Edina Public Schools
DEFINING EXCELLENCE

School Board Special Meeting
Thursday, March 4, 2021; 4:30 PM
Virtual Meeting

I. Determination of Quorum and Call to Order

II. Action
A. Contract with United Health Group – Optum Labs, LLC *(walked in)*

III. Board Chair Updates

IV. Superintendent Updates

Board Meeting Date: 3/4/2021

TITLE: Study Agreement between Optum Labs, LLC and Independent School District No. 273, Edina Public Schools

TYPE: Action

PRESENTER(S): Julie Greene; Matthew Fox; Owen Michaelson; Sarah Prebil, MD; Al Tsai, Ph. D.

BACKGROUND: Over the last months a committee (See membership, below) has worked to plan a student COVID testing program with community partner United Health Group. The enclosed study agreement has gone through the research process of Edina Public Schools and was approved. Trevor Helmers, Esq., Edina School District Legal Counsel, will be present to discuss the agreement. This agreement has also gone through review at United Health Group.

Committee members include:

Matt Fox, School Board
Julie Greene, School Board
Owen Michaelson, School Board
Nicole Tuescher, EPS, Director of Human Resources and Administrative Services
Mary Heiman, EPS, Director/Health Services,
Trevor Helmers, EPS External Legal Counsel
Nick Kelley, PhD, Acting Public Administrator, Bloomington Public Health
Kelly DeWeese, MPH, Public Health Planner, Bloomington Public Health
Al Tsai, PhD, MPH, Community member
Sarah Prebil, MD, Community member

RECOMMENDATION: That the School Board approve the Study Agreement between Optum Labs, LLC and Independent School District No. 273, Edina Public Schools

PRIMARY ISSUE(S) TO CONSIDER: Student COVID Testing

ATTACHMENT: Study Agreement between Optum Labs, LLC and Independent School District No. 273, Edina Public Schools

STUDY AGREEMENT

This Study Agreement (this "**Agreement**") is dated as of the date last indicated on the signature page below (the "**Effective Date**") by and between Optum Labs, LLC, a Delaware limited liability company, whose address is 5995 Opus Parkway, Minnetonka, MN 55343 ("**Company**") and Independent School District No. 273, Edina Public Schools, having its principal place of business address at 5701 Normandale Road, Edina, MN 55424 ("**Institution**").

WHEREAS, Company and Institution desire to conduct a research study (the "**Study**") to evaluate the operational feasibility of sample pooling and transport to a near-site high complexity lab for SARS-CoV-2 testing to reduce asymptomatic spread in a school environment, according to the clinical protocol entitled, "Effectiveness of a near-site high complexity lab processing pooled samples for SARS-CoV-2 testing in a 6-12th grade school population", as such may be modified from time to time, included as Appendix A (the "**Protocol**"), and in accordance with the terms of this Agreement; and

WHEREAS, the Study is of mutual interest and benefit to the parties because it furthers academic and research objectives and may benefit the educational mission of the Institution and population health interests generally.

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties, and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1.0 Study

1.1 Study Conduct. Both parties agree to carry out their respective obligations as identified in the Protocol and this Agreement. Institution shall be responsible for the conduct and supervision of its Personnel (as defined in Section 2.2). Institution will, and will cause its Personnel, to: (a) carry out the roles and responsibilities as identified in the Protocol, except to the extent that Sample Collection Monitors (as defined in Section 2.3) complete such roles and responsibilities, as well as any written instructions provided by or on behalf of Company including the study device instructions for use (collectively, "**Study Documentation**"), and this Agreement; and (b) comply with all (i) applicable local, state and federal laws and regulations relating to the conduct of the Study and their obligations under this Agreement; and (ii) obtain prior written informed consent ("**Informed Consent**") in accordance with the requirements of the Food and Drug Administration or its successor entity ("**FDA**") and a qualified Institutional Review Board that complies with all applicable laws and regulations ("**IRB**") reviewing the Study, in a form reasonably acceptable to Company, and as further set forth in Section 3.2; and (iii) the requirements for obtaining prior written authorization to use and disclose health information for research ("**Authorization**") in accordance with the health information privacy standards promulgated under federal law as well as applicable state laws and regulations governing the privacy and confidentiality of protected health information ("**Privacy Laws**") and as further set forth in Section 3.2.

1.2 Subject Enrollment. Institution and Study Lead (as defined in Section 2.1) will use reasonable efforts to timely recruit potential subjects, each of whom meets the Protocol criteria, in accordance with the Study timeline.

2.0 Personnel and Sample Collection Monitors

2.1 Study Lead. Institution designates John Schultz, Superintendent, an employee of

Institution, to serve as the lead administrator of the Study at Institution (the "**Study Lead**"). If, at any time during the Study, Study Lead is unable or unwilling to perform its duties as Study Lead or ceases to be an employee of Institution, Institution shall promptly notify Company in writing of the same, propose a substitute, and provide Company with any reasonable documentation and assistance requested by Company to evaluate the qualifications of such substitute. Company shall notify Institution of its decision either to continue the Study with the proposed substitute or to terminate the Study under this Agreement.

2.2 Personnel. With the exception of Sample Collection Monitors (as defined and described below in Section 2.3), Institution will arrange for personnel, including, and subject to Section 17, subcontractors, that are necessary or desirable for the performance of the Study under this Agreement (collectively with the Study Lead, "**Personnel**"). Prior to commencing any services in connection with the Study, all Personnel must be: (a) properly and fully trained by the Company and the Institution, in accordance with the Protocol, to perform their respective obligations under this Agreement; and (b) subject to obligations to Institution under which they are bound to non-disclosure and non-use obligations with regard to Confidential Information (as defined in Section 9.1) under terms that are no less stringent that those set forth in this Agreement.

2.3 Sample Collection Monitors. Institution and Company will collaborate to recruit healthcare professionals (e.g., doctors or nurses) from the community-at-large to serve as volunteers (the "**Sample Collection Monitors**") to attend and monitor each of the pooled sample collections conducted at Institution under the Study. Institution shall reasonably cooperate with Company and the Sample Collection Monitors to schedule each of the sample collection procedures at a time when a Sample Collection Monitor is able to attend and shall ensure that a sufficient number of Sample Collection Monitors are in attendance at all times when pooled samples are being collected. Institution shall grant the Sample Collection Monitors reasonable access to EPS facilities to enable them to attend and monitor each of the pooled sample collections. Company will be responsible for ensuring that the Sample Collection Monitors are properly and fully trained, in accordance with the Protocol, to oversee the sample collection process. As between Institution and Company, Company shall be solely and exclusively liable for the acts or omissions of the Sample Collection Monitors with respect to the monitoring of the pooled sample collection process. For the avoidance of doubt, Sample Collection Monitors shall not be employees or contractors of Institution and are not deemed Personnel of Institution for purposes of this Agreement.

