UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 18, 2020

BIO-TECHNE CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Minnesota	**0-17272**	**41-1427402**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

614 McKinley Place NE
Minneapolis, Minnesota 55413
(Address of Principal Executive Offices) (Zip Code)

(612) 379-8854
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TECH	NASDAQ

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

☐ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry Into a Material Definitive Agreement.

On May 18, 2020, Bio-Techne Corporation (the "Company") entered into a Development, Supply and Commercialization Agreement (the "Agreement") with Kantaro Biosciences LLC ("Kantaro"), a limited liability company majority owned and controlled by Icahn School of Medicine at Mount Sinai ("Mount Sinai"). The Agreement sets forth the terms and conditions under which the parties will undertake the activities necessary to manufacture and commercialize serologic test kits to detect and measure the presence of antibodies to the COVID-19 virus in humans (the "Serology Tests").

The Agreement sets forth the responsibilities of each party with respect to the co-development of the Serology Tests, with the Company developing the Serology Tests based on a prior test developed by Mount Sinai and in accordance with specifications agreed to by the parties. Kantaro will validate the Serology Tests, and will apply to the FDA for Emergency Use Authorization to market and sell the tests. Kantaro will be the registered holder of the EUA. Each party owns any intellectual property it developed prior to the collaboration; any intellectual property developed during the collaboration shall be co-owned by the parties.

Upon FDA's grant of Emergency Use Authorization, which shall be held by Kantaro, the Agreement further describes the Company's responsibilities, as the contract manufacturer, to manufacture the Serology Tests to meet certain minimum specified quantities. The Company will be responsible for certain commercial functions associated with sales and delivery of the Serology Tests to customers and will share revenue with Kantaro.

The Agreement also anticipates that Kantaro will apply for FDA clearance after the Emergency Use Authorization expires, as well as subsequent manufacture and commercialization of "Research Use Only" equivalent kits by the Company.

The initial term of the Agreement is five years, after which the Agreement automatically extends for additional successive twelve-month terms absent delivery of prior written notice of non-renewal by either party.

A copy of the Agreement is attached as Exhibit 10.1 and a copy of the press release announcing the entry into the Agreement is attached as Exhibit 99.1 to this Current Report on Form 8-K and both are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

10.1	Development, Supply and Commercialization Agreement by and between Bio-Techne Corporation and Kantaro Biosciences, LLC dated May 18, 2020 (portions of which have been redacted as noted, subject to confidential treatment).
99.1	Press Release, dated May 19, 2020.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 19, 2020

BIO-TECHNE CORPORATION
/s/ Brenda S. Furlow
Brenda S. Furlow
General Counsel and Secretary

EXHIBIT 10.1

Certain information identified by [******] in certain sections of the Agreement and attached Schedules are redacted because they contain information that is commercially sensitive, not material and would be competitively harmful if publicly disclosed.

DEVELOPMENT, SUPPLY AND COMMERCIALIZATION AGREEMENT

This Development, Supply and Commercialization Agreement (this "**Agreement**"), effective as of May 19, 2020 (the "**Effective Date**"), is by and between Kantaro Biosciences LLC, a Delaware limited liability company with a principal business address of 1460 Broadway, New York, NY 10036 ("**Sponsor**") and Bio-Techne Corporation, a Minnesota corporation having a principal business address at 614 McKinley Place NE, Minneapolis, MN 55413 ("**Bio-Techne**"). Capitalized terms used and not defined elsewhere in this Agreement have the meanings set forth in Section 1 of this Agreement.

WHEREAS, Sponsor has been formed by and is majority owned and controlled by Icahn School of Medicine at Mount Sinai, a New York educational corporation ("**ISMMS**");

WHEREAS, on February 4, 2020, pursuant to Section 564(b)(1)(C) of the FDC Act, the Secretary of the Department of Health and Human Services ("**HHS**") determined that there is a public health emergency (the "**Public Health Emergency**") that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Severe Acute Respiratory Syndrome Coronavirus 2 ("**SARS-CoV-2**");

WHEREAS, pursuant to Section 564 of the FDC Act, and on the basis of the determination by the Secretary of the HHS, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of an EUA;

WHEREAS, ISMMS developed the MS Lab Test in response to the Public Health Emergency, and on April 15, 2020, the FDA issued the MS Lab Test EUA;

WHEREAS, Sponsor and ISMMS entered into the ISMMS IP License Agreement and ISMMS TM License Agreement in order to enable Sponsor to enter into this Agreement and fulfill certain of its obligation under this Agreement;

WHEREAS, Bio-Techne is in the business of developing, manufacturing and supporting diagnostic tests and related products;

WHEREAS, subject to the terms and conditions of this Agreement, Sponsor desires to (i) collaborate with Bio-Techne to co-Develop the Co-Developed Test that is based on the MS Lab Test and that has the specifications and performance characteristics set forth on Schedule 3.1(a) and satisfies the other criteria set forth in this Agreement, (ii) obtain the necessary authorizations to commercialize the Co-Developed Test as described in this Agreement, and (iii) engage Bio-Techne to provide services in collaboration with Sponsor to Manufacture and Commercialize Co-Developed Test Kits containing the necessary components, labeling and instructions and meeting the other requirements of this Agreement so as to enable providers and reference laboratories to conduct testing that will rapidly and effectively support societal efforts to respond to the Public Health Emergency and advance public health; and

WHEREAS, the Parties desire to set forth the rights and obligations of each Party (and the rights of ISMMS to the extent provided herein) with respect to the Development of the Co-Developed Test, the Manufacturing of the Co-Developed Test Kits and the Commercialization of the Co-Developed Test Kits:

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and wishing to be legally bound hereby, the Sponsor and Bio-Techne hereby agree as follows:

1. DEFINITIONS

The following terms have the meanings specified or referred to in this Section 1:

"**Action**" means any claim, action, suit, corrective action plan, cause of action, lawsuit, arbitration, audit, survey, investigation, intermediate or other sanction, fine or penalty, written notice of violation or noncompliance, administrative proceeding, litigation, citation, summons, subpoena, inquiry, or investigation of any nature, civil, criminal, administrative, regulatory, or otherwise, whether at law or in equity, before or by any Governmental Authority.

"**Adjusted Gross Receipts**" means for any calendar month (i) the amounts actually received in cash by Bio-Techne in consideration of the sale, licensing, use, lease, transfer or other disposition of Co-Developed Test Kits during such calendar month in accordance with this Agreement, less (ii) the amount of any credits or refunds for returns of or allowances for Co-Developed Test Kits granted by Bio-Techne during such calendar month in accordance with this Agreement and that were applied against amounts described in clause (i) of this definition, less (iii) any losses incurred by Bio-Techne in the conversion of a currency other than U.S. dollars in which any amount described in clause (i) of this definition is paid, plus (iv) any gains realized by Bio-Techne in the conversion of a currency other than U.S. dollars in which any amount described in clause (i) of this definition is paid.

"**Affiliate**" means any Person that controls, is controlled by, or is under common control with, a Party, directly or indirectly. For purposes of this definition, "control" and its various forms means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Party will be deemed to control another Person if such Party owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other securities of the Person.

"**Agreement**" has the meaning set forth in the introductory paragraph.

"**Approved Alternative Component**" has the meaning set forth in Section 9.6.

"**Bio-Techne**" has the meaning set forth in the introductory paragraph.

"**Bio-Techne Background IP**" means all Intellectual Property of Bio-Techne related to the Development, Manufacture or Commercialization of serologic or similar tests that Bio-Techne possesses (other than as a result of the receipt by Bio-Techne prior to the date hereof of information communicated by ISMMS or Sponsor related to the MS Background IP) or that, after the date hereof, Bio-Techne develops without any contribution from ISMMS or Sponsor. Bio-Techne Background IP shall not include MS Background IP or Jointly Developed Intellectual Property.

"**Bio-Techne Indemnitees**" has the meaning set forth in Section 17.1(b).

"**Bio-Techne Licensed Marks**" has the meaning set forth in Section 6.3(k).

"**Bio-Techne NDA**" means that certain Mutual Non-Disclosure Agreement entered into by and between Sponsor and Bio-Techne, effective as of the Effective Date, as the same may be amended from time to time.

"**Calendar Year**" means January 1 through December 31 of a given year.

"**CLIA HC Lab**" means a laboratory that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a to perform high complexity tests.

"Co-Developed Test" means a serologic test or tests to detect and/or measure the presence of antibodies to the COVID-19 virus each of which is based on the MS Lab Test, and which in the case of any particular test has the applicable specifications and performance characteristics set forth on Schedule 3.1(a) and required by any applicable End User-Specific Requirements and that has been accepted by Sponsor pursuant to Section 3.1(a).

"**Co-Developed Test Kits**" means one or more assemblies of the Components and material that an End User needs to administer the Co-Developed Test, as Developed by Bio-Techne in accordance with this Agreement and any applicable End User-Specific Requirements and approved by the Steering Committee in accordance with Section 3.1(a), Section 3.1(c) and Section 8.1(a).

"**Commercialization**" means any and all activities related to the promotion, distribution, marketing, offering for sale and selling of or otherwise granting rights to the Co-Developed Test Kits, including advertising, educating, planning, supporting and adhering to pricing and reimbursement approvals and Regulatory Authorizations, investigating and responding to End User adverse events involving the Co-Developed Test Kits, pricing, price reporting, marketing, promoting, tracking, storing, handling, shipping, distributing, importing, exporting, using, offering for sale, or selling the Co-Developed Test Kits anywhere in the world, billing and collections and in each case as responsibility for each such activity is allocated between Sponsor and Bio-Techne in accordance with this Agreement. Commercialization excludes activities related to the Development and/or Manufacturing of the Co-Developed Test Kits. Without limiting the generality of the foregoing, "Commercialization" includes all of the activities described in Section 8.1(a). When used as a verb, "**Commercialize**" means to engage in Commercialization.

"**Components**" means the Original Components and any additions, replacements or changes in and to the Original Components that have been adopted pursuant to and as contemplated by Section 9.6, which is intended to be included as part of or used in the Manufacture of the finished, packaged, and labeled Co-Developed Test Kits.

"**Confidential Information**" means information that a Party owns or controls and maintains as confidential that such Party discloses to the other Party during the term of the Bio-Techne NDA, including without limitation, any such information regarding products, services, research, prototypes, samples, software, inventions, processes, formulas, technology, designs, drawings, hardware configurations, business, and marketing. For clarity, "**Confidential Information**" includes the foregoing information of a third party in possession of the disclosing Party, that disclosing Party has a legal right to disclose to the other Party under terms of confidentiality as set forth herein.

"**Contract**" means any agreement, contract, lease, deed, mortgage, license, instrument, promissory note, evidence of indebtedness, security agreement, commitment, undertaking, indenture or joint venture, whether written or oral.

"**COVID-19**" means Coronavirus Disease 2019.

"**Designated Executives**" has the meaning set forth in Section 2.2(a).

"**Development**" means any and all activities related to researching or developing the Co-Developed Test and the Co-Developed Test Kits or process or service, including preclinical and clinical research, testing and development activities relating to the discovery and/or development of product or process candidates and submission of information and applications to a Regulatory Authority, including toxicology, pharmacology, and other discovery, optimization, and preclinical efforts, test method development and stability testing, manufacturing process development, formulation development, upscaling, Validation, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre and post Regulatory Approval studies), and activities relating to obtaining Regulatory Approvals, but excluding Commercialization activities, in each case as responsibility for each such activity is allocated between Sponsor and Bio-Techne in accordance with this Agreement. When used as a verb, "**Develop**" means to engage in Development.

"**Deviation**" means departure from established procedure or specification.

"**Effective Date**" has the meaning set forth in the introductory paragraph.

"**ELISA**" means serological enzyme-linked immunosorbent assays.

"**EMA**" means the European Medicines Agency or any successor thereto.

"**Embargoed Purchaser**" has the meaning set forth in Section 8.3.

"**Encumbrance**" means any encumbrance, charge, claim, pledge, equitable interest, lien (statutory or other), option, security interest, mortgage, hypothecation, easement, encroachment, right of way, right of first refusal, restriction, levy or charge of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

"**End of EUA Period**" means the earlier of: (a) the effective date on which the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the FDC Act or (b) the effective date on which the EUA for any Co-Developed Test is revoked under Section 564(g) of the FDC Act.

"**End User**" means with respect to the Co-Developed Test Kit, a healthcare provider, clinical laboratory, or other authorized Person that orders the Co-Developed Test Kit to detect if there has been an immune response to COVID-19 in the diagnosis of individuals suspected of prior SARS-CoV-2 infection; provided that the applicable healthcare provider, clinical laboratory or other authorized Person has satisfied any qualification requirements established by the FDA or other applicable Governmental Authority to purchase and utilize the applicable Co-Developed Test Kit.

"**End User-Specific Requirements**" means any requirements established pursuant to the terms of an agreement between Sponsor and any Governmental Authority or other End-User relating to the specifications, characteristics, manufacturing methodologies or other aspects of the Development, Manufacturing or Commercialization of any Co-Developed Test Kit and of which Sponsor has given Notice to Bio-Techne.

"**Escalation Process**" means the process described in Section 2.1 and Section 2.2.

"**EUA**" means an Emergency Use Authorization for emergency use of a product pursuant to Section 564 of the FDC Act and/or any equivalent authorization promulgated that pertains to a serological antibody test, in each case as the same may have been amended or supplemented as of the time of any reference thereto.

"**EUA Compliance Protocol**" has the meaning set forth in Section 9.3(a).

"**FDA**" means the United States Food and Drug Administration or any successor entities thereto.

"**FDC Act**" means the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended as of the time of any reference thereto.

"**Good Clinical Practices**" means the then-current standards, practices and procedures for good clinical practices in the conduct of clinical trials, including adequate human subject protections, as promulgated or endorsed by the FDA and other applicable Governmental Authorities, such as set forth in, "International Conference on Harmonization - Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," 21 C.F.R. Parts 50, 54, 56, and 812 and relevant FDA guidance, as applicable, or as otherwise required by applicable Law.

"**Good Laboratory Practices**" means the then-current standards, practices and procedures for good laboratory practices by facilities that perform non-clinical (including pre-clinical) laboratory studies, as promulgated or endorsed by the FDA and other applicable Governmental Authorities, including as set forth in 21 C.F.R. Part 58 and relevant FDA guidance, as applicable, or as otherwise required by applicable Law.

"**Good Manufacturing Practices**" means the then-current standards, practices and procedures for the manufacture of drugs or medical devices, as applicable to the Co-Developed Test Kits (including the practices of and methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packaging, sterilizing, labeling, testing or holding of the Co-Developed Test Kits), as promulgated or endorsed by the FDA and other applicable Governmental Authorities, including, as applicable, as set forth in 21 C.F.R. Parts 210, 211, and 820 and relevant FDA guidance, as applicable, or as otherwise required by applicable Law.

"**Governmental Authority**" means any supranational, national, federal, state, provincial, local or foreign Person of any nature exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, department, board, commission, court, tribunal, judicial body or instrumentality of any union of nations, federation, nation, state, municipality, county, locality or other political subdivision thereof, whether of the United States or any other country.

"**Health Care Laws**" means all applicable Laws relating in any way to patient care and human health and safety, including such Laws pertaining to: (a) the Development, Manufacture and Commercialization of drugs, serologic tests and medical devices, including, without limitation, the FDC Act, the Public Health Service Act, 42 U.S.C. § 201 *et seq.*, the regulations, rules, policies, orders, and guidance of the FDA administered, issued, or promulgated thereunder (including with respect to Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices, in each case to the extent applicable), and equivalent applicable Laws of other Governmental Authorities; (b) the reimbursement and payment for health care products and services, including any United States federal health care program (as such term is defined in 42 U.S.C. § 1320a-7b(f)), and programs and arrangements pertaining to providers of health care products or services that are paid for by any Governmental Authority or other Person, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), 42 U.S.C. § 1320a-7 and 42 U.S.C. § 1320a-7a, and the regulations promulgated pursuant to such statutes, Medicare (Title XVIII of the Social Security Act) and the regulations promulgated thereunder, Medicaid (Title XIX of the Social Security Act) and the regulations promulgated thereunder, and equivalent applicable Laws of other Governmental Authorities; (c) the privacy and security of patient-identifying information, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) and the regulations promulgated thereunder and equivalent applicable Laws of other Governmental Authorities; (d) to the extent required, registration and reporting of clinical trials in accordance with 42 U.S.C. § 282(j) in each of the foregoing (a) through (d), as may be amended from time to time and (e) state health care laws including those corresponding to the federal laws described in (a) through (d).

"**HHS**" has the meaning set forth in the recitals.

"**Initial Term**" has the meaning set forth in Section 18.1(a).

"**Insurance Policies**" has the meaning set forth in Section 14.6.

"**Intellectual Property**" means all intellectual property, intangible property and proprietary rights, title, interests and protections, however arising, pursuant to the Laws of any jurisdiction throughout the world, including all United States, foreign and international: (a) inventions (whether or not patentable), patents, patent applications and statutory invention registrations, utility models, reissues, divisionals, continuations, continuations-in-part, extensions and reexaminations thereof; (b) trademarks, service marks, trade dress, logos, trade names and corporate names, uniform resource locator addresses, symbols, slogans, and other indicia of source or origin, including the goodwill of the business symbolized thereby or associated therewith, common law rights, registrations and applications thereof; (c) internet domain names, website content, social media handles, tags, hashtags, social media accounts, or any other online indicia of source; (d) original works of authorship in any medium of expression (whether or not published), copyrights and copyrightable works, registrations and applications for registration of such copyrights, and all issuances, extensions and renewals of such registrations and applications; (e) trade secrets, formulas, designs, devices, technical data, technology, know-how, research and development, advertising and promotional materials, inventions and invention disclosures, methods or processes, and other confidential or proprietary technical, business and other information; (f) computer software (including source and object code) and computer programs and databases in any form, including firmware, development tools, algorithms, data, data files, records, database management code, utilities, graphic user interfaces, internet web sites, all versions, updates, corrections, enhancements and modifications of any of the foregoing, and all related documentation; (g) all rights and remedies against past, present and future infringement, misappropriation or any other violations relating to any of the foregoing; and (h) all tangible embodiments of any of the foregoing.

