizing a cartridge-based microfluidic design, the new Simple Plex HEK 293 HCP 3G assay provides consistent and controlled assay conditions for HCP detection that is exceptionally accurate and reproducible. The assay features a streamlined hands-free workflow and results in 90 minutes, giving therapeutic developers a robust and convenient tool for HCP impurity quantitation. Unlike traditional immunoassay methods, Simple Plex assays on the Ella platform employ built in calibration to minimize set up time and user dependent variability.

Cygnus Technologies' HEK 293 HCP ELISA Kit, 3G is considered the gold standard in HEK 293 HCP impurity quantification. The antibody used in the kit has been evaluated for reactivity to nearly 3,000 individual HCPs present in HEK 293 strains by state-of-the-art antibody affinity extraction and mass spectrometry methods. The kit has been qualified with many viral vector-based drug substances and in-process samples, providing the specificity and sensitivity to detect HEK 293 HCP impurities with reproducibility that supports regulatory compliance. The Simple Plex HEK 293 HCP 3G assay features the same HEK 293 HCP antibodies from industry leader Cygnus Technologies, ensuring the broad HCP detection coverage and industry recognized specificity of the Cygnus ELISA, along with the workflow advantages of the automated Ella platform.

"We continue to enjoy the fruits of the Bio-Techne-Cygnus Technologies partnership as it provides the therapeutic development and manufacturing community an automated platform-based approach for HEK 293 host cell impurity testing," commented Will Geist, President of Bio-Techne's Protein Sciences Segment. "Fast and efficient process development and monitoring is crucial for biopharmaceutical companies providing a safe and efficacious product in a cost-effective manner."

"The field of cell and gene therapy development has experienced exciting growth as the FDA and other regulatory agencies around the world have supported companies developing

new cell and gene therapy products," said Christine Dolan, Cygnus Technologies Chief Operating Officer. "To support their projects, process development and manufacturing quality control, teams need faster and higher throughput HCP impurity assays. The new Simple Plex HEK 293 HCP 3G assay provides an automation solution for fast and efficient bioprocess impurity testing to address our customer needs."

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 \$931 million in net sales in fiscal 2021 and has approximately 2,700 employees worldwide. For more information on Bio-Techne and its brands, please visit <http://www.bio-techne.com>

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About Cygnus Technologies

Cygnus Technologies, part of Maravai LifeSciences, is the biopharmaceutical industry's partner in host cell protein (HCP) and other process-related impurity detection and analytics as well as in innovative viral clearance solutions. Cygnus helps companies developing therapeutic proteins, vaccines, antibodies, plasma derivatives and gene therapies to ensure the safety of biotherapeutics prior to human trials, regulatory approval and commercial release. For more information on Cygnus Technologies, please visit www.cygnustechnologies.com

About Maravai

Maravai is a leading life sciences company providing critical products to enable the development of drug therapies, diagnostics and novel vaccines and to support research on human diseases. Maravai's companies are leaders in providing products and services in the fields of nucleic acid synthesis and biologic safety testing to many of the world's leading biopharmaceutical, vaccine, diagnostics, and cell and gene therapy companies. For more information about Maravai LifeSciences, visit www.maravai.com.

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