2.4 Qualifications. Institution represents and covenants, on behalf of itself and its Personnel, that to its knowledge, none of itself nor any of its Personnel: (a) has been found by the FDA, U.S. Department of Health and Human Services, or other multi-national, international or domestic regulatory or governmental agencies or officials (each an "**Agency**" and collectively, the "**Agencies**") to have violated any laws or regulations concerning the conduct of clinical or research investigations or the practice of medicine, nor has received an Agency warning or other regulatory letter alleging the same; (b) has been excluded from participation in any government healthcare program, debarred from or under any other federal or state program, convicted of any offense defined in 42 U.S.C. Section 1320a-7, or otherwise deemed ineligible for participation in healthcare programs, nor is aware of any pending or potential actions that would give rise to any such ineligibility; (c) is the subject of a disqualification proceeding nor has been disqualified under any Agency laws or regulations; (d) has been terminated from any investigation or research project for misconduct; or (e) is currently nor has been the subject of any litigation, arbitration, mediation, or any other proceedings that imposed restrictions or limitations on its practice of research or medicine. In the event that Institution becomes aware of any change to the foregoing representations, Institution shall promptly notify Company of such change and in all events within five (5) business days thereof.

2.5 Covenants. Institution represents and covenants that: (a) it and its Personnel have, and shall maintain throughout the term of the Study, all necessary licenses, permits, and authorization to conduct the Study and perform its obligations under this Agreement in accordance with applicable laws and regulations; (b) neither it nor, to Institution's knowledge, any of its Personnel are under any contractual or other obligation or restriction that is inconsistent with its obligations under this Agreement nor will enter into such obligation or restriction during the term of the Study; (c) it and its Personnel have the right to disclose any information or data disclosed by it or its Personnel in the performance of this Agreement. In the event that Institution becomes aware of any change to the foregoing representations, Institution shall promptly notify Company of such change and in all events within five (5) business days thereof.

3.0 IRB Approval, Informed Consents, and Authorization

3.1 IRB Approval. Company has arranged for the IRB to provide initial and continuing review of the Study conducted at Institution, including the Informed Consent and Authorization, the Protocol, and Study Documentation, and will provide Institution with written notice of the IRB's approval (or disapproval) of the Study. Institution shall not, and shall ensure that its Personnel do not, enroll any subjects in the Study, nor perform any procedures under the Protocol, until receipt of such written IRB approval.

3.2 Informed Consent and Authorization. (a) Institution shall cause Personnel to obtain from each subject at the time of enrollment in the Study, a signed Informed Consent and Authorization, each in a form reasonably acceptable to Company and in accordance with Privacy Laws and give immediate notice to Company of any failure to do so. Any modification to the Company-approved Informed Consent or Authorization must be reasonably acceptable to Company and Institution shall not implement, nor permit the implementation by its Personnel of any such modifications until receipt of both written Company and IRB approval. All original signed Informed Consent and Authorization forms shall be retained by Institution and be available for inspection by Company, its designees and any Agency in accordance with Section 6.2.

(b) Study Records (as defined in Section 6.1), shall be provided by Institution and its Personnel to, and may be received, used, copied and disclosed by, Company, its affiliates, their designees, and companies that work with Company and its affiliates for any purpose relating to the Study and the study devices, including monitoring and auditing the Study, analyzing the Study findings, developing new proposals for, and conducting new medical research on, new medical products and therapies with respect to the study devices, complying with applicable law and regulations, and as not otherwise prohibited by law.

(c) Institution will, and will cause its Personnel to, obtain such authorizations or consents as may be required under Privacy Laws, FDA and other federal and state laws and regulations to permit Company, its designees, and Agencies to exercise the rights set forth in this Agreement. Without limiting the foregoing, Institution will, and will cause its Personnel to, cooperate with Company to cause subjects to re-execute any Informed Consent and/or Authorization when reasonably requested by Company or as may be required to comply with applicable laws and regulations.

4.0 Supply of Company Property

4.1 Company Property. During the Study, Company shall provide a mutually agreed upon quantity of the study device and other supplies necessary for the conduct of the Study consistent with Section 11.1 of this Agreement. Institution shall, and shall cause its Personnel involved in the receipt, administration, storage, transport, handling, and/or return of the study device to, (a) at all times keep all study devices in a locked, secured, and monitored area on Institution premises at all times in

accordance with the Protocol and Study Documentation, and (b) maintain complete, accurate, organized, and legible records showing the receipt, administration, disposition and return of each unit of the study device ("**Study Device Records**"). The study device and other tangible property provided by or on behalf of Company to Institution or Personnel in connection with this Agreement or the Study, including any power adaptors (collectively "**Company Property**") shall be and remain, as between the parties, the exclusive property of Company, except that any property subject to Section 11.1 shall be the property of Institution upon reimbursement of Company for the actual costs of the same. Institution shall, and shall cause its Personnel to, hold, store, handle, and transport Company Property in compliance with all applicable laws and regulations, the Protocol and Study Documentation. Without limiting the foregoing, Institution shall not, and shall cause its Personnel to not (x) distribute, sell, lend or otherwise transfer Company Property to any third party; (y) co-mingle the study device with any other materials or remove any component of the study device unless expressly required by the Protocol or Study Documentation; or (z) analyze the study device or in any way attempt to reverse engineer any component of the study device. Institution shall, and shall cause its Personnel to, use Company Property only to conduct the Study in accordance with the Protocol and Study Documentation, and for no other purpose, except that Institution shall maintain use and control over any property subject to Section 11.1 upon completion or termination of the Study to the extent Institution has reimbursed Company for the actual costs of the same. Institution shall permit only those Personnel and Sample Collection Monitors who have been fully trained on the proper use of study device in accordance with the Protocol and Study Documentation to use the study device to conduct the Study. Upon termination or completion of the Study, termination or expiration of this Agreement, or upon request by Company at any time, Institution shall return all Company Property to Company or its designee in accordance with Company's instructions subject to the terms of this Section and Section 11.1. Should any Company Property be damaged for any reason, Institution shall promptly return such Company Property to Company, or, at Company's express direction, send it to a third-party for analysis.