"**ISMMS**" means Icahn School of Medicine at Mount Sinai, a New York educational corporation.

"**ISMMS IP License Agreement**" means that certain License and Collaboration Agreement entered into by and between ISMMS and Sponsor, dated as of May 4, 2020, pursuant to which ISMMS grants to Sponsor a non-exclusive license to use certain Intellectual Property related to the MS Lab Test, including the MS Background IP, for the purposes contemplated by this Agreement.

"**ISMMS License Agreements**" means the ISMMS IP License Agreement and the ISMMS TM License Agreement.

"**ISMMS TM License Agreement**" means that certain Trademark License Agreement entered into by and between ISMMS and Sponsor, dated as of May 4, 2020, pursuant to which ISMMS grants to Sponsor a non-exclusive license to use the Sponsor Licensed Marks for the purposes contemplated by this Agreement and as permitted by Section 6.3.

"**ISO 13485:2016 Quality System Standards**" means (i) the standards for a quality management system for medical devices established by the International Organization for Standards designated as ISO 13485:2016 by such organization, as the same may have been amended as of the time of any reference thereto and (ii) any corresponding standards imposed by any applicable End User-Specific Requirements.

"**IVD**" means in vitro diagnostic product as that term is defined in 21 C.F.R. § 809.3(a) and used by the FDA in its regulations, guidance, and procedures.

"**Jointly Developed Intellectual Property**" has the meaning set forth in Section 3.3(c).

"**Jointly Owned Patents**" means (a) the United States and foreign patents and/or patent applications relating to the Co-Developed Tests; (b) any and all patents issuing from the foregoing; (c) any and all claims of continuation-in-part applications that claim priority to the United States patent applications, in the case of each of (a), (b) and (c) to the extent relating to the Jointly Developed Intellectual Property, but only where such claims are directed to inventions disclosed in the manner provided in the first paragraph of 35 U.S.C. § 112 in such United States patent applications, and such claims in any patents issuing from such continuation-in-part applications; (d) any and all foreign patent applications, foreign patents, or related foreign patent documents that claim priority to the patents and/or patent applications relating to the Jointly Developed Intellectual Property; and (e) any and all divisionals, continuations, reissues, re-examinations, renewals, substitutions, and extensions of the foregoing.

"**Laws**" means all active governmental constitutions, laws, statutes, ordinances, treaties, rules, common laws, rulings, regulations, orders, charges, directives, determinations, executive orders, writs, judgments, injunctions, decrees, restrictions or similar legally effective pronouncements of any Governmental Authority, including, without limiting the generality of the foregoing, Health Care Laws.

"**Licensed Use**" means for Bio-Techne to brand the Co-Developed Test Kits with the Sponsor Licensed Marks in accordance with the requirements of Section 6.2 and the other terms and conditions of this Agreement and for the Parties to market, promote, distribute and/or sell the Co-Developed Test Kits under this Agreement.

"**Losses**" means out-of-pocket losses, damages, liabilities, deficiencies, Actions, judgments, interest, awards, penalties, fines, Taxes, costs or expenses of whatever kind, including reasonable fees of accountants, attorneys and other similar professionals, the cost of enforcing any right to indemnification hereunder, and the cost of pursuing any insurance providers.

"**Manufacturing**" means all activities directed to sourcing of necessary Raw Materials, producing, processing, packaging, labeling, quality assurance testing, release of the Co-Developed Test Kits, whether for Development or Commercialization, in each case as responsibility for each such activity is allocated between Sponsor and Bio-Techne in accordance with this Agreement. When used as a verb, "**Manufacture**" means to engage in Manufacturing.

"**Manufacturing Milestones**" has the meaning set forth in Section 5.2(a).

"**Marks**" means and all trademarks whether registered or unregistered, trademark registrations, trademark applications, service marks whether registered or unregistered, service mark registrations and service mark applications, brand names, corporate names, trade names, logos, designs, slogans, trade dress, domain names, social media handles and user names, and other proprietary indicia of goods and services, and all registrations and applications for registration of the foregoing, all issuances, extensions and renewals of such registrations and applications, and all goodwill associated with any of the foregoing, of Mount Sinai Health System, Inc. or any of the other Mount Sinai Entities and any derivative, translation, transliteration, or adaptation thereof, including, without limitation, the Sponsor Licensed Marks.

"**Materials**" means the tangible physical material, if any, delivered to Bio-Techne under this Agreement, and any progeny, derivatives, or improvements thereof developed by Bio-Techne or its Affiliates.

"**Material Transfer Agreement**" means that certain Material Transfer Agreement effective as of April 15, 2020, by and between ISMMS and Bio-Techne, as the same may be amended from time to time.

"**MS Background IP**" means all Intellectual Property of the Mount Sinai Entities embodying the MS Lab Test (and any improvements thereto made by ISMMS and/or any Affiliates of ISMMS to the extent that Bio-Techne has not contributed to such improvements) utilizing a 96-well plate ELISA technology, including without limitation, the Intellectual Property described in the "Authorized Product Details" set forth in the MS Lab Test EUA and the document entitled "Accelerated Emergency Use Authorization (EUA) Summary COVID-19 ELISA IgG Antibody Test (Mount Sinai Laboratory)" submitted by the MS Lab in connection with the obtaining of the MS Lab Test EUA and any future versions of the MS Lab Test that are developed by ISMMS and/or Affiliates of ISMMS to the extent that Bio-Techne has not contributed to such future versions, utilizing a 96-well plate ELISA technology. MS Background IP shall not include Bio-Techne Background IP or Jointly Developed Intellectual Property.

"**MS Lab**" means the Mount Sinai Laboratory, Center for Clinical Laboratories, a division of the Department of Pathology, Molecular, and Cell-Based Medicine, New York, New York that is certified as a CLIA HC Lab.

"**MS Lab Test**" means the qualitative test for the detection of IgG antibodies against SARS-CoV-2 in serum and plasma specimens collected from individuals suspected of prior infection with the virus that causes COVID-19 by their healthcare provider as described in the MS Lab Test EUA.

"**MS Lab Test EUA**" means the EUA issued by the FDA to the MS Lab on April 15, 2020, with respect to the use of the MS Lab Test in the MS Lab, subject to the terms and conditions of such EUA.

"**Mount Sinai Entities**" means Mount Sinai Health System, Inc. and the Affiliates of Mount Sinai Health System, Inc., including, without limitation, The Mount Sinai Hospital, Beth Israel Medical Center, St. Luke's-Roosevelt Hospital Center, The New York Eye and Ear Infirmary, South Nassau Communities Hospital and ISMMS.

"**Notice**" has the meaning set forth in Section 19.5.

"**Notice Address**" has the meaning set forth in Section 19.5.

"**Order**" means any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority but not including Permits.

"**Original Components**" means the Raw Material, substance, piece, part, software, firmware, labeling, or assembly or any other component of the Co-Developed Lab Test specified in the application for EUA, 510(k) clearance or *de novo* classification therefor, or the application submitted to any other applicable Regulatory Authority.

"**Outside Date**" means September 30, 2020.

"**Part 820**" means the regulations of the FDA at 21 C.F.R. Part 820, as the same may have been amended at the time of any reference thereto.

"**Part 820 Compliance Protocol**" has the meaning set forth in Section 9.3(b).

"**Party**" means (a) the Sponsor or any successor or permitted assign thereof or (b) Bio-Techne or any successor or permitted assign thereof.

"**Permits**" means all permits, licenses, franchises, clearances, approvals, authorizations, registrations, certificates, variances and similar rights obtained, or required to be obtained, from Governmental Authorities.

"**Permitted Use**" has the meaning set forth in Section 3.2(a).

"**Person**" means a corporation, an association, a joint venture, a partnership, a trust, a business, an institution, an individual, a government or political subdivision thereof, including an agency, or any other organization that can exercise independent legal standing.

"**Phase I**" has the meaning set forth in Section 3.1(a).

"**Phase II**" has the meaning set forth in Section 5.1(a).

"**Portal**" has the meaning set forth in Section 8.6.

"**Product**" means a finished component, for example, a reagent or device.

"**Prosecution**" means the filing, preparation, prosecution (including any interferences, reissue proceedings, reexaminations, and oppositions), extension, term adjustment, and maintenance of any patents. When used as a verb, "**Prosecute**" means to engage in Prosecution.

"**Public Health Emergency**" has the meaning set forth in the recitals.

"**Quality Agreement**" means the separate quality agreement, dated as of the date hereof, being executed by Sponsor and Bio-Techne in connection with this Agreement.

"**Raw Materials**" means the excipients, chemicals, processing aids necessary for processing or manufacture of Components or Products per specification.

"**real time**" for purposes of this Agreement does not mean that the applicable data or information is provided on an instantaneous basis but rather means that the applicable data or information is provided on a basis that is updated no less frequently than daily or as mutually agreed.

"**Regulatory Approval**" means, with respect to a country or other jurisdiction, all approvals, licenses, clearances,*de novo* classification request decisions, marks, registrations, authorizations certificates, exemptions, consents, franchises, concessions, notices or other like item of or issued by any Governmental Authority, from the relevant Governmental Authority necessary or useful to commercially distribute, sell or market the Co-Developed Test Kits in such country or other applicable jurisdiction (not including any applicable pricing and governmental reimbursement approvals unless legally required to market the Co-Developed Test Kits in a country or other applicable jurisdiction).

"**Regulatory Authorities**" means any applicable Governmental Authority involved in granting Regulatory Approval for, and responsible for the regulation of, the Co-Developed Test Kits in any Jurisdiction, including the FDA, EMA, or such other state or foreign country equivalent Governmental Authority as applicable.

"**Renewal Term**" has the meaning set forth in Section 18.1(b).

"**Research Use Only**" or "**RUO**" has the meaning ascribed to the term "research use only" as defined in 21 C.F.R. § 809.10(c)(2)(i) and used by the FDA in its applicable regulations and guidance as of the time of any reference thereto.

"**RUO Addendum**" has the meaning set forth in Section 11.1.

"**SARS-CoV-2**" has the meaning set forth in the recitals.

"**Specification**" means any requirement with which a product, process, service, or other activity must conform.

"**Sponsor**" means Kantaro Biosciences LLC, a Delaware limited liability company.

"**Sponsor Indemnitees**" has the meaning set forth in Section 17(a).

"Sponsor Licensed Marks" has the meaning set forth in Section 6.3(a).

"**Sponsor Patent Option**" has the meaning set forth in Section 3.3(c)(ii)(1).

"**Steering Committee**" has the meaning set forth in Section 2.1(a).

"**Term**" has the meaning set forth in Section 18.1(b).

"**Transaction Documents**" means this Agreement, the Material Transfer Agreement, the Bio-Techne NDA, and such other agreements, instruments and documents as the Parties may enter into from time to time in connection with the transactions contemplated by this Agreement.

"**Working Group**" has the meaning set forth in Section 2.1(e).

"**Validation**" means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce results meeting predetermined acceptance criteria.

2. GOVERNANCE

2.1 Steering Committee

(a) Establishment of Steering Committee. The Parties share a common objective of collaborating to enable the development of the Co-Developed Test Kit, obtaining EUA authorization to distribute and sell Co-Developed Test Kits (and, subject to the terms and conditions herein, obtaining a 510(k) clearance, *de novo* classification, or approval, as applicable) and, subject to the terms and conditions set forth herein, distributing and selling Co-Developed Test Kits in accordance with applicable Laws in a manner that most rapidly and effectively supports societal efforts to respond to the Public Health Emergency and advances public health. The Parties recognize that to do so will require the Parties to build into their relationship sufficient flexibility to respond to rapidly changing circumstances without compromising the Parties' commitment to compliance with Law and appropriate risk management. Therefore, the Parties hereby establish a committee (the "**Steering Committee**") to support the Parties efforts to achieve their common objective.

(b) Authority of Steering Committee. The Steering Committee shall have the specific authorities ascribed to it in this Agreement. The Steering Committee shall also serve as a forum in which the Parties shall discuss any evolution in the terms of this Agreement that either Party believes is necessary, any matters affecting the Parties' performance hereunder that were not foreseen as of the Effective Date, and any differences that may arise between the Parties. The Steering Committee shall not have any authority that is not expressly provided for in this Agreement.

(c) Composition and Requirements for Steering Committee Action. The Steering Committee shall be composed of an equal number of appointees of each Party. The initial appointees of each Party are listed on Schedule 2.1(c). Either Party may change any of its appointees to the Steering Committee, provided that such Party gives the other Party two (2) days' prior Notice and the Designated Executive of the Party receiving such Notice approves the change in the requesting Party's appointee(s) (such approval not to be unreasonably withheld). The Steering Committee may meet in person or by telephonic or electronic means. In order for the Steering Committee to act, the unanimous vote of all members of the Steering Committee appointed by each Party shall be required.

(d) Establishment of Subcommittees of the Steering Committee. The Steering Committee may establish subcommittees to assist the Steering Committee in the fulfillment of its role under this Agreement, provided that no subcommittee of the Steering Committee shall have any authority that the Steering Committee does not itself have. The Steering Committee shall establish a written charter for each subcommittee established by the Steering Committee. Members of any subcommittee established by the Steering Committee need not be members of the Steering Committee. Unless the Steering Committee determines otherwise with respect to any given subcommittee, (i) each subcommittee shall be composed of an equal number of appointees of each Party and either Party may change any of its appointee to a subcommittee by notice given to the other Party, and (ii) in order for a subcommittee to act, the vote of a majority of all members of the subcommittee shall be required. Each subcommittee may meet in person or by telephonic or electronic means. If the vote of a majority of all members of a subcommittee is not able to be obtained as to any matter, the matter will be referred to the Steering Committee for resolution.

(e) Establishment of Working Groups. The Steering Committee or any subcommittee may establish one or more working groups composed of individuals with specific subject matter expertise (each a "**Working Group**") in order to assist the Steering Committee or any subcommittee in considering or developing approaches to or recommendations with respect to specific categories of work under this Agreement, provided that no Working Group shall have any authority that the Steering Committee or the subcommittee does not itself have. The Steering Committee or applicable subcommittee shall establish a written charter for each Working Group established by the Steering Committee or subcommittee. A Working Group may be established and have responsibilities relating to a discrete project, or may be established on a temporary basis. Members of any Working Group need not be members of the Steering Committee or any subcommittee. Unless the Steering Committee or subcommittee determines otherwise with respect to any given Working Group, (i) each Working Group shall be composed of subject matter expert appointees of each Party and either Party may change any of its appointee to a Working Group by notice given to the other Party, and (ii) the Working Group members are expected to make a written recommendation to the Steering Committee and any dissent within the group can be so noted. Each Working Group may meet in person or by telephonic or electronic means. The initial Working Groups are listed on Schedule 2.1(e).

2.2 **Designated Executives**

(a) Reference to Designated Executives. The Parties acknowledge that there may be matters that come before the Steering Committee that the Steering Committee is not able to resolve. The Steering Committee shall have the authority to refer any such matter to two senior executives (the "**Designated Executives**"), one appointed by each Party. Each Party agrees to appoint as its Designated Executive only a senior executive with the standing and authority within the organizational structure of such Party to be able to deal with and resolve matters referred to the Designated Executives by the Steering Committee. The initial Designated Executives are listed on Schedule 2.1(c). The Designated Executives shall not have the authority to determine matters that are not within the authority of the Steering Committee. However, the Designated Executives shall have the authority to recommend to the Parties amendments to this Agreement that the Designated Executives believe should be made.

(b) Requirements for Designated Executives' Action. The Designated Executives may meet in person or by telephonic or electronic means. In order for the Designated Executives to act the unanimous vote of both Designated Executives shall be required, provided that if a unanimous vote of both Designated Executives is not able to be obtained in respect of any matter, the determination of the Designated Executive appointed by Sponsor as the manufacturer of record of the Co-Developed Test Kits shall be deemed to be the determination of the Designated Executives.

3. DEVELOPMENT OF CO-DEVELOPED TEST

3.1 **Development Process for Co-Developed Test.**

(a) Bio-Techne Development Responsibilities. During the period ("**Phase I**") between the Effective Date and the date on which EUA is obtained for the Co-Developed Test Kit, Bio-Techne shall devote appropriate resources to (i) the Development of a Co-Developed Test that (A) is based on the MS Lab Test, (B) meets the specifications and has the performance characteristics set forth on Schedule 3.1(a), (C) is able to be Manufactured and Commercialized in quantities that meet the Manufacturing Milestones, (D) complies with Law and any End User-Specific Requirements and has the necessary attributes to be granted EUA and (E) is accepted by Sponsor as meeting the requirements of this Agreement and (ii) the Development of a prototype of the Co-Developed Test Kit that can be used for the purposes of obtaining EUA for the Co-Developed Test Kit and that has been accepted by Sponsor as meeting the requirements of this Agreement. Subject to contractual commitments existing prior to April 17, 2020 and subject to any contrary requirements of Law, during Phase I Bio-Techne shall not prioritize any other project over the Development of a Co-Developed Test.

