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EKF Diagnostics Holdings PLC
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**EKF Diagnostics Holdings plc
("EKF", the "Company" or the "Group")**

COVID-SeroKlir receives FDA Emergency Use Authorisation

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, welcomes the news from its partner Kantaro Biosciences, LLC ("Kantaro") yesterday confirming that it had received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for COVID-SeroKlir, its semi-quantitative SARS-CoV-2 IgG antibody test kit.

EKF has exclusive rights to market and distribute COVID-SeroKlir, a quantitative SARS-CoV-2 IgG antibody test kit, in the UK and Germany and non-exclusive rights in Europe. The statement from Kantaro is reproduced in full below:

Kantaro Receives FDA Emergency Use Authorization for Semi-Quantitative COVID-19 Antibody Test Kit that Detects the Presence and Level of SARS-CoV-2 IgG Antibodies

COVID-SeroKlir is a high-performance semi-quantitative antibody test kit based on Mount Sinai technology, with a broad range of applications in the fight against COVID-19

The Kantaro test is being manufactured at scale and immediately available in the U.S.

NEW YORK, November 24, 2020 - Kantaro Biosciences, LLC, a joint venture between the Mount Sinai Health System and RenalytixAI (NASDAQ: RNLX), has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for COVID-SeroKlir, its semi-quantitative SARS-CoV-2 IgG antibody test kit. Unlike other antibody tests, COVID-SeroKlir determines the presence and precise level of IgG antibodies and has a broad range of applications in the fight against COVID-19. Through a commercial partnership with Bio-Techne Corporation (NASDAQ: TECH) the test kits are being manufactured at scale with a capacity of up to 10 million tests per month and the ability to scale up.

COVID-SeroKlir has demonstrated 98.8% sensitivity and 99.6% specificity for detecting SARS-CoV-2 specific IgG antibodies against two virus antigens, the full-length spike protein and its receptor-binding domain. COVID-

SeroKlir is a two-step enzyme-linked immunosorbent assay (ELISA) and can be used by any CLIA-certified laboratory without the need for proprietary equipment. The Kantaro test kit received CE mark in October 2020 and is available in 29 countries in Europe.

"COVID-SeroKlir is based on Mount Sinai technology that was developed at the height of the COVID-19 pandemic in New York City," **said Sara Barrington, Kantaro's chief commercial officer.** "It is a high performing test that quantifies antibody levels for individuals, which medical professionals and policymakers alike can trust. Having a numerical understanding of antibody levels can be especially powerful for patients, enabling them to take control of their health and enjoy some peace of mind during these uncertain times."

Measuring IgG antibody levels with COVID-SeroKlir can inform healthcare decision-making and public health strategies, as well as assess vaccine response. Semi-quantitative antibody testing is also an essential component of a general health check to determine past COVID-19 infections. An increased risk of potentially life-threatening complications, including lung, kidney, and cardiovascular disease, has been linked to COVID-19.

"Widespread testing is critical in the fight against COVID-19. With this EUA in hand, we are ready to immediately supply this best-in-class serologic assay to clinicians across the U.S.," **said Chuck Kummeth, president and chief executive officer of Bio-Techne Corporation.** "Manufacturing will begin with a capacity of up to 10 million tests per month. We anticipate that COVID-SeroKlir will play an increasingly important role in the decision making of healthcare providers and policymakers and are prepared to scale up to meet additional demand."

Mount Sinai developed the underlying technology in COVID-SeroKlir, which has been used and validated in a highly diverse population of over 80,000 patient samples. The peer-reviewed journal [Science](#) recently published five-month data from an ongoing Mount Sinai study using the underlying technology. Data show that most people who have had COVID-19 mount a robust antibody response that remains relatively stable for at least five months following infection. This antibody response correlates with the body's ability to neutralize SARS-CoV-2.

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About EKF Diagnostics Holdings plc (www.ekfdiagnostics.com)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate analyzers in regular use across more than 100 countries. EKF specializes in

developing tests for use in anemia and diabetes diagnosis and management, as well as providing a portfolio of reagents for use in clinical chemistry analyzers.

About Kantaro Biosciences

Kantaro Biosciences ("Kantaro"), a Mount Sinai Health System venture, is dedicated to ensuring that high-quality diagnostic tests for critical health challenges are accessible. The company provides rigorous, results-driven and reproducible diagnostics to advance the care and well-being of people, communities and society. Kantaro specializes in the rapid scale-up of groundbreaking diagnostic innovations and the creation of partnerships to bring these crucial technologies to market. For more information, visit www.kantarobio.com and follow Kantaro on Twitter @kantarobio.

About Bio-Techne Corporation

Bio-Techne Corporation (NASDAQ: [TECH](https://www.tech.com)) 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 \$739 million in net sales in fiscal 2020 and has over 2,300 employees worldwide. For more information on Bio-Techne and its brands, please visit www.bio-techne.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 Report's* "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 plc

RenalytixAI 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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