4.2 No Warranties. INSTITUTION ACKNOWLEDGES THAT THE STUDY INCLUDING THE USE OF THE STUDY DEVICE IS INVESTIGATIONAL IN NATURE AND EXCEPT AS EXPLICITLY STATED HEREIN, COMPANY HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, WITH RESPECT TO THE STUDY, INCLUDING THE STUDY DEVICE, INCLUDING ANY REPRESENTATION OR WARRANTY OF ACCURACY OF RESULTS, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR NONINFRINGEMENT.

5.0 Informing Company

5.1 Required Reporting. Company will provide Institution with physical or electronic access to all necessary case report forms for the conduct of the Study. Institution shall submit to Company, complete, accurate, and legible case report forms and any other records, reports, and data that may be required to be delivered to Company pursuant to the Protocol and Study Documentation (collectively "**Study Data**") and in accordance with the schedules set forth in the Protocol. All Study Data will be recorded in the web-based electronic data capture system ("**EDC System**") provided on behalf of Company within 24 hours of the testing event during which such data was collected. All other primary information and data collected or created pursuant to or prepared in connection with the Study other than Study Data, including medical records, and all primary data sources underlying data recorded on the case report forms (collectively "**Source Records**") shall remain at Institution and shall be available for inspection in accordance with Section 6.2. Institution will, and will cause its Personnel to, provide any additional data, access or assistance reasonably requested by Company in connection with the conduct of the Study.

5.2 Specimens. Institution will, and will cause its Personnel to, and Company will, and will cause the Sample Collection Monitors to (a) collect, and use Specimens solely as set forth in the Protocol; (b) properly label all such Specimens and store, handle, package, and deliver them in a manner to prevent contamination and in accordance with the instructions set forth in the Protocol, Study Documentation, and all applicable laws, and (c) not use or retain any such Specimens for any other purpose. "**Specimens**" mean the swab sample collected from Study subjects as set forth in the Protocol, and tangible materials directly or indirectly derived from such samples.

5.3 Adverse Events; Other Notice. Institution shall notify Company of all adverse events (as defined in the Protocol) experienced by a Study subject in the EDC System in accordance with the schedule set forth in the Protocol and Study Documentation or, if no schedule is set forth in the Protocol, then within seventy-two (72) hours of the adverse event. If the adverse event is serious or unexpected, or requires action by Company to prevent an unreasonable risk of substantial harm to the public, then notice shall be given immediately (but in no event later than twenty-four (24) hours after learning of such experience) by telephone to Company and, to the extent required by applicable FDA regulations and IRB policy, the IRB. Institution will, and will cause its Personnel to, (a) provide Company with all associated documentation (e.g., lab reports, operative reports, etc.) for each adverse event, and (b) cooperate with Company and its designees in the investigation and resolution of each such event. Company will timely advise Institution in accordance with applicable laws and regulations of any adverse reactions or side-effects related to the study device which become known to Company during the course of the Study that would alter the conduct of the Study, including adversely affecting the participation of any Study subject.

5.4 Correspondence with IRB. Institution will send Company a copy of all material correspondence and communications with the IRB relating to the Study, if any.

5.5 Deviations. All modifications to the Protocol shall only be made by Company and Institution shall not implement nor permit the implementation by its Personnel of any such modifications until receipt of any necessary FDA or IRB approvals. In addition, Institution will not, and will cause its Personnel not to, deviate from the Protocol and Study Documentation except to the extent clinically necessary to protect the health or safety of subjects enrolled in the Study, which clinical judgment shall be in conformity with the generally accepted standards of the medical community. Any such deviation (e.g., late or missed testing events, tests not performed) shall be fully, accurately, and timely recorded in accordance with the Protocol and Study Documentation and, in the event of a major deviation (as defined in the Protocol and Study Documentation), Institution shall notify Company and the IRB as soon as possible, but in no event later than forty-eight (48) hours after such major deviation occurred.

6.0 Data Storage and Access

6.1 Collection and Storage of Data. In addition to any collection, security and storage provisions imposed under Privacy Laws and other applicable laws and regulations, Institution will, and will cause its Personnel to, (a) promptly, completely, legibly, and accurately report and label the Study Data, Source Records, and Study Device Records (collectively, "**Study Records**") and (b) cooperate with Company and its designees in promptly resolving any data inquiries, with respect thereto, in all events within ten (10) days of the initial query generation. Institution shall, and shall cause its Personnel to maintain and store Study Records in a secure manner consistent with Institution's normal practices for maintaining private educational and/or personnel data and in compliance with state and federal law. Institution will maintain Study Records in a manner consistent with its records retention policy and state law, and in no event for less than a period of two (2) years after the date the Study is terminated or completed. Institution will cooperate with Company and its designees in transferring over any such

Study Records as requested by Company provided that such request is made within two (2) years after the date the Study is terminated or completed, and is consistent with the other terms of this Agreement and applicable law.

6.2 Data Monitoring. To the extent requested or required by an Agency or otherwise required by law or the IRB overseeing the Study, Institution shall allow Company, its designees, Agencies and their designees reasonable access to Institution's and its Personnel's, as applicable, facilities and records to permit monitoring the Study and reviewing, inspecting, and copying of Study Records, including Informed Consents and Authorizations to ensure compliance with the terms of this Agreement. Access by Company and its designees shall be with reasonable advance notice, and during normal business hours. Institution will, and will cause its Personnel to, cooperate with Company and its designees to verify such compliance, including promptly correcting any errors or omissions to the Study Data and making available to Company and its designees the corrected Study Data and supporting records for further verification. Institution will notify Company immediately by telephone (with a follow-up by mail) upon, but not later than twenty-four (24) hours after, learning that an Agency inspection related to the Study is scheduled to take place at its or Personnel's facilities, or, if there is no prior notice by an Agency, that an inspection has commenced. Institution will, and will cause its Personnel to, make all reasonable efforts to coordinate any scheduling of Agency inspections to permit Company and its designees to attend such inspections, if so requested by Company. Institution will, and will cause its Personnel to, provide Company and its designees with reasonable access to and copies of all materials, correspondence and documents that Institution or its Personnel receives, obtains, or generates pursuant to any such inspection or audit or in connection with any inquiries, communications or correspondence from any Agency. If FDA issues to Institution (or Personnel) a Form FDA-483 Notice of Observations relating to the Study or another Agency issues a similar document relating to the Study, then Institution will send a copy of such document promptly to Company, along with its or its Personnel's, as applicable, draft response to such document before it is sent to the applicable Agency. Without limiting the foregoing, Institution will, and will cause its Personnel to, participate as necessary in any requested follow-up to monitoring visits and audits to ensure compliance with the foregoing. The parties acknowledge and agree that the requirements of this Section 6.2 are subject to Sections 6.3 through 6.6, and state and federal law, which shall control.