(b) Sponsor Development Responsibilities. To the extent not provided by ISMMS prior to the Effective Date, during Phase I, Sponsor shall (i) promptly provide all information that Bio-Techne requests in connection with the MS Background IP licensed to Bio-Techne hereunder, (ii) promptly cooperate with Bio-Techne in Bio-Techne's efforts to Develop the Co-Developed Test and (iii) comply with the Material Transfer Agreement and use reasonable commercial efforts to facilitate Bio-Techne's access to sources of supply for the development of the Co-Developed Test.

(c) Sponsor Acceptance of Co-Developed Test and Test Kit. The determination that a test satisfies the criteria of this Agreement to constitute a Co-Developed Test and that a prototype of a Co-Developed Test Kit is ready to be submitted for EUA shall be made by Sponsor. Sponsor may undertake such Validation processes as Sponsor may determine are necessary or appropriate in connection with such determination, and Bio-Techne shall cooperate in any such processes. Sponsor shall use reasonable commercial efforts to complete such processes as promptly as is feasible.

3.2 **License Grant with Respect to MS Background IP**.

(a) License Grant to MS Background IP. Subject to the terms and conditions of this Agreement, Sponsor hereby grants Bio-Techne a non-exclusive, non-sublicensable, and non-transferable license to use the MS Background IP (i) during the Term, solely for the purpose of Developing the Co-Developed Test and Developing, Manufacturing and Commercializing the Co-Developed Test Kits in accordance with this Agreement, (ii) during the Term, solely to the extent the Co-Developed Test Kits are contemplated to be sold pursuant to the RUO Addendum, and (iii) after the Term in connection with Bio-Techne's exploitation of Jointly Developed Intellectual Property provided that the Parties and ISMMS shall first have agreed, each in its own discretion, upon the economic terms of such license and exploitation (including in respect of any appropriate revenue share or other compensation payable to Sponsor in respect of such sublicense) (the uses described in (i), (ii) and (iiii), the "**Permitted Use**").

(b) Use Restrictions. Bio-Techne shall only use the MS Background IP for the Permitted Use and shall not disclose, release, distribute, or deliver the MS Background IP, or any portion thereof, to any other Person without Sponsor's prior written consent. Any purpose or use not specifically authorized herein is prohibited unless otherwise agreed to in writing by Sponsor.

(c) Delivery. To the extent not delivered by ISMMS prior to the Effective Date, Sponsor shall deliver the MS Background IP electronically, on tangible media, or by other means to Bio-Techne promptly following the Effective Date.

(d) Confidentiality. The MS Background IP shall constitute Confidential Information of Sponsor and shall be subject to the requirements of the Bio-Techne NDA.

3.3 **License Grant; Intellectual Property Ownership; Jointly Developed Intellectual Property.**

(a) Rights to MS Background IP. Bio-Techne acknowledges that all MS Background IP is and shall remain the sole property of ISMMS. Except for the limited rights and licenses expressly granted under this Agreement, nothing in this Agreement grants, by implication, waiver, estoppel, or otherwise, to Bio-Techne or any third party any Intellectual Property rights or other right, title or interest in or to the MS Background IP.

(b) Rights to Bio-Techne Background IP. Sponsor acknowledges that all Bio-Techne Background IP is and shall remain the sole property of Bio-Techne. Except for the limited rights and licenses expressly granted under this Agreement, nothing in this Agreement grants, by implication, waiver, estoppel, or otherwise, to Sponsor or any third party any Intellectual Property rights or other right, title or interest in or to the Bio-Techne Background IP.

(c) Jointly Developed Intellectual Property Relating to the Co-Developed Test

(i) Ownership of Jointly Developed Intellectual Property. Each Party shall own an equal and undivided interest in (1) such Intellectual Property as does not constitute MS Background IP or Bio-Techne Background IP and as is discovered or created in the course of the Development of the Co-Developed Test and/or the Co-Developed Test Kits and (2) any related information, developments, improvements, and Intellectual Property as is jointly developed by the Parties in connection with the Manufacture and/or Commercialization of the Co-Developed Test Kits (the Intellectual Property, information, developments and improvements described in clause (1) and (2) of this sentence, the "**Jointly Developed Intellectual Property**"). Bio-Techne acknowledges that Sponsor has the right to enter into an agreement with ISMMS granting to ISMMS a perpetual, worldwide, royalty-free license to use the Jointly Developed Intellectual Property to the same extent that Sponsor itself would have the right to use the Jointly Developed Intellectual Property, provided that any such agreement expressly provides that Bio-Techne is a third party beneficiary of and is entitled to enforce the obligations of ISMMS thereunder to observe and adhere to the restrictions and limitations on the use of Jointly Developed Intellectual Property that are imposed on Sponsor by this Agreement and that Sponsor has provided to Bio-Techne a copy of such agreement.

(ii) Right to Prosecute Jointly Owned Patents.

(1) Sponsor shall have the first right, but shall not be obligated, to Prosecute any and all Jointly Owned Patents (the "**Sponsor Patent Option**"). If Sponsor exercises the Sponsor Patent Option, Sponsor will, in consultation with Bio-Techne, Prosecute the Jointly Owned Patents in the joint names of the Parties, and shall pay all expenses for Prosecuting the Jointly Owned Patents, including without limitation, any taxes, annuities or maintenance fees on such Jointly Owned Patents.

(2) If at any time Sponsor has not exercised the Sponsor Patent Option with respect to a particular discovery that is part of the Jointly Developed Intellectual Property, and Bio-Techne wishes to Prosecute a Jointly Owned Patent with respect to such discovery, Bio-Techne shall consult with Sponsor regarding whether Sponsor wishes to Prosecute such Jointly Owned Patent, and if Sponsor declines to Prosecute such Jointly Owned Patent, then Bio-Techne shall have the right, in consultation with Sponsor, to Prosecute such Jointly Owned Patent in the joint names of the Parties, and Bio-Techne shall pay all expenses for Prosecuting such Jointly Owned Patent, including without limitation, any taxes, annuities or maintenance fees on such Jointly Owned Patent.

(3) If at any time either Party indicates to the other Party by written notice that it no longer desires to Prosecute any Jointly Owned Patent(s), the other Party may take over the rights of such Party with respect to the applicable Jointly Owned Patent, and shall pay all expenses for Prosecuting such Jointly Owned Patent(s), including without limitation, any taxes, annuities or maintenance fees on such Jointly Owned Patent(s).

(iii) Exploitation of Patent Rights. Each Party shall be entitled, on a royalty-free basis, to use the Jointly Owned Patent(s) for any purpose permitted by Law. Subject to the approval of the other Party, each Party shall have the right to grant license(s) under the Jointly Owned Patents to any third-party subject to mutual agreement on the applicable economic terms (including in respect of any appropriate revenue share or other compensation payable to each Party in respect of such license) of such license; provided, however, Bio-Techne agrees that Sponsor shall have the right to license any Jointly Owned Patents to ISMMS for research and education purposes for no consideration without the prior approval of Bio-Techne.

(iv) Cooperation of Parties. The Parties agree to cooperate fully with each other to provide any information or documentation necessary to support the Prosecution of a Jointly Owned Patent and each Party Prosecuting a Jointly Owned Patent shall provide such information regarding such Prosecution as the other Party shall reasonably request.

(v) Limited License to Bio-Techne Background IP. Sponsor is hereby granted a non-exclusive, perpetual, worldwide, royalty-free paid-up license to use the Bio-Techne Background IP during and after the Term solely for the purpose of (A) using the Co-Developed Test and any modifications thereof and all Jointly Developed Intellectual Property for patient care, education and/or research purposes, (B) performing the obligations of Sponsor under this Agreement and applicable Law, and (C) subject to Section 3.4(a), Developing, Manufacturing and Commercializing serologic tests that have the same or similar functions as the Co-Developed Test Kits. Bio-Techne acknowledges that Sponsor has the right to enter into an agreement with ISMMS granting to ISMMS a perpetual, worldwide, royalty-free license to use the Bio-Techne Background IP to the same extent that Sponsor itself would have the right to use the Bio-Techne Background IP, provided that any such agreement expressly provides that Bio-Techne is a third party beneficiary of and is entitled to enforce the obligations of ISMMS thereunder to observe and adhere to the restrictions and limitations on the use of the Bio-Techne Background IP that are imposed on Sponsor by this Agreement and that Sponsor has provided to Bio-Techne a copy of such agreement.

3.4 **Rights to Sublicense.**

(a) Sublicensing Rights of Sponsor. Other than the Bio-Techne Background IP, Sponsor shall have the right to freely sublicense any Intellectual Property in which Sponsor has rights hereunder, provided that it shall be a condition of the right of Sponsor to sublicense Jointly Developed Intellectual Property that the Parties shall first have agreed, each in its own discretion, upon the economic terms of such sublicense (including in respect of any appropriate revenue share or other compensation payable to Bio-Techne in respect of such sublicense); provided, however, Bio-Techne agrees that Sponsor shall have the right to license any Jointly Developed Intellectual Property to ISMMS for research and education purposes for no consideration without the prior approval of Bio-Techne. For the avoidance of doubt, Sponsor shall not have the right to sublicense Bio-Techne Background IP except as expressly provided in Section 3.3(c)(v).

(b) Sublicensing Rights of Bio-Techne. Other than the MS Background IP, Bio-Techne shall have the right to freely sublicense any Intellectual Property in which Bio-Techne has rights hereunder, provided that it shall be a condition of the right of Bio-Techne to sublicense Jointly Developed Intellectual Property that the Parties shall first have agreed, each in its own discretion, upon the economic terms of such sublicense (including in respect of any appropriate revenue share or other compensation payable to Sponsor in respect of such sublicense). For the avoidance of doubt, Bio-Techne shall not have the right to sublicense MS Background IP.

3.5 **Escrow of Bio-Techne Background IP**. Within ninety (90) days after the date on which Sponsor confirms pursuant to Section 3.1(a) that it accepts the Co-Developed Test Kit as meeting the specifications and having the performance characteristics set forth on Schedule 3.1(a), the Parties shall negotiate in good faith an escrow of appropriate tangible materials describing the Bio-Techne Background IP that is necessary or useful for the Manufacture of the Co-Developed Test Kit that would be sufficient for Sponsor to utilize such Bio-Techne Background IP for the purposes contemplated by Section 18.2(d) in the event of a termination of this Agreement by Sponsor pursuant to Section 18.1(c)(i). To the extent that any such escrow requires a third party to hold tangible materials on behalf of Sponsor and Bio-Techne, Sponsor shall pay the fees of such third party.

4. FDA REGULATORY PROCESS

4.1 FDA Regulatory Process Prior to EUA Issuance.

(a) Responsibilities of Sponsor in Respect of EUA. Commencing no later than the date on which Sponsor accepts a Co-Developed Test and a prototype Co-Developed Test Kit pursuant to Section 3.1(a) and Section 3.1(c), Sponsor shall use all reasonable commercial efforts to obtain EUA for the Co-Developed Test Kit and shall pay all expenses relating to obtaining EUA for the Co-Developed Test Kits. Sponsor shall keep Bio-Techne reasonably informed of the process of applying for EUA in respect of the Co-Developed Test, and shall provide Bio-Techne with copies of any correspondence between Sponsor and the FDA with respect to the application for EUA in respect of the Co-Developed Test Kit reasonably promptly after such correspondence is received by Sponsor. Promptly upon obtaining EUA for the Co-Developed Test Kit, Sponsor shall notify Bio-Techne of such EUA and shall provide Bio-Techne with a copy of such EUA.

(b) Responsibilities of Bio-Techne. Bio-Techne shall promptly provide to Sponsor such information, data and materials as Sponsor reasonably requests in order to obtain EUA in respect of the Co-Developed Test Kit.

(c) No Other Responsibility to Seek Approvals of Government Authorities. Unless and until EUA is obtained in respect of a Co-Developed Test Kit, Sponsor shall have no obligation to seek 510(k) clearance, review of a *de novo* classification request, premarket approval (PMA), or any other type of required premarket review and authorization from the FDA of a Co-Developed Test Kit as an IVD or to seek or obtain any approval or clearance of any Governmental Authority for the Commercialization of a Co-Developed Test Kit in any country other than the United States. To the extent that Sponsor elects to undertake any such process or seek any such clearance, required premarket review and authorization, Bio-Techne shall promptly provide to Sponsor such information, data and materials as Sponsor reasonably requests in connection therewith.

4.2 FDA Regulatory Process After EUA Issuance.

(a) Responsibilities of Sponsor After Issuance of EUA. Commencing no later than the date on which EUA is issued by the FDA in respect of a Co-Developed Test Kit and thereafter during the Term, Sponsor shall (i) seek 510(k) clearance, review of a *de novo* classification request, or other applicable type of required premarket review and authorization by the FDA of the Co-Developed Test Kit as an IVD and (ii) in such order and with such priorities as are determined by the Steering Committee, use reasonable commercial efforts to obtain the approval or clearance of the applicable Governmental Authorities in countries other than the United States for the Commercialization of a Co-Developed Test Kit in such countries. Sponsor shall keep Bio-Techne reasonably informed of the processes described in this Section 4.2(a). The Steering Committee shall have the authority to suspend or terminate the process of obtaining 510(k) clearance, review of a *de novo* classification request, or other applicable type of required premarket review and authorization by the FDA of the Co-Developed Test Kit and/or the process of obtaining the approval or clearance of the applicable Governmental Authorities in countries other than the United States for the Commercialization of a Co-Developed Test Kit in such countries, in each case to the extent the Steering Committee determines that market, regulatory or other conditions make such suspension or termination appropriate (and any difference of views in the Steering Committee with respect to such matters shall be resolved through the Escalation Process). Promptly upon obtaining clearance, *de novo* classification, or approval, as applicable, by the FDA of the Co-Developed Test Kit as an IVD, Sponsor shall notify Bio-Techne of such clearance, *de novo* classification, or approval and shall provide Bio-Techne with a copy of such clearance, *de novo* classification, or approval. Promptly upon obtaining the approval or clearance of an applicable Governmental Authority in a country other than the United States for the Commercialization of a Co-Developed Test Kit in such country, Sponsor shall notify Bio-Techne of such approval or clearance and shall provide Bio-Techne with a copy of such approval.

(b) Responsibilities of Bio-Techne After Issuance of EUA. Bio-Techne shall promptly provide to Sponsor such information, data and materials as Sponsor reasonably requests in order to obtain clearance, *de novo* classification, or approval by the FDA of the Co-Developed Test Kit as an IVD and/or to obtain the approval or clearance of an applicable Governmental Authority in a country other than the United States for the Commercialization of a Co-Developed Test Kit in such country.

5. MANUFACTURING OBLIGATIONS; MILESTONES

5.1 **Manufacturing of Co-Developed Test Kits.**

(a) Responsibilities of Bio-Techne. Subject to the terms and conditions of this Agreement, and without purporting to limit the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test, commencing no later than the date on which EUA is obtained in respect of a Co-Developed Test Kit and thereafter throughout the Term (such being referred to as "**Phase II**"), as between Sponsor and Bio-Techne, Bio-Techne shall be responsible for the Manufacturing of the Co-Developed Test Kits in accordance with applicable Law and any End User-Specific Requirements; provided, however, Sponsor shall retain the oversight responsibilities provided for in Section 9 and all other applicable provisions of this Agreement. Without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test, in the course of Manufacturing Co-Developed Test Kits, Bio-Techne shall observe, adhere to and comply with all obligations in relation to Manufacturing of the Co-Developed Test Kits that are imposed on Sponsor as the holder of the EUA in respect thereof (including without limitation the quality and compliance obligations described in Section 9) and any applicable End User-Specific Requirements. In the Manufacturing process, Bio-Techne shall not Deviate from the specifications set forth on Schedule 3.1(a) unless such Deviation is approved in writing by Sponsor in its sole discretion. Without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test, as between Sponsor and Bio-Techne, Bio-Techne agrees that it shall be solely responsible for such obligations and that Sponsor shall have no obligations to Bio-Techne in respect thereof except as is expressly set forth in Section 5.1(b). In the event the Parties mutually determine to jointly engage a third party to provide increased Manufacturing capacity, the Parties shall do so only on mutually agreeable terms with each other, as well as with the selected third party manufacturer.

(b) Responsibilities of Sponsor. Sponsor shall promptly provide to Bio-Techne such information as Bio-Techne reasonably requests in connection with Bio-Techne's discharge of its responsibilities under Section 5.1(a) and as Sponsor can obtain without unreasonable effort or expense. Upon Sponsor's receipt of any communication from any Governmental Authority or any End User that relates to or may affect the process of Manufacturing the Co-Developed Test Kits, Sponsor shall promptly provide a copy of such communication to Bio-Techne. Sponsor shall also retain the oversight responsibilities provided for in Section 9 and other applicable provisions of this Agreement.

5.2 **Manufacturing Milestones.**

(a) Establishment and Achievement of Manufacturing Milestones. Subject to the terms and conditions of this Agreement and to any requirements of applicable Law, and subject to contractual commitments existing prior to April 17, 2020, to the extent necessary to satisfy demand for the Co-Developed Test Kits as of any applicable date, Bio-Techne shall prioritize the Manufacturing of the Co-Developed Test Kits over any other business arrangement of Bio-Techne in accordance with this Agreement in such volumes as to achieve the milestones (the "**Manufacturing Milestones**") set forth on Schedule 5.2(a).

(b) Modification of Manufacturing Milestones and Resolution of Differences with Respect Thereto The Steering Committee shall have the authority to modify the Manufacturing Milestones. Any differences as to whether the Manufacturing Milestones should **be** modified shall be resolved through the Escalation Process.

