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Bio-Techne And Kantaro Biosciences Announce Partnership To Develop And Scale Production Of COVID-19 Serology Test

MINNEAPOLIS and NEW YORK, May 19, 2020 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) and the Mount Sinai Health System in New York, through its commercial affiliate Kantaro Biosciences LLC (Kantaro), today announced a partnership to initiate scaled manufacturing and distribution of testing kits based on the Mount Sinai-developed COVID-19 serology test. Kantaro Biosciences is a joint venture between Mount Sinai Health System ("Mount Sinai") and Renalytix AI (LSE: RENX) formed exclusively to ensure that diagnostic tests for critical health challenges are accessible to all. The Mount Sinai COVID-19 serology test was one of the first widely published serology tests in the United States and has gained recognition as a trusted, high-performing assay and comparator for subsequent COVID-19 serology tests. Kantaro has partnered with Bio-Techne to develop a test kit based on the Mount Sinai test and to scale up, manufacture, sell and distribute these kits. Initial kit production capacity is expected to enable laboratories to conduct in excess of 10 million tests monthly in July, scaling to higher capacity in subsequent months. The two companies have formed a joint commercialization and distribution team to support rapid distribution of the assay.

Mount Sinai was issued an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for clinical testing in its CLIA certified laboratory on April 15th. Based on this success, Bio-Techne and Mount Sinai have partnered to develop high-quality production test kits, based upon the Mount Sinai test, which can be manufactured and distributed globally at scale. Kantaro will lead regulatory processes with the intention of submitting the scaled assay for FDA EUA review in May. Kit shipments are expected to begin immediately following the receipt of FDA regulatory authorization.

The IgG antibody test kit, an enzyme-linked immunosorbent assay or ELISA, is designed to measure the presence or absence of anti-COVID-19 antibodies in addition to measuring the titer (level) of antibodies a person has produced. It utilizes not one, but two virus antigens, the full-length Spike protein, and its Receptor Binding Domain, which is necessary for viral entry into cells, and is potentially linked with neutralization. The test kit will use a simple patient blood draw and is designed to be easily run by any laboratory in the world without costly proprietary equipment. The technology underlying the diagnostic test was created by internationally recognized virology and pathology teams from the Icahn School of Medicine at Mount Sinai.

In a recent comparison of EUA tests published by the FDA ([link](#)), which assumed a 5% incidence of COVID-19 in the population, the "Mount Sinai Hospital Clinical Laboratory COVID-19 ELISA Antibody Test" was reported to show a Positive Predictive Value (the

probability of disease if the test is positive) of 100% and a Negative Predictive Value (the probability of no disease if the test is negative) of 99.6%. Bio-Techne and Kantaro are in the process of validating the scaled assay and expect the data to confirm similar results.

"Combining Mount Sinai's strengths in disease management, patient monitoring and clinical study design with Bio-Techne's capabilities as a fully integrated, world leading ELISA developer and manufacturer, allows us to co-develop and validate what we believe will be the highest quality and highest utility assay for COVID-19 in the world," commented Dave Eansor, Bio-Techne's Protein Sciences Segment President. "The assay not only identifies individuals with prior exposure to the COVID-19 virus; the two step test is designed to minimize false negative and false positive results while delivering valuable, quantitative information regarding the immunity state of previously infected people."

"We are extremely excited to partner with Kantaro and Mount Sinai to launch what we believe will be a gold standard serology test for COVID-19," said Chuck Kummeth, President and Chief Executive Officer of Bio-Techne. "The Bio-Techne, Mount Sinai and Kantaro teams are working around the clock to develop this test, and we are on track to achieve in approximately eight weeks what would typically take 18 months or more. As the world leader in ELISA assays, Bio-Techne has substantial capacity and the ability to scale production levels to support much of our nation's needs. We look forward to providing the world with critical information related to past exposure to the virus."

"Antibody testing will be critical to providing patients and governments the essential information they need to help the world economies reopen and begin to recover from COVID-19," said Florian Krammer, PhD, Professor of Microbiology at Icahn School of Medicine. "Through Kantaro's partnership with Bio-Techne, we look forward to bringing this extremely high-quality test to every corner of the globe, so that COVID-19 can be monitored and isolated."

The original Mount Sinai assay has been performed on more than 30,000 patient samples. Mount Sinai is studying the use of the technology to measure antibody titer in previously infected individuals, to support vaccine development, and to help evaluate emerging immunotherapies.

Forward Looking Statements:

Bio-Techne's press releases may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Such statements involve risks and uncertainties that may affect the actual results of operations. The following important factors, among others, have affected and, in the future, could affect Bio-Techne's actual results: the market for and introduction, acceptance and performance of new products, obtaining the appropriate regulatory approvals, the impact of the growing number of producers of biotechnology products, including COVID-19 testing products, and related price competition, general economic conditions, manufacturing and supply chain disruptions, and the potential impact of COVID-19 on our operations or financial results.

For additional information concerning these and other such factors, see the section titled "Risk Factors" in Bio-Techne's annual report on Form 10-K and quarterly reports on Form 10-Q as filed with the Securities and Exchange Commission. Bio-Techne undertakes no obligation to update or revise any forward-looking statements made in its press releases due

to new information or future events. Investors are cautioned not to place undue emphasis on these statements.

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 \$714 million in net sales in fiscal 2019 and has over 2,200 employees worldwide. For more information on Bio-Techne and its brands, please visit www.bio-techne.com.

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About Kantaro Biosciences

Kantaro Biosciences ("Kantaro"), a Mount Sinai Health System venture, is dedicated to ensuring that diagnostic tests for critical health challenges are accessible to all. The company provides academically rigorous, validated and results-driven diagnostics to advance the wellbeing of people, communities and society. Kantaro specializes in the rapid scaleup of groundbreaking diagnostic innovations and the creation of partnerships to bring these crucial technologies to market. The company is majority owned and controlled by Mount Sinai. For more information, visit www.kantarobio.com.

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care—from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Reports* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians are in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit <https://www.mountsinai.org> or find Mount Sinai on [Facebook](#), [Twitter](#) and [YouTube](#).

About Renalytix AI

Renalytix AI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com

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