6.3 Access to Educational and Personnel Data. Institution will provide Company with access to educational data and personnel data that are reasonably necessary for Company to conduct the Study, which is meant to improve the delivery of instruction during the covid-19 pandemic. Specifically, Institution will provide Company access to the data identified in Sections 4.3 and 4.4 of the Protocol for those Institution staff and students who agree to participate in the Study.

6.4 Use of Private Data. Company understands that the data referenced in Section 6.3 may constitute personally identifiable information on Institution students and/or employees ("Private Data") and is subject to the privacy and confidentiality provisions of federal and state laws including, but not limited to the Family Educational Rights and Privacy Act (FERPA) and the Minnesota Government Data Practices Act (MGDPA). Company agrees to comply with the requirements of 34 C.F.R. § 99.33(a) with respect to the use and re-disclosure of personally identifiable information from educational data and any other Private Data. Specifically, Company shall use and disclose Private Data only to meet the specific purpose of the Study as set forth in this Agreement and the Protocol, to fulfill mandatory reporting obligations to public health officials with respect to SARS-CoV-2 test results, and as may otherwise be expressly permitted in the Informed Consent signed by a Study participant or his/her parent or legal guardian, as applicable. Company shall conduct and report on the Study in a manner that de-identifies personnel and educational data and does not permit access to Private Data of students, parents, or Institution employees by individuals other than representatives of Institution or

Company who have a legitimate interest in the information, except with prior written consent of the applicable parent, eligible student, or employee or as otherwise required or authorized by law.

6.5 Destruction of Private Data. Company must use a secure method to maintain and destroy all Private Data it receives from Institution. Company must destroy the Private Data when it no longer needs the information to conduct the Study or within two years after the expiration of this Agreement, whichever comes first.

6.6 Data Practices Responsibilities. The parties each agree to comply with all applicable provisions of FERPA and related federal regulations, the MGDPA, and any and all other applicable state and federal laws governing the privacy, security, and dissemination of educational data and/or personnel data shared pursuant to this Agreement and all student and/or personnel data created, collected, received, stored, used, maintained, or disseminated under this Agreement. Each party is individually responsible for compliance with applicable laws and regulations governing its collection, storage, use, sharing, disclosure, and dissemination of the data. Nothing in this Agreement shall be construed to allow either party to maintain, use, disclose, or disseminate student or personnel information and data in a manner not permitted by federal or state law.

7.0 Public Disclosure

7.1 Publicity. Except in a manner consistent with the Open Meeting Law (Minnesota Statutes Section 13D) and the First Amendment of the United States Constitution, Institution will not, and will use reasonable efforts to cause its Personnel to not, engage in interviews or other contacts with any media (including any financial or other analysts) in any medium, whether initiated by Institution or Personnel or any other of their employees, agents, officers, or directors or in response to any inquiries, including the Internet or any social media sites related to this Agreement or the Study (including the study devices or Study IP) without Company's prior written consent in each instance. Company understands and acknowledges that members of the public and media may obtain information about this Agreement or the Study during the ordinary course of meetings of the EPS School Board or pursuant to the Minnesota Government Data Practices Act and agrees that this provision applies specifically to direct and discretionary media contact by the Institution or on its behalf. Except as required by applicable laws or regulations, expressly provided herein, or those uses for which consent has already been obtained, neither party shall have the right, express or implied, to use in any manner the name or any other trade name, symbol, logo or trademark of the other party, without the prior written consent of such party.

7.2 Publication. Company may submit a paper regarding the Study and Study results for publication in a peer-reviewed journal. Such publication shall present the Study results and analysis of Study Data in a manner in accordance with applicable industry and professional guidelines governing scientific and research activities. Company will provide Institution with a proposed publication at least thirty (30) days in advance of (i) the planned submission of said manuscript(s) to a publisher or other third party or (ii) the planned public presentation. Institution shall have thirty (30) days after receipt of said manuscript to object to the inclusion of any Confidential Information of Institution and to provide any comments or suggested changes. The Parties will work together in good faith to incorporate such proposed comments or changes as appropriate, and any Confidential Information will be removed from the publication. Institution will have the opportunity to identify at least one co-author of the publication to the extent consistent with academic and scientific standards applicable to the journal or forum of publication or presentation, including, by way of example, the standards set forth in ICMJE.org. For the avoidance of doubt, any Study Data included in such publication will be de-identified in accordance with applicable Privacy Laws.

8.0 Ownership

8.1 Pre-existing Intellectual Property. Ownership of inventions, technologies, know-how, ideas, processes, techniques, algorithms, programs, discoveries, improvements, devices, drugs, biologics, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, specifications and other works of authorship existing as of the Effective Date or developed outside of this Agreement, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and neither party shall have any claims to or rights in any Pre-existing Intellectual Property of the other party. For the avoidance of doubt, Institution acknowledges that Company's Pre-existing Intellectual Property includes the Protocol, Study Documentation, and Company Property, and that all right, title, and interest in and thereto (including any improvements thereto) belongs solely to Company or its licensors (as applicable).

8.2 Study IP. Company shall own all right, title and interest in and to (a) any inventions, technologies, know-how, ideas, processes, techniques, algorithms, discoveries, improvements, biologics, devices, drugs, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, trade secrets and specifications that are conceived, first reduced to practice or created pursuant to this Agreement or otherwise related to Confidential Information (including the study device), whether by Company, Institution, or Personnel, individually or jointly ("**Inventions**") and (b) Study Data (Inventions and Study Data shall be collectively referred to as "**Study IP**"). Institution will, and will cause its Personnel to, promptly and fully disclose all Inventions to Company in writing. Institution, on behalf of itself, and its Personnel, hereby assigns to Company, (x) all of its intellectual property and proprietary right, title and interest in and to the Study IP and (y) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Institution shall cooperate and assist Company to execute, and shall cause its Personnel to execute all documents reasonably necessary for Company to secure, perfect, effectuate and preserve Company's ownership rights in the Study IP.