5.3 **Product Warranty**. A Working Group shall be established to develop, prior to the first sale of a Co-Developed Test to an End User, the product warranty in respect of the Co-Developed Test Kits, taking into account the labelling insert in the Co-Developed Test Kits and the Certificate of Analysis in respect of the Co-Developed Test Kits. The Steering Committee shall have the authority to approve the product warranty, and once approved to modify the product warranty. Any differences as to whether the product warranty should be modified shall be resolved through the Escalation Process. As of the date of any shipment of a Co-Developed Test Kit to an End User, Bio-Techne shall be deemed to have made to Sponsor with respect to such Co-Developed Test Kit the same warranty as Bio-Techne makes to such End User.

6. CO-DEVELOPED TEST KIT LABELING AND BRANDING

6.1 **Labeling of Co-Developed Test Kits**.

(a) Establishment of Labeling. The labeling of the Co-Developed Test Kits shall be established in conformity with the EUA in respect thereof (and from and after any 510(k) clearance, *de novo* classification request, or other type of required premarket review and authorization of the Co-Developed test Kits, in conformity with the applicable requirements of the FDA in respect thereof) and such other labeling requirements as are imposed by the FDA or any other applicable Governmental Authority. The labeling of the Co-Developed Test Kits shall be established by the Steering Committee from time to time, and any differences shall be resolved through the Escalation Process.

(b) Responsibilities of Sponsor in Respect of Labeling. Sponsor shall be responsible for providing Bio-Techne instructions as to the labeling of the Co-Developed Test Kits in order for the labeling to comply with applicable Law and any End User-Specific Requirements. Sponsor shall also be responsible for obtaining any necessary FDA approval with respect to the labeling of the Co-Developed Test Kits, including any changes to the labeling of the Co-Developed Test Kits.

(c) Responsibilities of Bio-Techne in Respect of Labeling. Without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test Kits, as between Sponsor and Bio-Techne, Bio-Techne shall be responsible for promptly and accurately implementing all instructions of Sponsor relating to the labeling of the Co-Developed Test Kits pursuant to Section 6.1(b) without any Deviations or errors.

6.2 **Branding of the Co-Developed Test Kits**. Subject to the terms of the licenses granted in Section 6.3, the Co-Developed Test Kits shall be branded in such manner as the Parties agree and is approved by the Steering Committee (with any differences being resolved through the Escalation Process), provided that such branding shall employ the marks, "Kantaro Biosciences", "Mount Sinai" and "R&D Systems".

6.3 **License under the Sponsor Licensed Marks and the Bio-Techne Licensed Marks**.

(a) License Grant. Subject to the terms and conditions of this Agreement and the ISMMS TM License Agreement, Sponsor hereby grants to Bio-Techne during the Term a limited, revocable, non-assignable, non-transferable, non-exclusive, non-sublicensable license to use the trademarks depicted and described on Schedule 6.3(a) (the "**Sponsor Licensed Marks"**) throughout the world solely for the Licensed Use, solely in accordance with the design specifications set forth on Schedule 6.3(a) and solely in a manner that has been approved in advance by ISMMS. The rights granted herein do not include any right to (i) use any of the trademarks other than the Sponsor Licensed Marks, (ii) use the Sponsor Licensed Marks for any purpose other than the Licensed Use, (iii) use the Sponsor Licensed Marks as part of Bio-Techne's legal name anywhere or in connection with any other facility or operation, or (iv) register any trade or assumed name that includes any of the Sponsor Licensed Marks. The rights granted herein do not grant Bio-Techne any authority either (y) to act as agent for, or on behalf of, Sponsor or any Mount Sinai Entity or (z) to represent or bind Sponsor or any Mount Sinai Entity in any manner whatsoever.

(b) Quality Control. Bio-Techne acknowledges, and is familiar with, the high standards of quality, style, image, reputation and workmanship of Mount Sinai Entities and recognizes the substantial value and goodwill associated with the Marks; and that the Marks have acquired a secondary meaning as being synonymous with the Mount Sinai Entities' medical services and education of the highest quality and pioneering health and medical research and related goods/services. Accordingly, Bio-Techne recognizes the vital importance of protecting the Mount Sinai Entities' exclusive and valuable rights in and to the Marks and covenants that it will at all times during the Term (i) conduct its business in accordance with the highest medical, legal and ethical standards and in compliance with all applicable Laws; (ii) use the Sponsor Licensed Marks in accordance with the Mount Sinai Entities' high standards and the requirements of this Agreement, and (iii) use its best efforts to protect and enhance the goodwill pertaining to the Sponsor Licensed Marks for the exclusive benefit of the Mount Sinai Entities. Notwithstanding anything to the contrary contained in this Agreement, Bio-Techne shall not use the Sponsor Licensed Marks in any manner that ISMMS, in its sole and absolute discretion, deems to be illegal, improper, obscene, undesirable or inconsistent with the professional image and reputation of the Mount Sinai Entities. Bio-Techne may not modify or change the Sponsor Licensed Marks in any manner.

(c) Marketing Activities. Bio-Techne agrees that any marketing, promotion or advertising of the Co-Developed Test Kits using the Sponsor Licensed Marks shall be pre-approved in writing by ISMMS in each instance. Bio-Techne shall submit complete and accurate samples of each applicable proposed marketing, promotional and advertising materials reflecting its intended use of the Sponsor Licensed Marks to ISMMS and Sponsor for ISMMS's and Sponsor's review prior to commencing any such use. In addition, ISMMS and/or Sponsor shall have the right to request at any time samples of Bio-Techne's then current marketing, promotional and advertising materials that contain the Sponsor Licensed Marks and to reject any such materials by Notice given to Bio-Techne if in ISMMS's and Sponsor's reasonable discretion such materials would violate any term of this Agreement. Upon the giving of any such Notice of rejection of any such materials, Bio-Techne shall discontinue its use of such materials immediately and, if reasonably requested by Sponsor and/or ISMMS, Bio-Techne shall at its expense implement a corrective publicity program that has been approved by ISMMS and Sponsor (such approval not to be unreasonably withheld).

(d) License Restrictions. Bio-Techne agrees and covenants that it will in no event use the Sponsor Licensed Marks in any way, or take any action (or fail to take any action) that (i) could impair the validity or distinctiveness of the Sponsor Licensed Marks, or otherwise that would tend to allow them to become generic or (ii) in ISMMS's reasonable opinion, might mislead the public or be materially detrimental to, or inconsistent with the good name, goodwill, reputation and image of any Mount Sinai Entity. During the Term and thereafter (thus surviving termination or expiration of this Agreement for any reason), Bio-Techne agrees and covenants that it will not, directly or indirectly through any other Person (w) challenge the validity, enforceability, or any of the Mount Sinai Entities' use, registration or attempted registration, or ownership of the Marks, whether or not registered, or cause any other Person (including any government or quasi-governmental agency, including but not limited to intellectual property organizations) to do so; (x) register, seek to register or cause to be registered, any trade names, logos, trademarks, service marks, trade dress, domain names, social media handles and user names, brand names, designs or other proprietary indicia of goods and services for the Marks or confusingly similar to the Marks even if used in conjunction with other words, phrases or designations; (y) otherwise compromise the Marks or dispute any rights of ISMMS or the other Mount Sinai Entities in and to the Marks; or (z) aid or encourage any other Person in any manner in doing any of the foregoing ((w), (x) or (y)), whether (under (w), (x) or (y)) anywhere in the world.

(e) No Composite Mark Rights. Notwithstanding any of the foregoing, the Parties hereby agree and acknowledge that Bio-Techne's use of the Sponsor Licensed Marks, which shall at all times be in compliance with the terms of this Agreement, shall in no event permit Bio-Techne to use, create, file or register any new or composite mark based on any Licensed Mark or which is confusingly similar to any Licensed Mark, or confer to Bio-Techne any right, title or interest in or to any of the Sponsor Licensed Marks (including any goodwill associated therewith), except for the limited license grant expressly granted herein, or any new or composite mark consisting of any Licensed Mark or which is confusingly similar to any Licensed Mark. Without limiting the foregoing provision, if Bio-Techne during the Term acquires any right, title or interest in or to any Licensed Mark (including any goodwill associated therewith) beyond the limited rights expressly granted herein, or any new or composite mark consisting of any Licensed Mark or which is confusingly similar to any Licensed Mark, Bio-Techne hereby irrevocably assigns to ISMMS, in each case without additional consideration, all right, title and interest throughout the world and in perpetuity in and to any such Licensed Mark or any new or composite mark consisting of any Licensed Mark or any confusingly similar variation thereof (including any goodwill associated therewith). Upon the request of ISMMS or Sponsor, Bio-Techne shall each promptly take such further actions, including execution and delivery of all appropriate instruments of conveyance, as may be necessary to assist ISMMS to prosecute, register, perfect, record or enforce its rights in any Licensed Mark or in any new or composite mark consisting of any Licensed Mark or any confusingly similar variation thereof. In the event ISMMS is unable, after reasonable effort, to obtain Bio-Techne's signature on any such documents, ISMMS hereby irrevocably designates and appoints ISMMS as Bio-Techne's agent and attorney-in-fact, to act for and on Bio-Techne's behalf solely to execute and file any such application or other document and do all other lawfully permitted acts to further the prosecution and issuance of any Intellectual Property right related to the Sponsor Licensed Marks or to any new or composite mark consisting of any Licensed Mark with the same legal force and effect as if Bio-Techne had executed them.

(f) Reserved Rights. ISMMS and Sponsor expressly reserve all rights not expressly granted to Bio-Techne under this Agreement. Nothing in this Agreement shall be construed to prevent Sponsor or any Mount Sinai Entity from granting any other licenses for the use of the Sponsor Licensed Marks or from using the Sponsor Licensed Marks in any manner whatsoever. Any use of the Sponsor Licensed Marks in any manner that is not in complete conformity with the terms and conditions of this Agreement and that is not cured within the time permitted by this Agreement shall constitute a material breach of this Agreement. The license under this Agreement to use the Sponsor Licensed Marks in accordance with this Agreement does not confer any rights to any Marks other than the Sponsor Licensed Marks.

(g) Ownership. Bio-Techne hereby acknowledges and agrees that ISMMS is and shall remain the exclusive owner of all right, title and interest in and to the Marks, and that Bio-Techne's use of the Sponsor Licensed Marks under this Agreement and the goodwill associated therewith inures solely to the exclusive benefit of the Mount Sinai Entities. Bio-Techne hereby acknowledges and agrees that, other than the limited licenses granted hereunder, Bio-Techne has not acquired, and shall not acquire, any right, title or interest in or to the Marks anywhere in the world by virtue of this Agreement or Bio-Techne's exercise of the rights granted hereunder. Notwithstanding the foregoing, to the extent that Bio-Techne acquires any right, title or interest in the Marks, including any Intellectual Property rights therein, Bio-Techne hereby irrevocably assigns to the applicable Mount Sinai Entity, for no additional consideration, Bio-Techne's entire right, title or interest in the Marks and any Intellectual Property rights therein.

(h) Enforcement. Bio-Techne shall immediately give Notice to ISMMS and Sponsor upon becoming aware of: (i) any applications or petitions before any intellectual property organizations, authorities or registrars seeking to invalidate or challenge the Marks; and (ii) any actual or suspected infringement of the License Marks. ISMMS shall have the sole and exclusive right (but not the obligation) in its sole discretion to prosecute and enforce the Marks and shall exclusively retain all recoveries, revenues and other remedies deriving therefrom. Bio-Techne covenants that it will cooperate in good faith with ISMMS at ISMMS's expense in (y) the prosecution of any action, proceeding or claim brought before any intellectual property organizations, authorities or registrars, and (z) the defense or commencement of any judicial or administrative action, proceeding or claim brought to protect or enforce the Marks.

(i) Disclaimer of Representations and Warranties. BIO-TECHNE HEREBY AGREES AND ACKNOWLEDGES THAT SPONSOR AND ISMMS MAKE NO REPRESENTATION OR WARRANTY WHATSOEVER WITH RESPECT TO THE SPONSOR LICENSED MARKS, WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, THAT (I) ANY LICENSED MARK IS VALID; (II) ANY APPLICATION TO REGISTER A MARK WILL PROCEED TO REGISTRATION OR, IF SUCH REGISTRATION IS GRANTED, THAT SUCH REGISTRATION SHALL BE VALID; (III) THE EXERCISE BY BIO-TECHNE OF THE RIGHTS GRANTED WITH RESPECT TO THE SPONSOR LICENSED MARKS UNDER THIS AGREEMENT WILL NOT INFRINGE THE RIGHTS OF ANY PERSON.

(j) Injunctive Relief. Bio-Techne hereby acknowledges and agrees that a material breach of this Agreement with respect to provisions relating to the Sponsor Licensed Marks or confidentiality provisions will cause Sponsor and ISMMS irreparable damages, for which an award of damages would not be adequate compensation and agrees that, in the event of such a breach, Sponsor and ISMMS will be entitled to immediately seek equitable relief, including a restraining order, injunctive relief, specific performance and any other relief that may be available from any court or arbitration proceeding to restrain or otherwise enjoin or compel the act or omission resulting in such breach, in addition to and without prejudice to any other right or remedy to which Sponsor or ISMMS may be entitled at law or in equity and, to the extent permitted by Law, Bio-Techne consents and agrees that such remedy may be granted without any requirement that Sponsor or ISMMS post a bond or other security or make a showing of irreparable harm or lack of an adequate remedy at law. The remedies described in this Section 6.3(j) shall not be deemed to be exclusive but shall be in addition to all other remedies available at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

(k) Subject to the terms and conditions of this Agreement, Bio-Techne hereby grants to Sponsor during the Term a limited, revocable, non-assignable, non-transferable, non-exclusive, non-sublicensable license to use the trademarks depicted and described on Schedule 6.3(k) (the "**Bio-Techne Licensed Marks**") throughout the world solely for the Licensed Use and in accordance with the design specifications set forth on Schedule 6.3(k), and solely in a manner that has been approved in advance by Bio-Techne. Sponsor agrees that it is subject to the same terms, restrictions, acknowledgements and obligations set forth in Sections 6.3(a) through Section 6.3(j) regarding the Bio-Techne Licensed Marks as is required of Bio-Techne with respect to the Sponsor Licensed Marks. Notwithstanding the foregoing, Bio-Techne agrees that all content in marketing, promotion or advertising of the Co-Developed Test Kits *other than* the Bio-Techne Licensed Marks shall be pre-approved in writing by ISMMS in each instance, which approval shall not be unreasonably withheld.

(l) Sponsor and Bio-Techne may by mutual agreement add to or delete trademarks from the definition of either of the Sponsor Licensed Marks or Bio-Techne Licensed Marks (provided that in the case of any such addition or deletion that affects the Marks of the Mount Sinai Entities, ISMMS shall first have consented to such addition or deletion in writing).

7. PRICING AND REIMBURSEMENT

7.1 **Pricing and Terms of Sale of Co-Developed Test Kits**. The Steering Committee shall establish the list prices for the Co-Developed Test Kits and shall establish (and approve any changes in) ranges and parameters for Bio-Techne's authority to determine End User-specific pricing of the Co-Developed Test Kits (including any rebates, discounts or similar terms). Bio-Techne, in consultation with Sponsor, shall establish the terms of sale (e.g. shipping terms) for the Co-Developed Test Kits.

7.2 **Reimbursement Matters Affecting the Co-Developed Test Kits**.

(a) Responsibility of Sponsor. Sponsor shall use reasonable commercial efforts to make such documentary and informational submissions as are necessary in order for applicable Governmental Authorities to establish a rate at which End Users will be reimbursed under the Medicare program for the administration of the test contained in Co-Developed Test Kits.

(b) Acknowledgements of Bio-Techne. Bio-Techne acknowledges that the determination of reimbursement rates under the Medicare program lies within the discretion of the applicable Governmental Authorities; that there can be no assurance that any such reimbursement rate will be established for the administration of the test contained in Co-Developed Test Kits or that if established such rate will not be changed; or if any such reimbursement rate is established for the administration of the test contained in Co-Developed Test Kits that any third party payor other than the Medicare program will agree to utilize such rate.

8. SALES, DISTRIBUTION AND CUSTOMER SERVICE

8.1 **Responsibilities for Commercialization Activities**.

(a) Responsibilities of Bio-Techne. Without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test Kits, at all times during Phase II, as between Sponsor and Bio-Techne, Bio-Techne shall be solely responsible for all aspects of the Commercialization of the Co-Developed Test Kits that are not expressly ascribed to Sponsor under this Agreement; provided, however, Sponsor shall retain the oversight responsibilities provided for in Section 9 and the other applicable provisions of this Agreement. With the support of a number of Working Groups established by the Steering Committee the details of the responsibilities of Bio-Techne shall include, without limitation: (i) promoting the Co-Developed Tests through Bio-Techne's website and other means that are in accordance with Law and that have been approved by the Steering Committee, provided that all such promotional activities shall be strictly in compliance with the advertising and labeling requirements established by the EUA and/or other applicable Governmental Authorities with Health Care Laws and other applicable Laws, and with the standards established by the Steering Committee; (ii) taking and fulfilling orders for Co-Developed Test Kits from End Users at prices established in accordance with this Agreement; (iii) developing packaging for the Co-Developed Test Kits that is of a quality and durability that is approved by the Steering Committee (with the understanding that any text appearing on the packaging shall be governed by the provisions of Section 6.1); (iv) developing and overseeing, including tracking of the Co-Developed Test Kits and lots, safe and secure shipping methods for the Co-Developed Test Kits and effectuating the delivery of Co-Developed Test Kits in accordance with the terms of sale approved by the Steering Committee; (v)Tracking and handling End User complaints and returns and adverse events arising from the use of the Co-Developed Test Kits and providing information and support to Sponsor in connection therewith in accordance with the requirements of Section 9; (vi) collecting and accounting for the purchase price payable by End Users in accordance with the pricing and other terms established pursuant to this Agreement; (vii) acting as a fiduciary for Sponsor with respect to the share of Adjusted Gross Receipts to which Sponsor is entitled pursuant to Section 10; (viii) keeping complete and accurate books and records with respect to all Commercialization activities relating to the Co-Developed Test Kits including the books and records required by Section 9; (ix) effectuating all reporting obligations ascribed to Bio-Techne pursuant to Section 9; (x) providing all tracking reporting and accounting information in real time as described inSection 8.6; and (xi) carrying out all aspects of the Commercialization of the Co-Developed Test Kits that are not expressly ascribed to Sponsor under this Agreement in an orderly and businesslike manner.