8.3 Use of Study Data. Subject to the other provisions of this Agreement, Institution has the right to use Study Data for its own internal non-commercial educational purposes.

9.0 Confidential Information

9.1 Definition. "**Confidential Information**" shall mean any information which is disclosed by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") and that is reasonably considered to be confidential, whether existing prior to this Agreement or developed in connection with a Study, shall be deemed "Confidential Information" for purposes of this Agreement whether or not that information is marked or identified as confidential. Confidential Information of Company shall include (a) all scientific, technical, financial, or business information disclosed by or on behalf of Company and its designees to Institution or Personnel, including the study device, technical information relating to the study device, the Protocol, Study Documentation, and all Pre-Existing Intellectual Property of Company; (b) Study enrollment data, information pertaining to the status of the Study, communications to and from any Agency regarding the Study or study device, information relating to the study device's regulatory status, Study Device Records, and correspondence to or from any data safety monitoring board; and (c) Study IP. Confidential Information of Institution shall include any and all non-public information concerning or maintained by Institution, including, without limitation, information related to Institution's past or present students, faculty, staff, employees, administrators, independent contractors, officers, and/or trustees, information related to the parents or guardians of past or present students, information related to applicants to Institution, and/or parents or guardians of applicants to Institution. The terms and conditions of this Agreement shall be the

Confidential Information of both Parties, in all cases excluding Study Data. Confidential Information shall not include information that Institution can show by competent documentation: (i) to have been public knowledge prior to or after disclosure, other than through acts or omissions attributable to Institution or Personnel; or (ii) to have been in the possession of Institution or Personnel from sources other than Company or its designees that did not have an obligation of confidentiality prior to Company's disclosure.

9.2 Obligations. Receiving Party will not, and will cause its Personnel not to, use the Confidential Information of the Disclosing Party for any purpose other than to fulfill its obligations or exercise its rights under this Agreement, in each case in accordance with the Protocol and Study Documentation, or disclose the Confidential Information to any third party, except as expressly permitted by this Section 9 or as authorized in writing by Disclosing Party. To protect Confidential Information, Receiving Party will: (a) limit dissemination of Confidential Information to only those of its Personnel having a "need to know" such information in connection with the performance of its obligations and exercise of its rights under this Agreement; (b) advise all of its Personnel who receive Confidential Information of the confidential nature of such information and of the use and disclosure restrictions contained herein; and (c) use reasonable measures to protect the Confidential Information from unauthorized use, disclosure, or loss, using at a minimum the same measures used to protect its own confidential information, which in no event shall be less than reasonable care.

9.3 Compelled Disclosure. In the event that Institution or its Personnel receives notice of a third party (including any Agency) seeking to compel disclosure of any Confidential Information, Institution shall provide Company with prompt notice thereof so Company may assist Institution or Personnel in seeking, or Company may itself seek, a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, Institution shall, and shall cause its Personnel to, furnish only that portion of the Confidential Information which it is advised by its counsel, in consultation with Company, to be legally required to be disclosed, and shall exercise its best efforts to obtain reliable assurance that the Confidential Information will be afforded confidential treatment.

9.4 Minnesota Government Data Practices Act. The Parties acknowledge that Institution is a public entity existing under the laws of the State of Minnesota, and therefore is subject to the Minnesota Government Data Practices Act. In recognition of the foregoing and notwithstanding anything to the contrary in this Agreement, all of the rights and obligations of Institution set forth in this Section 9 are subject to Institution's obligations under the Minnesota Government Data Practices Act.

10.0 Term; Termination

10.1 Term. This Agreement shall be effective as of the Effective Date and shall continue in effect until completion of the Study at Institution, unless earlier terminated pursuant to this Section 10.

10.2 Termination by Institution. Institution may terminate this Agreement for Company's material breach if such breach remains uncured for a period of thirty (30) days after Company's receipt of written notice thereof. Institution may suspend the Study immediately, if (a) in the reasonable opinion of the Study Lead, the Study results support suspension of the Study due to subject health or safety concerns; or (b) Institution's campus is closed due to a *force majeure* event, including, but not limited to, acts of God, governmental action, riot, war, fire, epidemic, pandemic, civil unrest, flood, act of terrorism, earthquake, weather, other threats to the safety of students, national emergencies, or any other cause beyond either party's reasonably foreseeable control. In the event of any such suspension, Institution shall promptly notify Company of the same by telephone, and, within five (5) days after

such suspension, shall provide Company with a detailed written explanation for Institution's suspension of the Study, including any associated documentation in support thereof. Institution may terminate this Agreement at any time and for any reason, effective twenty (20) days after giving Company written notice of its election to terminate.

10.3 Termination by Company. Company may terminate this Agreement for Institution's, or Personnel's material breach if such breach remains uncured for a period of thirty (30) days after Institution's receipt of written notice thereof. Company may terminate this Agreement or suspend the Study at any time and for any reason, effective twenty (20) days after giving Institution written notice of its election to terminate.

10.4 Effect of Termination. Upon any receipt of a notice of termination, Institution will, and will cause its Personnel to, immediately stop enrolling subjects in the Study and to the extent medically advisable, Institution will, and will cause its Personnel to, cease conducting procedures on subjects already participating in the Study; provided however, that Institution will and will cause its Personnel to continue to perform the follow-up testing in accordance with the Protocol and Study Documentation and provide Study Data (including the accurate completion of all case report forms) required under the Study for those subjects who were enrolled in the Study prior to the receipt of the notice of termination, unless instructed otherwise by Company in writing. The terms of this Agreement shall continue to apply with respect to all such follow-up testing and data. Upon completion of the Study, termination or expiration this Agreement, or upon Company's request, Institution shall promptly return all Company Property and Confidential Information in its, or its Personnel's possession or control to Company in accordance with Company's instructions; provided however, that Institution may retain a single copy of certain written Confidential Information solely to the extent such retention is required by applicable law, which copy shall remain subject to the non-disclosure and non-use restrictions set forth in Section 9. Termination of this Agreement shall not affect any other rights or remedies which may be available to a party at law or in equity.

10.5 Survival. In addition to any provisions that by their nature survive expiration or termination of this Agreement, including, without limitation, Sections 3.2(b), 4.2, 5-9, 10.4, 10.5, and 12-15 shall survive the termination or expiration of this Agreement for any reason.