(b) Responsibilities of Sponsor. Sponsor shall refer to Bio-Techne all inquiries received by the Sponsor from any potential End User during the Term. Sponsor will provide technical support to Bio-Techne in responding to inquiries from potential End-Users.

8.2 **Sponsor as End User**. To the extent that Sponsor and/or its Affiliates are qualified to act as End Users, during Phase II Sponsor and such Affiliates shall be entitled to purchase Co-Developed Test Kits from Bio-Techne on the same pricing (taking into account applicable discounts for other End Users of similar volumes), and other terms and conditions as apply to other End Users. With respect to each production run of Co-Developed Test Kits, during the first two months of such production run, Sponsor shall have the right by Notice to Bio-Techne to designate up to [******] of such production run for purchase by Mount Sinai Entities or other End Users designated by Sponsor, and Bio-Techne shall adhere to such designation.

8.3 **Embargoed Purchasers**. Sponsor has advised Bio-Techne that ISMMS is subject to certain restrictions that require that Co-Developed Test Kits not be sold to certain entities in which a Mount Sinai Entity has a certain level of equity interest ("**Embargoed Purchasers**"). Bio-Techne agrees not to sell Co-Developed Test Kits to any End User that Sponsor has by Notice to Bio-Techne designated as an Embargoed Purchaser.

8.4 **Responding to Priority Governmental Needs**. Sponsor and Bio-Techne acknowledge and agree that the state and local Governmental Authorities in the areas served by the Mount Sinai Entities and Bio-Techne respectively may request or require priority in the supply of Co-Developed Test Kits, and that it will be the policy of Sponsor and Bio-Techne to use reasonable commercial efforts to respond to such requests and/or requirements to the extent permitted by Law. The Steering Committee shall administer the response to any such requests and/or requirements, and any differences will be resolved through the Escalation Process. To the extent that federal, state and/or local Governmental Authorities impose conflicting obligations on Bio-Techne with respect to the supply or distribution of Co-Develop Test Kits, the Parties will immediately meet to determine how best to comply with all applicable requirements of Law.

8.5 **Policy with Respect to Back Orders**. To the extent that the demand for Co-Developed Test Kits exceeds the available supply of inventory, the Steering Committee shall have the authority to determine (subject to the requirements of applicable Law, and taking into account the provisions of Section 8.3), the manner in which the available supply of inventory of the Co-Developed Test Kits will be allocated (and if the Steering Committee is unable to reach consensus, such determination will be made through the Escalation Process).

8.6 **Portal for Real-Time Commercialization Information**. The Steering Committee shall establish a Working Group for the purpose of collaborating on the design and launch by Bio-Techne of an electronic data portal that is for the specific use of Sponsor in tracking Commercialization information with respect to the Co-Developed Test Kits (the "**Portal**"). The Working Group charged with the design of the Portal shall take into account the existing information technology infrastructure and data security needs of Bio-Techne so as to develop a Portal that is both practicable for Bio-Techne and that provides the real-time access to relevant information reasonably required by Sponsor. Within thirty (30) days of the Effective Date, Bio-Techne shall launch such Portal and during Phase II, Bio-Techne shall load into the Portal, on a daily basis, true, correct and complete information with respect to the Commercialization of the Co-Developed Test Kits in conformity with the requirements established by the Working Group. The Steering Committee shall have the authority to modify the Portal terms. Any differences as to whether the Portal design should be modified shall be resolved through the Escalation Process.

8.7 **Sponsor Rights with respect to Commercialization Responsibilities**.

(a) If at any time during Phase II, Sponsor and Bio-Techne mutually determine and agree that a third-party distributor should be engaged to take on specific commercial functions relating to the Co-Developed Test Kits in order to accelerate distribution to specific marketplaces or to reallocate functions that were initially the responsibility of Bio-Techne pursuant to the terms of this Agreement, then the Parties shall jointly assign such functions to a mutually agreed upon third-party distributor on terms mutually acceptable to both of the Parties. The revenue received from any such third-party distributor shall be considered cash actually received in consideration of the sale, licensing, use, lease, transfer or other disposition of Co-Developed Test Kits for purposes of determining Adjusted Gross Receipts and shall be subject to the terms of Section 10.2.

(b) If at any time during Phase II Bio-Techne determines or is concerned that it is unable or unwilling to discharge, or Sponsor reasonably determines or is concerned that Bio-Techne is not discharging, specific product fulfillment, billing, collections, customer service or similar obligations under this Agreement at a level that is at least equal to the level of industry standards for internationally-recognized manufacturers and distributors of in vitro medical devices, the Steering Committee shall promptly convene to consider the extent to which the issues that gave rise to such determinations and/or concerns are within Bio-Techne's control and to that extent how such issues can be collaboratively addressed and resolved. The Steering Committee shall have the authority to recommend any necessary changes to this Agreement that the Steering Committee believes could resolve the applicable issues, but no change to this Agreement shall be made except in accordance with Section 19.3. If after reasonable efforts to collaboratively address the applicable issues the Sponsor continues to believe that deficiencies exist in Bio-Techne's performance of specific product fulfillment, billing, collections, customer service or similar obligations, and that the correction of such deficiencies is within Bio-Techne's control, then by Notice to Bio-Techne, Sponsor may require that any or all of the responsibilities of Bio-Techne relating to product fulfillment, billing, collections, customer service or similar functions ascribed to Bio-Techne in this Section 8 be contracted to a third party organization whose core business includes the Commercialization of in vitro medical devices on terms that correspond to the terms of this Section 8 (and any other applicable provisions of this Agreement), and, until Bio-Techne is able to demonstrate to the reasonable satisfaction of Sponsor that Bio-Techne is able to discharge the applicable functions at a level that is at least equal to the level of industry standards for internationally-recognized manufacturers and distributors of in vitro medical devices, Bio-Techne shall bear the reasonable costs charged by such third party organization for the performance of the applicable responsibilities without any right of reimbursement therefor.

9. QUALITY, COMPLIANCE OBLIGATIONS AND CERTAIN FINANCIAL MATTERS

9.1 **Sponsor Audit at Bio-Techne**.

(a) Right to Oversee and Audit. Sponsor shall have the right as the manufacturer of record of the Co-Developed Test Kits to take such action and exercise such authority as Sponsor deems necessary or appropriate to oversee and monitor the performance by Bio-Techne of its compliance with Health Care Laws and its obligations to Sponsor under this Agreement. Without limiting the generality of the foregoing, Bio-Techne agrees that Sponsor and/or any representative of Sponsor shall at any reasonable agreeable time be entitled to audit the quality systems of Bio-Techne insofar as they are pertinent to assess Bio-Techne's compliance with Health Care Laws and with the provisions of this Agreement. Sponsor has the right to inspect and audit all of Bio-Techne's equipment facilities, operations, procedures, and records directly related to any Sponsor product or to the system support used to process them, and to audit and certify Bio-Techne's laboratory where quality control testing of the product is conducted. Terms and conditions for inspections and audits will be established by the Steering Committee (or if necessary through the Escalation Process).

(b) Audit Process for Audits by Sponsor or Sponsor's Authorized Contractor. Depending on the extent of the audit, the audit team will consist of one (1) or two (2) people, typically a lead auditor from quality assurance and a subject matter expert. The audit team will develop an audit protocol to use during the audit. The audit may last up to five (5) days and will include an opening meeting, audit activities with a daily wrap-up meeting held between the audit team and representatives of Bio-Techne to review audit progress, and a closing meeting to discuss the observations. Within five (5) days of the closing meeting, Sponsor will issue a draft audit finding report that includes recommended action items as a courtesy to Bio-Techne for review and comment within five (5) days of receipt to ensure that Bio-Techne is represented fairly. Sponsor will take the comments from Bio-Techne into consideration, but is not bound by the input, and may include agreed comments in the final report.

(c) Report of Audit. Within fifteen (15) days of the conclusion of the audit, Sponsor will provide a final written report of their findings along with recommended action items to Bio-Techne. Bio-Techne will provide a written action plan to Sponsor's report to Sponsor within fifteen (15) days after receipt of the report by Bio-Techne, unless Sponsor agrees to any extension.

(d) Implementation of Action Items. Sponsor and Bio-Techne will agree to a suitable time period to implement any action items. Bio-Techne will submit progress reports to Sponsor on either a monthly or quarterly basis. At the end of this period, the Sponsor audit team will schedule a follow-up audit, if necessary, or obtain documented evidence of successful completion.

(e) Follow-On Audit Activity . Subsequent audits may include an annual product review to recap quality issues occurring over the past year, product changes, and supplier performance. The continued suitability of this Agreement may also be discussed.

(f) Right to Audit Records Relating to Sale of Co-Developed Test Kits. Upon prior written notice to Bio-Techne and not more than once per Calendar Year, Sponsor shall have the right to access during normal business hours of Bio-Techne and on reasonable advance written notice, the applicable books and records of Bio-Techne, as may be reasonably necessary to verify the accuracy of the written report of the Adjusted Gross Receipts required to be delivered by Bio-Techne to Sponsor pursuant to Section 10.2(b) of this Agreement. If such audit shows any underpayment of Adjusted Gross Receipts by Bio-Techne, then, within seven (7) days after Bio-Techne's receipt of such report, Bio-Techne shall remit to Sponsor:

(i) the amount of such underpayment; and

(ii) if such underpayment exceeds five percent (5%) of the total Adjusted Gross Receipts owed for the Calendar Year then being reviewed, the reasonably necessary fees and expenses of Sponsor relating to such audit, including, but not limited to, fees of a third-party auditing firm performing such audit.

9.2 **Audit, Inspection or Investigation of Bio-Techne by a Regulatory Authority**. Bio-Techne shall allow representatives of Regulatory Authorities to inspect and audit its facility, the quality systems of Bio-Techne insofar as they are pertinent to such Regulatory Authority's audit in connection with the Co-Developed Test Kits. Bio-Techne shall cooperate with any inquiry or investigation by a Regulatory Authority with respect to Bio-Techne's compliance with Law in relation to the Co-Developed Test Kits and Bio-Techne's marketing or sale thereof. Bio-Techne shall immediately notify Sponsor of any inspection, audit, inquiry or investigation made by a Regulatory Authority that may involve the Co-Developed Test Kits, its facilities or business. Sponsor shall have the option of having its representatives on-site, by video conference or by phone during any such site visit by any Regulatory Authorities or meeting with such Regulatory Authorities to discuss the ongoing inquiries, questions and results of such inspection, audit, inquiry or investigation. Bio-Techne shall provide Sponsor in writing of the results of such inspection, audit, inquiry or investigation, immediately after such inspection, audit, inquiry or investigation has occurred, including without limitation providing to Sponsor copies of any resulting document of action (e.g., FDA Form 483 inspection observation report, regulatory letters, etc.) resulting there from to the extent relevant to Sponsor within five (5) days of their receipt. With the support of a Working Group established for this purpose, Sponsor and Bio-Techne shall collaborate in good faith in preparing responses to and plans of correction for any issues raised in the course of such inspection, audit, inquiry or investigation. The Working Group shall endeavor to fashion responses and plans of correction that both achieve the necessary compliance objectives as promptly as is reasonably practicable and that can be implemented by Bio-Techne on a cost-effective basis. Bio-Techne acknowledges, however, that ultimately the Sponsor is the manufacturer of record and therefore has legal responsibility for regulatory compliance, and that therefore in the event that a consensus cannot be achieved with respect to any response or plan of correction, Sponsor shall have the authority to determine the final form and content of the response or plan of correction, taking into account cost-effectiveness but also the need to maintain continuity of production, and Sponsor shall be responsible for submitting responses and plans of correction to the applicable Regulatory Authority. Sponsor shall provide a copy of each final response and plan of correction to Bio-Techne. If any Regulatory Authority determines that Bio-Techne is not in compliance with any applicable Laws, Bio-Techne shall promptly inform Sponsor of its plans to come into compliance with such Laws, to the extent the Co-Developed Test Kits are or may be affected, and shall continue to keep Sponsor informed of its progress until compliance has been attained.

9.3 **Quality Related Communication**

(a) **Prior to 510(k) Clearance/Granting of *de novo* Classification Request**. Prior to the issuance of a 510(k) clearance or the granting of a *de novo* classification request, with respect to the Co-Developed Test, and without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test Kit, as between Sponsor and Bio-Techne, Bio-Techne shall Manufacture the Co-Developed Lab Test in accordance with any and all quality-related requirements imposed by the EUA, or the requirements of any other applicable Regulatory Authority, and any End User-Specific Requirements in respect of the Co-Developed Test Kit (including without limitation any requirements of 21 C.F.R. Part 820 that are not waived by such EUA); provided, however, Sponsor shall retain the oversight responsibilities provided for in Section 9 and the other applicable provisions of this Agreement . The Steering Committee shall have the authority to establish a compliance protocol (the "**EUA Compliance Protocol**") based upon the terms of the EUA, and the requirements of any other applicable Regulatory Authority, in respect of the Co-Developed Test Kit and to amend the EUA Compliance Protocol from time to time as deemed necessary or appropriate by the Steering Committee (and any differences in the Steering Committee shall be resolved through the Escalation Process). Upon the establishment of the EUA Compliance Protocol, the EUA Compliance Protocol shall be deemed to be incorporated by reference into this Agreement and to form a part hereof.

(b) **Upon 510(k) Clearance / Granting of a *de novo* Classification Request**. Upon the issuance of 510(k) clearance or the granting of a *de novo* classification request with respect to the Co-Developed Test, and without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test Kit, as between Sponsor and Bio-Techne, Bio-Techne shall Manufacture the Co-Developed Lab Test in accordance with 21 C.F.R. Part 820 and any and all other applicable quality-related requirements imposed by the FDA, or the requirements of any other applicable Regulatory Authority, and any End User-Specific Requirements in respect of the Co-Developed Test Kit. The Steering Committee shall have the authority to establish a compliance protocol (the "**Part 820 Compliance Protocol**") based upon the requirements of 21 C.F.R. Part 820, and the requirements of any other applicable Regulatory Authority, and to amend the Part 820 Compliance Protocol from time to time as deemed necessary or appropriate by the Steering Committee (and any differences in the Steering Committee shall be resolved through the Escalation Process). Upon the establishment of the Part 820 Compliance Protocol, the Part 820 Compliance Protocol shall be deemed to be incorporated by reference into this Agreement and to form a part hereof.

9.4 **Quality Related Communication**

(a) Notification of Deviations. Bio-Techne shall notify Sponsor within two (2) days in the event of any procedural Deviation from product specification, the requirements of Section 9.3, or test failure for supplied product. Unless otherwise obligated by law or impractical due to requiring an immediate response, such as a spill, Bio-Techne shall consult with Sponsor before taking action in connection with these events.

(b) Sponsor Contact Person. Should Deviations arise, Bio-Techne will contact Sponsor in accordance with this Agreement, to address the issues depending upon the state of urgency. In such instances, the management representative at Sponsor or designee will assign a contact person at Sponsor for further action. As of the Effective Date, such contact person shall be the person listed on Schedule 2.1(c).

9.5 **Resolution of Quality Issues**. In accordance with this Agreement, representatives from both the Sponsor and the Bio-Techne Quality Department will be involved in resolution of quality issues, such as, but not limited to Deviations, errors, or out of specification/aberrant-suspect results, in an effort to reach a mutually agreeable decision. If a mutually agreeable resolution is not reached with respect to a given quality issue, the matter will be referred to the Steering Committee for resolution (if necessary through the Escalation Process).

9.6 **Component Control**. Bio-Techne and Sponsor shall mutually agree upon the specification of the Original Components and approved alternatives to the Components that can be substituted for an Original Component (the "**Approved Alternative Components**") prior to the time of submission of applications for EUA, 510(k) clearance or *de novo* classification, or the submission to any other applicable Regulatory Authority. Bio-Techne shall have the authority on notice to but without any further approval of Sponsor to make changes to the Original Components to the extent such change is to an Approved Alternative Component. Any changes to the Original Components or Approved Alternative Components, and any changes to any Components that are substituted for Original Components through the following process (other than through the substitution of Approved Alternative Components), shall be determined as follows: (i) if Bio-Techne desires to propose changes to any Component or Approved Alternative Component, Bio-Techne shall provide Sponsor with a detailed description of such proposed changes, and no such changes to the Components or Approved Alternative Components, shall be introduced without Sponsor's prior approval, (ii) if a Component or Approved Alternative Component becomes unavailable, Bio-Techne shall promptly provide Sponsor with a detailed description of a proposed replacement (and if Sponsor requests, alternative replacement approaches), and no such replacement shall be introduced without Sponsor's prior approval, (iii) if Sponsor desires to change a Component or an Approved Alternative Component based on Sponsor's belief that such change is required in order to comply with regulatory requirements for which Sponsor is responsible as a result of Sponsor's position as manufacturer of record of the Co-Developed Test Kits, Sponsor and Bio-Techne shall consult together (if necessary with the support of a Working Group) to endeavor to achieve consensus on such change, however if consensus is not able to be achieved then Sponsor shall have the ultimate authority to require such change to be made, taking into consideration considerations of cost-effectiveness but ultimately prioritizing the need for regulatory compliance and quality, and (iv) if Sponsor desires to propose changes to any Component or Approved Alternative Component for reasons other than those described in clause (iii) of this sentence, then Sponsor shall provide Bio-Techne with a detailed description of such proposed changes, and no such changes to the Components or Approved Alternative Components shall be introduced without Bio-Techne's prior approval. Bio-Techne agrees to promptly and precisely implement any changes to the Components or Approved Alternative Components that have been determined pursuant to the process that is described in this Section 9.6. Sponsor shall be responsible for making any submissions to any Regulatory Authority with respect to any changes in Components or Approved Alternative Components and Bio-Techne agrees to promptly make available to Sponsor any and all support and documentation necessary in connection with such filings. In addition, Bio-Techne shall notify Sponsor of changes in the Manufacturing processes and methods, including, but not limited to:

(a) changes in Manufacturing processes which could reasonably be expected to affect the function or quality of the Co-Developed Test Kits;

(b) changes in Component or Approved Alternative Component suppliers which could reasonably be expected to affect the quality of the Co-Developed Test Kits; and

(c) other changes which could reasonably be expected to affect the function or quality of the Co-Developed Test Kits.

9.7 **Annual Product Review**

(a) Review Activities. Where appropriate, a periodic product review will be prepared and reviewed according to Bio-Techne's policies and procedures. All review activities, which are the responsibility of Bio-Techne, will be completed and documented as per a mutually agreed timeframe. The annual product review documentation completed by Bio-Techne will be provided to Sponsor for review.

(b) Quality Reviews. The Steering Committee will meet periodically to review quality issues related to the obligations and responsibilities as described in this Agreement. During this periodic review, quality issues related to the past production by Bio-Techne will be reviewed. The information presented and discussed during the review meeting will be documented by Bio-Techne as a part of the Annual Product Review. The Steering Committee will approve the final draft.

9.8 **Regulatory Filing Requirements**.

(a) Bio-Techne Support of Sponsor Reporting Obligations. If Sponsor is required to submit to the Regulatory Authorities any information concerning the processing or Manufacturing of any of the Co-Developed Test Kits from Bio-Techne, Bio-Techne will promptly provide to Sponsor copies of documentation, data, and other information with respect to processing, packaging, and the facility as shall be reasonably necessary. Bio-Techne shall also make available its cooperation and consultation if reasonably requested by Sponsor and/or required by the Regulatory Authorities for development of additional data or performance of studies concerning Sponsor products. Bio-Techne shall also promptly provide, if required by the Regulatory Authorities, information concerning its production processes and quality control procedures with respect to the product. Bio-Techne shall promptly provide to Sponsor all documentation, data, and information reasonably in advance of their required submission to allow for Sponsor review. Bio-Techne shall endeavor in good faith to satisfactorily resolve all reasonable Sponsor comments raised during review prior to submission if such submission is to be made by Sponsor Terms for development of additional data or performance studies will be mutually agreed upon in writing.

(b) Submission of Regulatory Documentation. If Sponsor is required or intends to submit any documentation to, or otherwise communicate with the FDA, and those communications directly relate to the Co-Developed Test Kits in a material manner, prior to any submission or communication, Sponsor will discuss the submission of such documentation or communication with Bio-Techne; provided, however, Sponsor shall determine, in its sole discretion, the manner in which to submit such documentation or communicate to the FDA. Bio-Techne shall advise Sponsor in advance of any major planned changes to any documents, which directly relates to the Co-Developed Test Kits. Sponsor shall determine if the change requires FDA notification and, if appropriate, submit Sponsor-specific changes to the FDA. Bio-Techne shall notify Sponsor immediately of any adverse finding by the FDA that directly relates to the Co-Developed Test Kits or that could affect them. Sponsor agrees to inform Bio-Techne of any communication with the FDA which affect Bio-Techne's obligations hereunder. For all other communications or submission of documentation to any Regulatory Authority other than the FDA, Sponsor shall determine, in its sole discretion, whether such communication or submission of documentation shall be made by the Sponsor, the Parties jointly or by Bio-Techne. Bio-Techne shall immediately Notify and keep Sponsor informed of any adverse finding by any Regulatory Authority that directly relates to the Co-Developed Test Kits or that could affect them.

9.9 **Outsourcing and Vendor Qualification.** Bio-Techne will notify Sponsor prior to outsourcing of any aspect of manufacturing or testing and has the responsibility to ensure that the agreed upon third party is compliant with all applicable regulations. Bio-Techne shall obtain written authorization from Sponsor prior to outsourcing.

9.10 **Storage of Documentation by Bio-Techne**.

(a) Maintenance of Product Documentation. Upon Sponsor's request, Bio-Techne agrees to promptly make available to Sponsor all documentation related to the Co-Developed Test Kits. Bio-Techne shall keep all documentation that relates to the Co-Developed Test Kits in a manner so as to protect and secure the documentation against damage, destruction, unintended changes, or disposal during the required time of storage. Bio-Techne shall keep and maintain all such documentation in accordance with Bio-Techne's own policies and procedures and in compliance with 21 C.F.R. Part 820, and the requirements of any other applicable Regulatory Authority. Bio-Techne shall maintain records of test usage and ensure that any records associated with the EUA or any other clearance or approval of any Regulatory Authority are maintained until notified by Sponsor that such records may be disposed of. Bio-Techne shall not destroy any records described or referenced in this Section 9.10(a) unless and until so authorized by Sponsor.

(b) Storage Requirements. In order for Sponsor to comply with its obligations under Law as manufacturer of record of the Co-Developed Test, Bio-Techne shall keep backup copies of all documentation relating to the Co-Developed Test and Co-Developed Test Kits until authorized by Sponsor to destroy such documentation. For the archiving of data, media, diskettes, and similar media, Bio-Techne shall keep the original media and back-up copies in separate locations protected against damage, destruction, and or disposal during the required time of storage.

9.11 **Product Specifications**. Bio-Techne has the responsibility to have an established specification control procedure. Sponsor requires that the Components and Product will have written Specifications or SOPs under change/revision control. Specifications or SOPs serve as a basis for component and product quality evaluation. For any Major Changes to the Specification or SOPs, Bio-Techne shall give Notice to Sponsor and shall not implement such changes unless and until Sponsor approves such changes. Bio-Techne shall use its internal Specifications (approved by Sponsor) to test Components and Product. No materials shall be released or used before the evaluation of Sponsor has been completed.

9.12 **Product Complaints**. Without limiting the legal responsibility of Sponsor as the manufacturer of record of the Co-Developed Test, as between Sponsor and Bio-Techne, Bio-Techne shall be responsible for the collection and compilation in a compliant way of all information of which Bio-Techne becomes aware and that is necessary for compliance by Sponsor in respect of all known adverse event reporting and complaint-related requirements that are applicable to the Co-Developed Test Kits, with Sponsor retaining (i) the responsibility to provide to Bio-Techne any scientific or technical information that has been developed by ISMMS and that Bio-Techne requires to effectuate such compliant collection and compilation and (ii) oversight responsibility as provided in Section 9 and the other applicable provisions of this Agreement. Bio-Techne shall in compliance with applicable Law track all adverse events of which Bio-Techne becomes aware, including any occurrence of false results, and shall provide to Sponsor all information that Sponsor requires in order to fulfill its reporting obligations to FDA under 21 C.F.R. Part 803, and the requirements of any other applicable Regulatory Authority. Bio-Techne shall be responsible for the compliant collection and compilation of all information of which Bio-Techne becomes aware or that is requested by Sponsor and that is necessary to enable Sponsor to comply with adverse event or complaint information received (from End Users, patients and/or Regulatory Authorities) and shall deliver all such information to Sponsor promptly upon receipt by Bio-Techne. Upon request by Sponsor and to the extent required by Law, Bio-Techne will investigate each such adverse event and complaint and provide a written report on the results of the investigation to Sponsor within fifteen (15) days. To the extent that Sponsor, applicable Law or any Regulatory Authority so requires, Bio-Techne will conduct a root cause analysis of any such complaint and if required by the Steering Committee will involve the Steering Committee or a subcommittee thereof or a Working Group in the root cause analysis. Bio-Techne will communicate with the applicable End User the results of the complaints investigation, if necessary or required by Law or the Sponsor, provided that each such communication shall have been approved in advance by Sponsor.

9.13 **Compliance Program**. At all times during the Manufacturing process, Bio-Techne shall maintain with respect to the Co-Developed Test Kits a device master record and index, a quality management program and standard operating procedures that are (i) consistent with industry standards, (ii) no less stringent than those described in the applicable submissions for EUA, 510(k) clearance or *de novo* classification, or submissions to any other applicable Regulatory Authority and (iii) reasonably approved by Sponsor. A Working Group may oversee such quality programs and may recommend changes or additions thereto. In addition, at least ten (10) days prior to the sale of the first Co-Developed Test Kit, Bio-Techne shall provide to Sponsor a copy of Bio-Techne's compliance program for compliance with Health Care Laws relating to fraud and abuse. Promptly upon receipt of such compliance program, Sponsor shall review and provide Bio-Techne with recommended changes to such compliance program, which Bio-Techne agrees to implement prior to the sale of the first Co-Developed Test Kit.

9.14 **Compliance with Requirements Established by Non-U.S. Governmental Authorities**. At such time as any non-U.S. Governmental Authority approves the sale and distribution of the Co-Developed Test Kit outside the U.S., upon reasonable consultation with Bio-Techne, Sponsor shall have the unilateral right by Notice given to Bio-Techne to supplement this Section 9 with any additional protocols and obligations of Bio-Techne necessary to satisfy any applicable requirements established by any non-U.S. Governmental Authority (and effective upon the giving of such Notice the terms of such additional protocols and obligations shall be deemed to have been incorporated by reference into this Agreement for all purposes).

9.15 **Quality Agreement**. Simultaneously herewith, Sponsor and Bio-Techne are entering into the Quality Agreement. To the extent that any term of the Quality Agreement conflicts with any term of this Section 9, the applicable term of this Agreement shall prevail. To the extent that this Section 9 or the Quality Agreement addresses a subject that is not addressed in the other, the fact that the other agreement is silent as to such subject shall not affect the construction or interpretation of the terms of this Agreement or the Quality Agreement (as applicable) that apply to such subject. The Parties acknowledge that the Quality Agreement may provide for reporting and compliance terms and obligations that are not specifically set forth in this Section 9.

10. ECONOMIC OBLIGATIONS AND CASH MANAGEMENT.

10.1 **Responsibility for Expenses**. Each Party shall be responsible for its own expenses incurred by such Party in the performance of such Party's obligations under this Agreement, without any right of reimbursement from the other Party or any right to recoup such expenses prior to the division of Adjusted Gross Receipts that is contemplated by this Section 10.

10.2 **Sharing of Adjusted Gross Receipts**.

(a) Adjusted Gross Receipts from End Users of Co-Developed Test Kits. To the extent that during the Term Adjusted Gross Receipts arise from sales of Co-Developed Test Kits to End Users, Bio-Techne shall pay to Sponsor [******] of such Adjusted Gross Receipts.

(b) Payment of Share of Adjusted Gross Receipts. For each month in Phase II, including the month in which the Term ends, Bio-Techne will pay the amounts due to Sponsor as set forth in Section 10.2(a) as follows: (i) in the case of the last month in Bio-Techne's first, second and third fiscal quarter, within twenty-one (21) days after the end of such month, (ii) in the case of the last month in Bio-Techne's fiscal year, within thirty (30) days after the end of such month and (iii) for all other months, within fifteen (15) days after the end of such month. Together with each payment, Bio-Techne shall account to Sponsor for all Adjusted Gross Receipts arising during the applicable calendar month and shall deliver to Sponsor a written report of all such Adjusted Gross Receipts in the form prescribed by Sponsor. Bio-Techne shall pay to Sponsor by wire transfer to the account of which Sponsor shall give Notice to Bio-Techne the amount required to be paid to Sponsor in respect of such Adjusted Gross Receipts by the terms of this Section 10. Sponsor and Bio-Techne shall, by mutual agreement, true-up and reconcile any differences in monthly accounting and payments on a calendar quarterly basis.

(c) Sales at Below Cost of Production. To the extent that Governmental Authorities require the testing kits to be sold at below the cost of production, in lieu of the revenue sharing provisions of Section 10.2(b) through (d), Sponsor and Bio-Techne shall divide the applicable Adjusted Gross Receipts proportionately to each Party's expenses in connection with the applicable sales.

(d) Resolution of Payment Related Differences. If Sponsor has any differences with any calculation of any amount required to be paid to Sponsor pursuant to this Section 10, such differences shall promptly be referred to the Steering Committee, and any differences that the Steering Committee is unable to resolve shall be resolved through the Escalation Process.

11. RUO MATTERS

11.1 **Selling or Distributing Co-Developed Test Kits for Research Use Only**. The Steering Committee shall establish a Working Group for the purpose of considering the timing and appropriate scope of distribution of Co-Developed Test Kits for Research Use Only and the conditions and terms under which such Co-Developed Test Kits will be sold. After deliberation and mutual agreement by the Working Group as to the conditions and terms under which such Co-Developed Test Kits will be sold, the Parties will memorialize such terms in an addendum (the "**RUO Addendum**") to this Agreement, with the understanding that at a minimum the following terms will be included in the RUO Addendum:

(a) Bio-Techne shall pay to Sponsor [******] of Adjusted Gross Receipts arising from sales of Co-Developed Test Kits for Research Use Only; and

(b) Subject to the terms of Section 6.3, the Co-Developed Test Kits sold for Research Use Only shall be branded as "Mount Sinai 'powered by' R&D Systems" in such a manner as is approved by the Parties.

12. REPORTING

12.1 **Required Bio-Techne Reports**. During the Term, Bio-Techne shall provide to Sponsor in a timely manner all reports required to be provided by Bio-Techne to Sponsor under this Agreement. Except as may be determined by Sponsor under Section 9.8(b) or otherwise as expressly authorized under this Agreement, in no event shall Bio-Techne communicate directly with any Governmental Authority in respect of the Co-Developed Test Kits.

12.2 **Required Sponsor Reports**. During the Term, Sponsor shall provide to Bio-Techne in a timely manner all reports required to be provided by Sponsor to Bio-Techne under this Agreement. Sponsor shall also file or submit in a timely manner all reports required to be filed or submitted by Sponsor to any Governmental Authority as the manufacturer of record of the Co-Developed Test Kits. Promptly upon the provision thereof to any Governmental Authority, Sponsor shall provide to Bio-Techne a copy of any report filed or submitted by Sponsor with any Governmental Authority by the terms of this Agreement or applicable Law with respect to the Co-Developed Test Kits.

12.3 **Other Reports**. The Steering Committee may from time to time prescribe other reports that are required to be provided by Bio-Techne to Sponsor or by Sponsor to Bio-Techne, including the content and the timing thereof.

13. OTHER COVENANTS OF THE PARTIES

13.1 **ISO 13485**. At all times during the Term, Bio-Techne covenants that it shall be certified to be in compliance with the ISO 13485:2016 Quality System Standards. The notified body that issues any certificate of compliance to Bio-Techne shall be a body that is authorized by FDA to conduct audits under the Medical Device Single Audit Program (MDSAP).

13.2 **[******]**

13.3 **Further Assurances**. Each of Party hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement and the other Transaction Documents.

13.4 **Confidentiality**. The Parties agree that all information communicated or provided by either Party to the other Party pursuant to or in connection with this Agreement is subject to the terms of the Bio-Techne NDA, which such terms are hereby incorporated by this reference.

13.5 **Press Releases**. Without limiting the provisions of Section 6, neither Party shall issue any press release that names the other Party or any Mount Sinai Entity or that specifically refers to the transactions contemplated by this Agreement without the express prior written consent of the other Party, provided that Bio-Techne shall have the right to issue a press release or make a securities filing that, in the opinion of counsel to Bio-Techne, Bio-Techne is required by federal securities laws to issue or file so long as Bio-Techne consults with Sponsor with respect thereto and (to the extent permitted by Law) provides to Sponsor a copy of such press release or securities filing as much in advance of the issuance or filing as is feasible. The Parties shall agree upon the form, content and release date of a joint press release to be issued upon the execution of this Agreement.

13.6 **Independent Activities; Non-Exclusivity**. The only obligations undertaken by the Parties are those expressly provided in this Agreement. Each Party may engage in whatever activities it chooses, whether or not the same be competitive with the activities contemplated herein, without having or incurring any obligation to offer any interest in such activities to the other Party, and the other Party hereby waives, relinquishes and renounces any such right or claim of participation. The Parties expressly confirm and agree that this Agreement is non-exclusive. Nothing herein shall be deemed to give rise to an obligation on the part of either Party to deal exclusively with the other Party, nor to any obligation of either party to take or refrain from taking any action that would have the effect of increasing the amount of Adjusted Gross Receipts that may be derived from the Commercialization of the Co-Developed Test. Without limiting the generality of the foregoing, Bio-Techne recognizes that (i) Sponsor has licensed and in the future may continue to license to third parties the same Intellectual Property as is licensed to Bio-Techne hereunder; (ii) Sponsor shall have the right to enter into agreements and arrangements with third parties that are similar to and/or have the same or similar objectives as this Agreement (even if such agreements and arrangements result in products being Commercialized that are competitive with the Co-Developed Test Kits); and (iii) nothing in this Agreement shall be construed in a manner that would limit the ability of ISMMS or any other Mount Sinai Entity to carry out its or their research, education or patient care charitable missions.