11.0 Payment

11.1 Disposable Supplies. Company shall purchase in bulk and provide to the Institution all disposable supplies required for Institution to carry out the Study ("Disposable Supplies"), including, but not necessarily limited to, study devices, related collection materials, and personal protective equipment for Personnel and/or Sample Collection Monitors, prior to commencement of the Study. Company shall track the purchase costs for the Disposable Supplies that will be provided to Institution and ensure that such costs do not exceed a total of $45,000.00 for the time period from the signing of this Agreement through the end of May 2021. Company shall provide documentation of the actual cost of the Disposable Supplies that are provided to Institution. Institution shall be responsible to pay the actual cost of Disposable Supplies, up to a total of $45,000 from the period of time from the date of the signing of this Agreement through the end of May 2021, within thirty (30) days of receipt of an invoice from Company reflecting such costs. The parties agree to meet and confer on the payment of any future costs after that initial period of time. Provided that Institution has reimbursed Company in full for the actual cost of the Disposable Supplies as required under this Section 11.1, they shall be considered the property of Institution and to the extent that any such Disposable Supplies remain at the end of the Study or upon termination of this Agreement, Institutional shall retain sole ownership and control over the use of such property.

11.2 Remaining Costs. The parties acknowledge and agree that, except as provided in Section 11.1, (a) each party will bear its own costs in the conduct of the Study; (b) no amount shall be paid or payable by Company to Institution or Personnel for the conduct of the Study; (c) Institution shall be responsible for disbursing any funds or amounts payable to Personnel under the Study (if any); and (d) Company shall have no liability to Personnel for any failure of Institution to pay any such amounts. Institution shall be solely responsible for payment of any taxes due in connection with and/or as a result of their services provided hereunder. Company and Institution each acknowledges and agrees that the support provided by Company pursuant to this Agreement: (i) has been negotiated in an arms-length transaction; and (ii) has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between Company and its affiliates and Institution or any Personnel.

12.0 Indemnification

12.1 By Company. To the extent permitted under applicable law, Company shall indemnify, defend, and hold harmless Institution and its directors, officers, employees, and agents, including their Personnel (each, an "**Institution Party**" and collectively, the "**Institution Parties**") from and against any claims, actions or proceedings brought by a third party (each, a "**Claim**") to the extent arising from Company's breach of its obligations with respect to the Confidential Information of Institution or seeking compensation for a Research Injury, provided that the study device was used in accordance with the Protocol, Study Documentation and this Agreement, but solely to the extent that such Claims do not result from any Institution Party's: (a) failure to follow any applicable federal, state or local laws and regulations or to conform to reasonable and prudent clinical practices; (b) wrongful or negligent acts or omissions, willful malfeasance, or any misuse of the study device (including by any other person on Institution's or Personnel's premises or facilities); or (c) failure to follow the Protocol, Study Documentation or this Agreement. The term "**Research Injury**" means bodily injury or death to a Study subject resulting from the use of the study device. The term does not include the underlying or pre-existing condition or events for which the study device is being investigated, including the natural progression of such underlying or pre-existing condition, or injuries arising from using currently approved therapies for the Study subject's condition.

12.2 By Institution. To the extent permitted under applicable law, Institution shall indemnify, defend, and hold harmless Company and Company's affiliates and each of their respective directors, officers, employees, contractors, agents, and personnel (each, a "**Company Party**" and collectively, the "**Company Parties**") from and against any and all Claims to the extent resulting from any Institution Party's: (a) breach of its obligations with respect to the Confidential Information of Company; (b) failure to follow any applicable federal, state or local laws and regulations or to conform to reasonable and prudent clinical practices, including GCPs as applicable to device studies; (c) wrongful or negligent acts or omissions, willful malfeasance, or misuse of the study device (including by any other person on Institution's or Personnel's premises or facilities); (d) failure to follow the Protocol, Study Documentation or this Agreement; or (e) decisions, actions or measures made or taken in response to any test results generated by the study devices (whether or not determined to be "false" positive or negative results).

12.3 Conditions of Indemnity. The party claiming a right of indemnification or defense under this Agreement will: (a) provide the indemnifying party prompt notice (in all events within fifteen (15) days of receipt) of any such Claim, including a copy thereof, served upon it, provided however, that failure to notify the indemnifying party within such fifteen (15) day period shall not waive the indemnifying party's obligation except to the extent the indemnifying party is prejudiced by such failure; and (b) cooperate with the indemnifying party and its legal representatives in the investigation of such Claim, at the indemnifying party's expense. The indemnifying party shall have the right to

exercise sole control over the defense and settlement of any such Claim including the sole right to select defense counsel and to direct the defense or settlement of any such Claim in good faith; provided that the indemnifying party shall not enter into any non-monetary settlement or admit fault or liability on the indemnified party's behalf without the prior written consent of the indemnified party, which consent shall not be unreasonably withheld, delayed, or conditioned. The indemnified party shall have the right to select and to obtain representation by separate legal counsel, with all such costs and expenses incurred by the indemnified party for such separate legal counsel borne by the indemnified party. A party shall be relieved of its indemnification obligations if any member of the indemnified party: (i) materially fails to follow the procedures set forth herein; (ii) compromises or settles any Claim for which indemnification is available hereunder, without the indemnifying party's prior written approval; or (iii) makes any admission or takes any other action with respect to any Claim for which indemnification is available hereunder, that in the indemnifying party's reasonable judgment, is prejudicial to the defense or settlement of such Claim, without the indemnifying party's prior written approval. For clarity, an Indemnifying Party's assumption of the defense of a Claim shall not be construed as an acknowledgment that the indemnifying party is liable to indemnify such indemnified party in respect of the Claim, nor shall it constitute a waiver by the indemnifying party of any defenses it may assert against the indemnified party claim for indemnification.

13.0 Insurance

During the term of the Study and for a period of three (3) years thereafter, Institution shall maintain insurance coverage in the types and amounts as are set forth in Minnesota Statutes Chapter 466 and Company will maintain professional liability and comprehensive general liability coverage in the types and amounts as are commercially reasonable given the nature and scope of Company's business. In the event a Claim is invoked against a party, such party's insurance shall be primary to any insurance coverage maintained by the indemnified party. In addition, each party has and will maintain throughout the term of the Study, statutory workers' compensation and employer's liability insurance in accordance with applicable laws and regulations. Upon request, a party shall provide the requesting party with evidence of such insurance coverage. For clarity, any such insurance coverage shall not serve to limit a party's liability.