13.7 **ISMMS License Agreements**. During the Term, Sponsor hereby agrees not to amend, modify or terminate (or consent to or approve any amendment or modification of) the ISMMS License Agreements in any manner that would adversely affect the rights of Bio-Techne under this Agreement.

14. REPRESENTATIONS AND WARRANTIES OF BIO-TECHNE

Bio-Techne hereby represents and warrants to Sponsor that the statements contained in this Section 14 are true and correct as of the Effective Date, except to the extent that any such representation or warranty refers to a specified date, in which event such representation or warranty shall be true and correct as of such specified date.

14.1 **Organization and Qualification of Bio-Techne**. Bio-Techne is duly organized, validly existing and in good standing under the Laws of the State of Minnesota and has all necessary corporate power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as currently conducted. Bio-Techne is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the operation of its business as currently conducted makes such license or qualification necessary.

14.2 **Authority**. Bio-Techne has all necessary corporate power and authority to enter into this Agreement and the other Transaction Documents to which it is or will be a party, to carry out its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery by Bio-Techne of this Agreement and any other Transaction Document to which Bio-Techne is or will be a party, the performance by Bio-Techne of its obligations hereunder and thereunder and the consummation by Bio-Techne of the transaction contemplated hereunder and thereunder have been duly authorized by all requisite corporate action on the part of Bio-Techne, and no other proceedings on the part of Bio-Techne is required to authorize the execution, delivery and performance thereof by such Person. When each Transaction Document to which Bio-Techne is or will be a party has been duly executed and delivered by Bio-Techne (assuming due authorization, execution and delivery by each other party thereto), such Transaction Document will constitute a legal and binding obligation of Bio-Techne, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equitable principles (regardless of whether enforcement is sought in a proceeding at law or in equity).

14.3 **No Conflicts; Consents**. The execution and delivery by Bio-Techne of this Agreement and the other Transaction Documents to which it is or will be a party, and the consummation of the Transaction, and performance by Bio-Techne of the obligations hereunder and thereunder, do not and will not: (a) conflict with or result in a violation or breach of, or default under, any provision of the certificate of incorporation, bylaws or other organizational documents of Bio-Techne in any material respect; (b) conflict with or result in a violation or breach of any provision of any Law or Order applicable to Bio-Techne or its business as currently conducted; (c) require the consent, notice or other action by any Person under, conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a material default under or result in the termination or acceleration of or create in any party a right of purchase, sale, acceleration, termination, modification or cancellation under, any material contract to which Bio-Techne is a party; or (d) result in the creation or imposition of any lien or encumbrance on the Co-Developed Test Kits. The execution and delivery by Bio-Techne of this Agreement and the other Transaction Documents to which it is or will be a party, and the consummation of the transactions contemplated herein and therein, and performance by Bio-Techne of the obligations hereunder and thereunder will not conflict with or result in a violation or breach of any provision of any Contract. Other than the Governmental Approvals, no consent, approval, Permit, Order, declaration or filing with, or notice to, any Governmental Authority is required by or with respect to Bio-Techne in connection with the execution and delivery of this Agreement the other Transaction Documents and the performance and consummation by Bio-Techne.

14.4 **Compliance With Laws; Permits.**

(a) Bio-Techne has materially complied, and is now in material compliance, with all Laws applicable to this Agreement, the Co-Developed Test Kits and to the conduct of its business as currently conducted.

(b) All Permits required for Bio-Techne to conduct its business as currently conducted or for the ownership and use of its properties and assets to be used in connection with the Co-Developed Test Kits have been obtained by Bio-Techne and are valid and in full force and effect. All fees and charges with respect to such Permits as of the Effective Date have been paid in full. No event has occurred that, with or without notice or lapse of time or both, would reasonably be expected to result in the revocation, suspension, lapse or limitation of any of Bio-Techne's Permits necessary for the Development, Manufacturing and Commercialization of the Co-Developed Test Kits pursuant to this Agreement and the other Transaction Documents.

14.5 **Intellectual Property**. Bio-Techne represents and warrants that (i) it is the sole and exclusive legal and beneficial owner of all right, title and interest in and to the Bio-Techne Background IP free and clear of Encumbrances, (ii) it has full and sufficient right, title and authority to grant the rights and licenses granted to Sponsor hereunder, (iii) the Bio-Techne Background IP does not contain any materials developed by a third party and used by Bio-Techne, except pursuant to a license agreement, and (iv) the Bio-Techne Background IP does not infringe any Intellectual Property rights of a third party.

14.6 **Insurance**. Bio-Techne or its Affiliates maintain fire, liability, product liability, umbrella liability, real and personal property, workers' compensation, vehicular, fiduciary liability and other casualty and property insurance, including the insurance set forth on Schedule 17.2, relating to its business as currently conducted, its properties and assets (collectively, the "**Insurance Policies**"). There are no Actions related to Bio-Techne's business as currently conducted, its properties and assets pending under any such Insurance Policies as to which coverage has been questioned, denied or disputed or in respect of which there is an outstanding reservation of rights. Neither Bio-Techne nor any of its Affiliates has received any written notice of cancellation of, premium increase with respect to, or alteration of coverage under, any of such Insurance Policies. All premiums due on such Insurance Policies have either been paid or, if not yet due, accrued. All such Insurance Policies (a) are in full force and effect and enforceable in accordance with their terms; (b) are provided by carriers who are financially solvent; and (c) have not been subject to any lapse in coverage. None of Bio-Techne or any of its Affiliates is in default under, or has otherwise failed to comply with, in any material respect, any provision contained in any such Insurance Policy. The Insurance Policies are of the type and in the amounts customarily carried by Persons conducting a business similar to Bio-Techne's business as currently conducted and are sufficient for compliance with all applicable Laws and Contracts to which Bio-Techne is a party or by which it is bound.

14.7 **Due Diligence**. All documents, data and materials delivered by Bio-Techne to Sponsor in connection with any due diligence request of Sponsor were true, correct and complete when delivered.

14.8 **ISO 13485**. Bio-Techne has been certified to be in compliance with the ISO 13485:2016 Quality System Standards by a notified body that FDA has authorized to conduct audits under the Medical Device Single Audit Program (MDSAP).

15. REPRESENTATIONS AND WARRANTIES OF SPONSOR

Sponsor hereby represents and warrants to Bio-Techne that the statements contained in this Section 15 are true and correct as of the Effective Date, except to the extent that any such representation or warranty refers to a specified date, in which event such representation or warranty shall be true and correct as of such specified date.

15.1 **Organization and Qualification of Sponsor**. Sponsor is duly organized, validly existing and in good standing under the Laws of the State of New York and has all necessary corporate power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as currently conducted. Sponsor is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the operation of its business as currently conducted makes such license or qualification necessary.

15.2 **Authority**. Sponsor has all necessary corporate power and authority to enter into this Agreement and the other Transaction Documents to which it is or will be a party, to carry out its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery by Sponsor of this Agreement and any other Transaction Document to which Sponsor is or will be a party, the performance by Sponsor of its obligations hereunder and thereunder and the consummation by Sponsor of the transaction contemplated hereunder and thereunder have been duly authorized by all requisite corporate action on the part of Sponsor, and no other proceedings on the part of Sponsor is required to authorize the execution, delivery and performance thereof by such Person. When each Transaction Document to which Sponsor is or will be a party has been duly executed and delivered by Sponsor (assuming due authorization, execution and delivery by each other party thereto), such Transaction Document will constitute a legal and binding obligation of Sponsor, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equitable principles (regardless of whether enforcement is sought in a proceeding at law or in equity).

15.3 **Intellectual Property**. Sponsor represents and warrants that (i) the rights to use the MS Background IP have been duly and validly licensed by ISMMS to Sponsor for purposes of this Agreement pursuant to the ISMMS IP License Agreement, (ii) it has full and sufficient right, title and authority to grant the rights and licenses granted to Bio-Techne hereunder, (iii) the MS Background IP does not contain any materials developed by a third party and used by Sponsor, except pursuant to a license agreement, (iv) the MS Background IP does not infringe any Intellectual Property rights of a third party, and (v) the copies of the ISMMS License Agreements made available to Bio-Techne prior to the Effective Date are true, correct and complete copies, with the competitively sensitive and confidential terms thereof redacted. As of the Effective Date, each ISMMS License Agreement is in full force and effect.

16. DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITIES

16.1 **DISCLAIMER OF WARRANTIES**. EXCEPT AS IS EXPRESSLY SET FORTH IN SECTION 15.3, SPONSOR AND ISMMS MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, WITH RESPECT TO THE MS LAB TEST OR ANY MATERIAL DELIVERED BY SPONSOR TO BIO-TECHNE. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. RECIPIENT ASSUMES ALL RISKS ASSOCIATED WITH THE USE OF THE MATERIAL UNDER THIS AGREEMENT.

16.2 **CONSEQUENTIAL DAMAGES**. NOTWITHSTANDING ANYTHING CONTAINED IN THIS AGREEMENT TO THE CONTRARY, NEITHER PARTY OR ITS AFFILIATES, MEMBERS, TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND/OR FACULTY MEMBERS SHALL BE LIABLE IN ANY MANNER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR EXEMPLARY DAMAGES OF THE OTHER PARTY OR THE OTHER PARTY'S AFFILIATES, MEMBERS, TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND/OR FACULTY MEMBERS, EVEN IF SUCH PARTY, AFFILIATE(S), MEMBER(S) TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND/OR FACULTY MEMBERS HAS BEEN INFORMED IN ADVANCE OF THE POSSIBILITY OF SUCH DAMAGES. EACH PARTY UNCONDITIONALLY AND IRREVOCABLY FOREVER WAIVES, ON BEHALF OF ITSELF, ITS AFFILIATES, MEMBERS, TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, AND/OR FACULTIES, ANY RIGHT TO SEEK SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR EXEMPLARY DAMAGES HEREUNDER. THE LIMITATION IN THIS SECTION 16.2 SHALL NOT APPLY TO (I) THE PARTIES' INDEMNIFICATION OBLIGATIONS (II) ANY BREACH BY EITHER PARTY OF SUCH PARTY'S OBLIGATIONS TO THE OTHER UNDER ANY WRITTEN CONFIDENTIALITY OR NON-DISCLOSURE AGREEMENT ENTERED INTO BY THE PARTIES WHETHER PRIOR TO OR AFTER THE DATE HEREOF, OR (III) ANY VIOLATION BY EITHER PARTY OF SUCH PARTY'S OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO THE INTELLECTUAL PROPERTY OF THE OTHER PARTY.

16.3 **NO LIABILITY OF ISMMS**. BIO-TECHNE HEREBY ACKNOWLEDGES AND AGREES THAT IN NO EVENT SHALL ISMMS HAVE ANY LIABILITY TO BIO-TECHNE FOR THE OBLIGATIONS OR LIABILITIES OF SPONSOR UNDER THIS AGREEMENT UNDER ANY THEORY OF VICARIOUS LIABILITY INCLUDING WITHOUT LIMITATION ANY THEORY IN THE NATURE OF ACTUAL OR APPARENT AGENCY OR ALTER EGO.

17. INDEMNITY AND INSURANCE

17.1 **Indemnification**.

(a) Bio-Techne Indemnification. Bio-Techne, at its sole cost and expense, shall defend, indemnify and hold harmless Sponsor, its Affiliates, each of the Mount Sinai Entities and each and every one of their respective subsidiaries, parents, and Affiliates, and their respective trustees, directors, officers, members, shareholders, faculty members, medical staff, employees, students, agents and representatives (collectively, the "**Sponsor Indemnitees**") from and against any third-party Action, and shall pay and reimburse each of them for, any and all related Losses incurred or sustained by, or imposed upon, the Sponsor Indemnitees in favor of any third party to the extent based upon, arising out of, with respect to or by reason of: (i) any negligent or more culpable act or omission of Bio-Techne (including any reckless or willful misconduct) in connection with the performance of its obligations under this Agreement; (ii) Bio-Techne and its Affiliates' conduct of business activities that are unrelated to the activities contemplated by this Agreement; (iii) any bodily injury, death of any person, or damage to real or tangible personal property to the extent caused by the negligent or more culpable acts or omissions of Bio-Techne (including any reckless or willful misconduct); (iv) any breach or non-fulfillment of any of Bio-Techne's representation, warranty, or covenant under this Agreement (including without limitation any responsibilities allocated to Bio-Techne under this Agreement); (v) any infringement of Intellectual Property rights of any Person relating to the Bio-Techne Background IP; or (vi) any failure by Bio-Techne to comply with any applicable Law in the performance of its obligations under this Agreement.

(b) Sponsor Indemnification. Sponsor agrees, at its sole cost and expense, to indemnify and hold harmless Bio-Techne, Bio-Techne's Affiliates, and each and every one of their respective directors, officers, members, shareholders, employees, agents and representatives (collectively, the "**Bio-Techne Indemnitees**"), from and against any third-party Action, and shall pay and reimburse each of them for, any and all related Losses incurred or sustained by, or imposed upon, the Bio-Techne Indemnitees in favor of any third party to the extent based upon, arising out of, with respect to or by reason of: (i) any negligent or more culpable act or omission of Sponsor (including any reckless or willful misconduct) in connection with the performance of its obligations under this Agreement; (ii) Sponsor's and its Affiliates' conduct of business activities that are unrelated to the activities contemplated by this Agreement; (iii) any breach or non-fulfillment of any of Sponsor's representation, warranty, or covenant under this Agreement (including without limitation any responsibilities allocated to Sponsor under this Agreement); (iv) any infringement of Intellectual Property rights of any Person relating to the Sponsor Background IP or the Sponsor Licensed Marks; or (v) any failure by Sponsor to comply with any applicable Law in the performance of its obligations under this Agreement.

(c) Indemnification Procedure. The indemnified Party agrees to provide the indemnifying Party with prompt written notice of any Action to which this indemnification applies, provided that a failure of the indemnified Party to give written notice shall not affect the indemnifying Party's obligations hereunder to the indemnified Party except to the extent of actual prejudice suffered by the indemnifying Party due solely to the failure to give such written notice. The indemnifying Party shall have the exclusive right to control the defense of any such Action, at its sole expense and risk, provided that the indemnifying Party agrees in writing in connection with the Action that the indemnifying Party will fully indemnify and defend the other Party and the related indemnitees and shall comply with the following:

The indemnifying Party, upon the written request of such indemnified Party, shall, or upon written notice to such indemnified Party may elect to, assume the defense of such proceeding, at the indemnifying Party's own expense, with counsel reasonably satisfactory to such indemnified Party. Such indemnified Party shall have the right to employ separate counsel in any such proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such indemnified Party unless (i) the indemnifying Party has agreed in writing to pay such reasonable fees and expenses, (ii) the indemnifying Party has failed to assume the defense, pursue the defense reasonably diligently or to employ counsel in a reasonably timely manner, (iii) outside counsel to such indemnified Party has advised such indemnified Party in writing that in such proceeding there is an actual or potential conflict of interest or a conflict on any material issue between the indemnifying Party's position and the position of such indemnified Party, provided that the indemnifying Party shall be responsible for the reasonable fees and expenses of only one separate outside counsel at any time for all such indemnified Parties, which outside counsel shall be designated in writing by the indemnifying Party.

The indemnifying Party shall not settle, or consent to the entry of any judgment in, any Action without obtaining either: (y) an unconditional release of the indemnified Party and its related indemnitees from all liability with respect to all Actions underlying the applicable proceeding, such release not to include any limitation on the indemnified Party's rights to do business or to its rights under this Agreement or any admission of wrongdoing; or any other injunctive relief; or (z) the prior written consent of the indemnified Party.

If the indemnifying Party fails to acknowledge in writing its obligation to defend against each proceeding, the indemnified Party shall be free to dispose of the matter, at the expense of the indemnifying Party, in any way in which the indemnified Party reasonably deems to be in its best interest.

An indemnified Party may obtain separate counsel of the indemnified Party's choice if such indemnified Party reasonably believes the indemnifying Party's and such indemnified Party's interests may conflict. An indemnified Party's undertaking of defense and/or settlement will in no way diminish the indemnifying Party's obligation to indemnify such indemnified Party and to hold it harmless. In either case, the indemnifying Party will also reimburse such indemnified Party (and all other indemnified Parties) upon demand for all losses, including reasonable attorneys' fees and court costs the indemnified Party incurs to protect itself, or to remedy the indemnifying Party's defaults. Under no circumstances will the indemnified Parties be required to seek recovery from Third Parties or otherwise mitigate their losses to maintain an Action against the indemnifying Party, and their failure to do so will in no way reduce the amounts recoverable from the indemnifying Party by the indemnified Parties.

17.2 **Insurance**. During the Term and for a period of five years after the last date on which the applicable Party continues to exploit any Jointly Owned Intellectual Property, each Party will procure and maintain insurance policies, which initially shall be for the coverages, minimum premium amounts and other related requirements as set forth on Schedule 17.2; provided however that Sponsor shall not be required to procure and maintain such insurance until the date of shipment of the first Co-Developed Test to an End User. At any time during the Term, the Steering Committee shall have the authority by Notice given to both Parties to require both Parties to increase the insurance requirements set forth on Schedule 17.2. Within sixty (60) days after the giving of such Notice, each Party shall obtain and thereafter maintain such increased insurance for the period set forth in the first sentence of this Section 17.2.

18. TERM AND TERMINATION

18.1 **Term and Termination**.

(a) Term. The term of this Agreement (the "**Initial Term**") commences on the Effective Date and continues thereafter until the that date that is five (5) years following the Effective Date, unless and until sooner terminated as provided in 18.1(c).

(b) Renewal. Upon expiration of the Initial Term, this Agreement shall automatically renew for an additional successive twelve (12) months unless either Party provides written notice of nonrenewal at least ninety (90) days prior to the end of the then-current term or unless sooner terminated as provided in Section 18.1(c) (such period, a "**Renewal Term**" and together with the Initial Term, the "**Term**"). If the Term is renewed for a Renewal Term pursuant to this Section 18.1(b), the terms and conditions of this Agreement during each such Renewal Term shall be the same as the terms and conditions in effect immediately prior to such renewal. If either Party provides timely notice of its intent not to renew this Agreement, then, unless otherwise sooner terminated in accordance with its terms, this Agreement shall terminate on the expiration of the then-current Term.

(c) Termination.

(i) With Cause. This Agreement may be terminated before the expiration date of the Term on written notice:

(1) by either Party, if the other Party materially breaches any provision of this Agreement and either the breach cannot be cured or, if the breach can be cured, it is not cured by the breaching Party within the following period after the giving by the non-breaching Party of notice of such breach to the breaching Party: (A) in the case of any breach that relates to any requirement of applicable Law and that under applicable Law must be cured or remediated by a specific date or that under applicable Law gives rise to an obligation to make a filing or submit a report by a specific date, the period that ends five (5) days before such date; or (B) in the case of any breach not described in clause (A) that with reasonable diligence can be cured within thirty (30) days, a period of thirty (30) days; or (C) in the case of any breach not described in clause (A) that with reasonable diligence cannot be cured within thirty (30) days, that period within which with reasonable diligence such breach could reasonably be cured but not more than a period of thirty (60) days; or

(2) by either Party, if the other Party (A) becomes insolvent, (B) is generally unable to pay, or fails to pay, its debts as they become due, (C) files, or has filed against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law, (D) makes or seeks to make a general assignment for the benefit of its creditors, or (E) applies for, or consents to, the appointment of a trustee, receiver or custodian for a substantial part of its property or business.

(ii) Failure to Obtain EUA. If, notwithstanding the compliance by the Parties with their obligations under this Agreement, EUA is not obtained in respect of a Co-Developed Test Kit by the Outside Date, either Party may terminate this Agreement by notice to the other Party.

(iii) End of EUA Period. Notwithstanding anything to the contrary herein, at the End of the EUA Period the Parties shall assess in good faith the demand for and economics of the Co-Developed Test Kits, and within thirty (30) days after the End of the EUA Period, the Parties shall mutually determine whether to continue the efforts to obtain FDA 510(k) approval for the Co-Developed Test Kit as an IVD, the efforts to obtain the approval of the applicable Governmental Authorities in other countries for the sale of the Co-Developed Test Kits, and the Manufacturing and Commercialization of the Co-Developed Test Kits pursuant to this Agreement. Unless within such thirty (30) day period the Parties agree to continue the efforts to obtain FDA 510(k) approval for the Co-Developed Test Kit as an IVD, the efforts to obtain the approval of the applicable Governmental Authorities in other countries for the sale of the Co-Developed Test Kits, and the Manufacturing and Commercialization of the Co-Developed Test Kits pursuant to this Agreement, either Party shall have the right to terminate this Agreement effective as of the end of such thirty (30) period.

18.2 **Effect of Termination**.

(a) No Release. The expiration or termination of this Agreement, for any reason, shall not release either Party from any obligation or liability to the other Party, including any payment and delivery obligation, that: (i) has already accrued hereunder; (ii) comes into effect due to the expiration or termination of the Agreement; or (iii) otherwise survives the expiration or termination of this Agreement. The Party terminating this Agreement, or in the case of the expiration of this Agreement, each Party, shall not be liable to the other Party for any damage of any kind (whether direct or indirect) incurred by the other Party by reason of the expiration or termination of this Agreement.

(b) Return of Materials and Property. Each Party shall promptly, following the expiration or termination of this Agreement: (i) return to the other Party all documents and tangible materials (and any copies) containing, reflecting, incorporating, or based on the other Party's Confidential Information; provided, however, that Sponsor may retain copies of any Confidential Information of Bio-Techne incorporated in the Co-Developed Test Kits or to the extent necessary to allow it to make full use of the Co-Developed Test Kits; (ii) permanently erase all of the other Party's Confidential Information from its computer systems, except for copies that are maintained as archive copies on its disaster recovery and information technology backup systems in which case such copies shall be destroyed upon the normal expiration of the backup files; and (iii) return to the other Party all tangible property in its possession or control, belonging to the other Party.

(c) Sponsor Option to Acquire. If Sponsor terminates this Agreement pursuant to Section 18.1(d) as a result of a material breach by Bio-Techne or an event or occurrence described in Section 18.1(d)(ii) affecting Bio-Techne, then Sponsor shall have the option, but not the obligation, to acquire from Bio-Techne all unsold Co-Developed Test Kits and all work in progress related to the Co-Developed Test Kits in production for a purchase price equal to Bio-Techne's cost of production therefor (which Sponsor may offset against any damages suffered or incurred by Sponsor as a result of such material breach or termination).

(d) Negotiation of Sponsor Rights Upon Termination Under Section 18.1(c)(i). If Sponsor terminates this Agreement pursuant to Section 18.1(c)(i), then Sponsor shall have the right, by Notice given to Bio-Techne within thirty (30) days after such termination, to elect to enter into arrangements with other manufacturers to continue the Manufacture and Commercialization of the Co-Developed Test using the Bio-Techne Background IP to the extent necessary (and for such purpose to access and utilize the tangible materials describing the Bio-Techne Background IP that have been escrowed pursuant to Section 3.5), subject to the Parties reaching agreement (each in its sole discretion, but with the understanding that each Party will negotiate in good faith to endeavor to reach agreement) with respect to the terms on which Sponsor may exercise such right.

(e) Negotiation of Bio-Techne Rights Upon Termination Under Section 18.1(c)(iii). If Sponsor exercises its right to terminate this Agreement pursuant to Section 18.1(c)(iii), then Bio-Techne shall have the right, by Notice given to Sponsor within thirty (30) days after such termination, to elect to pursue obtaining 510(k) approval for the Co-Developed Test Kit at its sole expense with Bio-Techne acting as the manufacturer of record, and thereafter to Manufacture and Commercialize Co-Developed Test Kits, subject to the Parties reaching agreement (each in its sole discretion, but with the understanding that each Party will negotiate in good faith to endeavor to reach agreement) with respect to the terms on which Bio-Techne may exercise such right.

18.3 **Survival of Terms**. In addition to any provision which by its terms contemplates performance after the Term, the following provisions shall survive the expiration or termination of this Agreement: Section 3.2(d); Section 3.3; Section 5.3; Section 6.3(d); Section 6.3(f); Section 6.3(g); Section 6.3(j); Section 9.8; Section 9.10; Section 10; Section 11; Section 13.3; Section 13.4; Section 16; Section 17; Section 18; Section 19.2; Section 19.8; Section 19.9; and Section 19.11.

19. ADDITIONAL PROVISIONS

19.1 **Independent Contractors**. The Parties are independent contractors. Nothing contained in this Agreement is intended to create an agency, partnership or joint venture between the Parties. At no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.

19.2 **Compliance with Laws**. Bio-Techne shall comply with all prevailing Laws that apply to its activities or obligations under this Agreement. For example, Bio-Techne will comply with applicable United States export Laws. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Bio-Techne that Bio-Techne will not export data or commodities to certain foreign countries without prior approval of the agency. Sponsor does not represent that no license is required, or that, if required, the license will issue.

19.3 **Modification, Waiver and Remedies**. This Agreement may only be modified by a written amendment that is executed by an authorized representative of each Party. Any waiver must be express and in writing. No waiver by either Party of a breach by the other Party will constitute a waiver of any different or succeeding breach. Unless otherwise specified, all remedies are cumulative.

19.4 **Assignment**.

(a) General. Except as otherwise provided in this Section 19.4, neither Party may transfer, delegate or assign or otherwise dispose of this Agreement or any of its rights, duties, or obligations under this Agreement without the prior written consent of the other Party, which consent may be granted or denied in such Party's sole discretion.

(b) Assignment by Sponsor. Notwithstanding the provisions of Section 19.4(a), with the prior written consent of Bio-Techne (which Bio-Techne shall not unreasonably condition, withhold or delay), Sponsor may assign, delegate or subcontract Sponsor's rights and obligations hereunder to an Affiliate of Sponsor or to a Person which succeeds to Sponsor's business through a sale, merger, consolidation, corporate reorganization, sale of all or substantially all of Sponsor's assets, change of name or like event, provided that no such assignment shall relieve Sponsor of any duty, liability or responsibility under this Agreement (for all of which Sponsor shall remain primarily liable).

(c) Assignment by Bio-Techne. Notwithstanding the provisions of Section 19.4(a), with the prior written consent of Sponsor (which Sponsor shall not unreasonably condition, withhold or delay), Bio-Techne may assign, delegate or subcontract Bio-Techne's rights and obligations hereunder to an Affiliate of Bio-Techne or to a Person which succeeds to Bio-Techne's business through a sale, merger, consolidation, corporate reorganization, sale of all or substantially all of Bio-Techne's assets, change of name or like event, provided that no such assignment shall relieve Bio-Techne of any duty, liability or responsibility under this Agreement (for all of which Bio-Techne shall remain primarily liable).

19.5 **Notices**. Except as otherwise expressly set forth herein, any notice or other required communication under this Agreement (each, a "**Notice**") must be in writing, addressed to the Party's respective Notice Address, and delivered personally or by globally recognized express delivery service, charges prepaid. A Notice will be deemed delivered and received: (a) in the case of personal delivery, on the date of such delivery; and (b) in the case of a globally recognized express delivery service, five (5) days from transmittal by Sponsor to the address below. Notwithstanding the foregoing, during the pendency of any federally- or state-declared disaster emergency, Notices may be given by email addressed to the email address(es) provided below, provided that a Notice given by email shall only be deemed to have been given upon affirmative acknowledgement of receipt by the recipient (which shall not be deemed to have occurred by the generation of a machine-generated acknowledgment). The "**Notice Address**" of each Party is as follows:

if to Sponsor, to:

Kantaro Biosciences LLC
1460 Broadway
New York, New York 10036
Attn: Chief Operating Officer
Email: [******]

Kantaro Biosciences LLC
c/o Mount Sinai Innovation Partners
One Gustave L. Levy Place
Box 1675
New York, New York 10029-6754
Attn: President
Email: [******]

With a copy to (which shall not constitute notice):	Icahn School of Medicine at Mount Sinai One Gustave L. Levy Place Box 1099 New York, New York 10029-6574 Attn: General Counsel Email: [******]
if to Bio-Techne, to:	Bio-Techne Corporation Attn: President/CEO 614 McKinley Place NE Minneapolis, MN 55413 Email: legal@bio-techne.com
With a copy to (which shall not constitute notice):	Attn: Legal legal@bio-techne.com

19.6 **Severability and Reformation**. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then the remaining provisions of this Agreement will remain in full force and effect. Such invalid or unenforceable provision will be revised by such court to be a valid or enforceable provision that comes as close as permitted by Law to the Parties' original intent.

19.7 **Headings and Counterparts**. The headings of the articles and sections included in this Agreement are inserted for convenience only and are not intended to affect the meaning or interpretation of this Agreement. This Agreement may be executed in several counterparts, and execution signatures may be exchanged electronically including by facsimile or as scanned e-mail attachments, and signatures so exchanged shall be considered as original for all purposes and taken together will constitute one and the same instrument.

19.8 **Governing Law**. This Agreement will be governed and construed in accordance with the Laws of the State of New York, without giving effect to the conflict of law provisions of any jurisdiction.

19.9 **Dispute Resolution; Venue**. If a dispute arises between the Parties concerning any right or duty under this Agreement, then the Parties will attempt to resolve the dispute through the Escalation Process. If the Parties are unable to resolve the dispute amicably through the Escalation Process, the Parties each hereby irrevocably submit to the exclusive jurisdiction of the state and federal courts located in the borough of Manhattan, New York, New York.

19.10 **Integration**. This Agreement, together with all attached Schedules, and the other Transaction Documents contain the entire agreement between the Parties with respect to the Co-Developed Test Kits, and supersedes all other oral or written representations, statements, or agreements with respect to such subject matter, including but not limited to, the term sheet exchanged prior to this Agreement.

19.11 **Third Party Beneficiaries**. Bio-Techne acknowledges and agrees that each provision in this Agreement that names or refers to ISMMS shall be deemed to be have been made for the benefit of ISMMS. ISMMS shall be a third party beneficiary of this Agreement and shall be entitled to enforce the provisions hereof.

19.12 **Force Majeure**. If either Party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, action of a Governmental Authority arising from a pandemic or other public health emergency, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than one hundred eighty (180) days.

19.13 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, or Schedule shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, or Schedule of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) all definitions set forth herein shall be deemed applicable whether the words defined are used herein with initial capital letters in the singular or the plural, (b) the word "will" shall be construed to have the same meaning and effect as the word "shall," (c) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (d) any reference herein to any Party shall be construed to include the Party's successors and assigns, (e) the word "notice" shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (f) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (g) references to any specific Law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor Law, rule or regulation thereof, (h) words of any gender include each other gender, (i) words such as "herein," "hereof" and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (j) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to," "without limitation," "inter alia" or words of similar import, and (k) "days" shall mean "calendar days." In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

19.14 **Business Day Requirements**. In the event that any notice or other action is required to be taken by a Party under this Agreement on a day that is not a business day, then such notice or other action shall be deemed to be required to be taken on the next occurring business day.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

SPONSOR:	**BIO-TECHNE:**
Kantaro Biosciences LLC	**Bio-Techne Corporation**
By:/S/ Erik Lium Name: Erik Lium Its: Chairman, Board of Managers	By:/S/ Chuck Kummeth Name: Chuck Kummeth Its: Chief Executive Officer

[Signature Page to Development, Supply and Commercialization Agreement]

Schedule 2.1(c)

Initial Steering Committee Members; Initial Designated Executives; Initial Sponsor Contact Person for Quality Issues

Initial Steering Committee Members:

Sponsor:

- [******]
- [******]

Bio-Techne:

- [******]
- [******]

Initial Designated Executives:

Sponsor:

- [******]

Bio-Techne:

- [******]

Initial Sponsor Contact Person for Quality Issues:

- [******]

Schedule 2.1(e)

Initial Working Groups

1. Commercial
2. Logistics
3. Customer Service
4. Product Definition
5. Regulatory and Quality
6. Data Communications and IT
7. Government Contracting

Schedule 3.1(a)

Specifications and Performance Standards

[To be supplied; Parties to agree on schedule as soon as practicable]

Schedule 5.2(a)

Manufacturing Milestones

[******]

Schedule 6.3(a)

Sponsor Licensed Marks and Design Specifications for Usage

Mark	Registration Number	Classes of Goods/Services
MOUNT SINAI	5,298,636	41, 42, 44
MOUNT SINAI	5,234,607	36, 41, 42, 44, 45
MOUNT SINAI and Mountain Design 	5,234,608	36, 41, 42, 44, 45
MOUNTAIN Design 	4,558,806	36, 41, 42, 44, 45

Brand and Style Guidelines. The Marks shall be used in accordance with ISMMS's Brand Guidelines (the "**Brand Guidelines**") published on www.mountsinaibrandcenter.org (the "**Site**"), which may be updated by ISMMS from time to time in its sole discretion. Such changes to the Brand Guidelines will be posted to the Site.

Schedule 6.3(k)

Bio-Techne Licensed Marks and Design Specifications for Usage

Mark	Registration Number	Classes of Goods/Services
R&D SYSTEMS	3,119,257	001, 005
BIO-TECHNE	4,692,993	001, 009
	4,842,997	001
	4,932,928	009

Schedule 17.2

Insurance

In accordance with the requirements of Section 17.2, the Parties shall maintain, at their own expense, in full force and effect the following insurance:

- Commercial general liability insurance with a liability limit of [******] per occurrence and [******] in the annual aggregate and naming Sponsor and ISMMS as an additional insured covering personal and advertising injury, bodily injury and property damage.

- Product liability insurance coverage with limits of [******] per claim and [******] in the aggregate covering products, completed operations, bodily injury and property damage. Bio-Techne's coverage shall be written on a "claims made" basis and such insurance shall name, to the fullest extent permitted by Law, the Sponsor Indemnitees as additional insureds.

- Life Sciences Errors & Omissions insurance with limits of [******] liability per claim and [******] in the aggregate for bodily injury, property damage and financial injury. Bio-Techne's insurance shall name, to the fullest extent permitted by Law, the Sponsor Indemnitees as additional insureds.

- Workers' Compensation Insurance as required by laws and regulations applicable to Bio-Techne and covering any employees performing Bio-Techne's obligations hereunder.

- Employers' Liability Insurance with a limit of [******] protecting against liability for employee bodily injury arising out of an employee/employer relationship.

- System Security/Cyber Liability insurance with limits of [******] per occurrence and [******] in the aggregate covering damages and expenses related to breaches of data security from Bio-Techne's obligations hereunder.

- Bio-Techne to secure transit/warehouse insurance.

EXHIBIT 99.1

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.

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, and YouTube.

About Renalytix AI

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