14.0 Limitation of Liability

EXCEPT FOR LIABILITY ARISING UNDER SECTION 3.2 AND SECTIONS 4, 6 - 9, AND EACH PARTY'S INDEMNITY OBLIGATIONS FOR CLAIMS ASSERTED BY THIRD PARTIES, IN NO EVENT SHALL EITHER PARTY HEREUNDER BE LIABLE TO THE OTHER PARTY HEREUNDER FOR SPECIAL, CONSEQUENTIAL OR INDIRECT DAMAGES, INCLUDING, BUT NOT LIMITED TO THE LOSS OF OPPORTUNITY, LOSS OF USE, OR LOSS OF REVENUE OR PROFIT, IN CONNECTION WITH OR ARISING FROM OR IN RELATION TO THIS AGREEMENT, THE PROTOCOL, STUDY DOCUMENTATION OR THE STUDY DEVICE (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE). THIS LIMITATION SHALL APPLY EVEN IF SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

THE MAXIMUM LIABILITY OF EITHER PARTY AND ITS AFFILIATES TO THE OTHER PARTY AND ITS AFFILIATES FOR ALL INCIDENTS GIVING RISE TO CLAIMS UNDER THIS AGREEMENT SHALL BE FIVE MILLION DOLLARS ($5,000,000) IN THE AGGREGATE, UNLESS OTHERWISE LIMITED BY LAW. FOR THE AVOIDANCE OF DOUBT, THE LIABILITY CAP DESCRIBED IN THIS SECTION IS INTENDED TO BE AN AGGREGATE CAP FOR ALL CLAIMS MADE BY A PARTY AND ITS AFFILIATES UNDER THIS

AGREEMENT AND NOT A PER-CLAIM LIABILITY CAP. FURTHER, NOTHING IN THIS PROVISION SERVES AS A WAIVER OF ANY RIGHTS OR DEFENSES ARISING UNDER MINNESOTA STATUTES CHAPTER 466.

INSTITUTION ACKNOWLEDGES THAT THE STUDY IS INVESTIGATIONAL IN NATURE, THAT THE STUDY DEVICES MAY RESULT IN FALSE POSITIVE OR NEGATIVE RESULTS AND THEREFORE NEITHER THE STUDY NOR THE STUDY DEVICES SHALL SERVE AS A SUBSTITUTE FOR INSTITUTION'S OWN POLICIES AND PROCEDURES REGARDING THE IDENTIFICATON OF, AND RESPONSE TO, ACTUAL OR SUSPECTED COVID-19 INFECTIONS AMONG INSTITUTION'S STAFF, VISITORS, STUDENTS, FAMILY MEMBERS OR ANY OTHER PERSON. INSTITUTION HEREBY RELEASES COMPANY, ITS AFFILIATES AND THE MANUFACTURER OF THE STUDY DEVICE FROM ANY AND ALL LIABILITY RESULTING OR ARISING FROM TEST RESULT OBTAINED THROUGH THE USE OF THE STUDY DEVICES (WHETHER OR NOT DETERMINED TO BE "FALSE" POSITIVE OR NEGATIVE RESULTS) AND FROM ANY AND ALL DECISIONS, ACTIONS OR MEASURES MADE OR TAKEN BY INSTITUTION AND ITS PERSONNEL IN RESPONSE TO ANY SUCH TEST RESULTS.

15.0 Notices

Except as otherwise expressly provided within this Agreement, and for clarity, excluding day to day communications, which will be handled in accordance with the Protocol and Study Documentation, any other notices under this Agreement shall be in writing and in English and delivered to the individuals at the postal addresses set forth below, or to the postal address subsequently provided by a party in accordance with this section, by (a) personal delivery, with notice deemed given upon actual receipt as evidenced by the date on the courier's receipt; (b) a reputable national overnight carrier, return receipt requested, with notice deemed given upon actual receipt as evidenced by the date on the return receipt, (c) facsimile, with notice deemed given on the date received as evidenced by the confirmation of receipt generated by the transmitting machine, or (d) by e-mail, with notice deemed given on the date of acknowledged by the receiving party's return email.

If to Institution:

Independent School District No. 273, Edina Public Schools
5701 Normandale Road
Edina, MN 55424
Attn: Superintendent
E-mail: John.Schultz@edinaschools.org

If to Company:

Optum Labs
5995 Opus Parkway, Floor 5
Minnetonka, MN 55343
Attn: General Counsel
E-mail: stacy.schultz@optum.com

16.0 Independent Contractors

Institution and Company are each an independent contractor of the other for the sole purpose of carrying out the terms of this Agreement. No employees or agents of either party shall be considered

to be an employee, partner, joint venturer or agent of the other party. Neither party nor any of its employees or agents shall have the authority to legally to bind the other and shall not represent, warrant, suggest or otherwise imply that such person or entity represents the other party, has the authority to bind the other party or is operating on the other party's behalf.

17.0 Assignment and Subcontracting

Institution may not assign or otherwise transfer this Agreement, or any rights or obligations hereunder, without Company's prior written consent. Without limiting the foregoing, and only upon Company's prior written consent, Institution may subcontract the performance of certain of its activities under this Agreement to qualified third parties, provided that: (a) such third parties perform such activities in compliance with the terms and conditions in this Agreement, including all confidentiality and regulatory obligations, Company inspection and audit rights, insurance coverage, and Company ownership rights; (b) Institution remains liable for the performance, and acts and omissions of its subcontracted third parties as if such acts or omissions were performed by Institution; and (c) neither Institution nor Personnel has any financial interest (direct or indirect) in any such third parties. For the avoidance of doubt, Company may assign or transfer this Agreement, in whole or in part, without Institution's consent, in connection with any transfer of Company's rights to the study device or to an affiliate. This Agreement shall be binding upon the parties, their legal representatives, and permitted successors and assigns. Any attempted sale, pledge, assignment, sublicense or other transfer in violation of this Section 17 shall be void and of no force or effect.

18.0 Governing Law

This Agreement and any disputes arising hereunder, including the rights and obligations of the parties hereunder, shall be governed by and interpreted, construed, and enforced in accordance with the substantive laws of the State of Minnesota, without regard to its conflict of law rules, and shall take into account usages, customs and practices in the performance of clinical trials.

19.0 Miscellaneous

This Agreement, including the Protocol and Study Documentation, all of which are incorporated herein by reference, constitutes the entire agreement between the parties with respect to the subject matter herein and supersedes all prior and contemporaneous agreements, whether written or oral, of the parties hereto, relating to the subject matter herein, including any confidentiality or non-disclosure agreements entered into between the parties. In the event of any inconsistency or conflict between this Agreement and the Protocol or Study Documentation, the terms of this Agreement shall govern with respect to the commercial and contract terms, but the Protocol and Study Documentation will govern with respect to the clinical conduct of the Study. This Agreement, including the Protocol and other addenda, may be amended only by a writing signed by authorized representatives of Company and Institution. If any provision of this Agreement is for any reason found to be invalid or unenforceable, the remainder of this Agreement shall continue in full force and effect. Failure to enforce any rights hereunder, regardless of the length of time such failure continues, shall not constitute a waiver of those or any other rights, unless in a writing signed by an authorized representative of the waiving party. The provisions of this Agreement are for the sole benefit of the parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other person or entity. This Agreement has been prepared jointly and will not be strictly construed against any party, and any ambiguities in this Agreement, if any, will not be construed against any party, irrespective of which party may be deemed to have authored the ambiguous provision. The headings of each section have been inserted for convenience of reference only and are not intended to limit or expand the meaning of the language contained in any particular section. References to "days" shall

mean calendar days unless otherwise specified as a "business day". The words "include" or "including" will be construed to mean "including without limitation", and the word "will" will be construed to have the same meaning as the word "shall". References to any contract, statute, act, or regulation are to that contract, statute, act, or regulation as amended, modified, or supplemented from time to time. This Agreement may be executed in any number of counterparts, and delivered by .pdf format, or other electronic means, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.

IN WITNESS WHEREOF, Company and Institution have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

COMPANY

By:_____

Name Printed:_____

Title:_____

Date:_____

INSTITUTION

By:_____

Name Printed:_____

Title:_____

Date:_____

STUDY LEAD I have read this Agreement, the Protocol, and Study Documentation and will comply with the obligations of Study Lead hereunder.

By:_____

Name Printed:_____

Date:_____

Project TEST THE NEST:
COVID-19 Pooled Testing Pilot for Edina Public Schools 2020-2021

"TEST THE NEST" COVID-19 Pooled Testing Pilot

What is project "Test The Nest"?

Edina Public Schools is committed to remain open for hybrid/in-person learning for our students. Partnering with United Health Group ("UHG"), EPS is launching a research-based COVID-19 pooled voluntary testing pilot for the Edina Public School system that uses a proactive and surveillance testing strategy to identify asymptomatic spread of the COVID-19 virus. This program can be an important and effective mitigation measure in helping to sustain hybrid/in-person learning for students. This will supplement existing mitigation measures within the school district.

"TEST THE NEST" COVID-19 Pooled Testing Pilot: *Timeline*

RECOMMENDATION
→ *Board consensus secured for UHG/EPS pilot*

TRIAL RUN: TEST THE NEST
→ Small-scale trial run testing of registered students at all school sites by UHG Edina community volunteers

LAUNCH COVID TESTING PILOT: PROJECT TEST THE NEST
→ Testing rolls out for all registered students at all secondary sites

FEBRUARY | MARCH | SPRING BREAK | APRIL | MAY | JUNE

AGREEMENT
→ UHG/EPS Testing Pilot agreement presented for Special Board Meeting

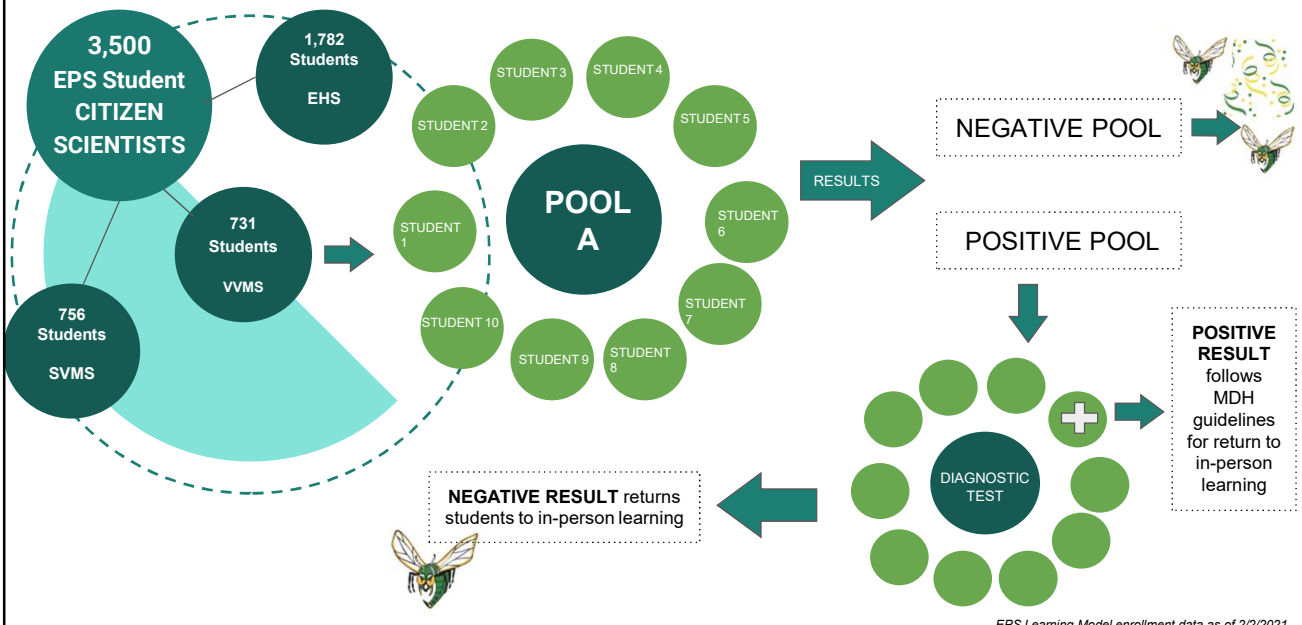
COMMUNICATION
→ Info to families, registration for student participation opens, etc.

SURVEY #1
→ Testing Pilot Survey of students & families

SURVEY #2
→ Testing Pilot Survey of students & families, plus staff

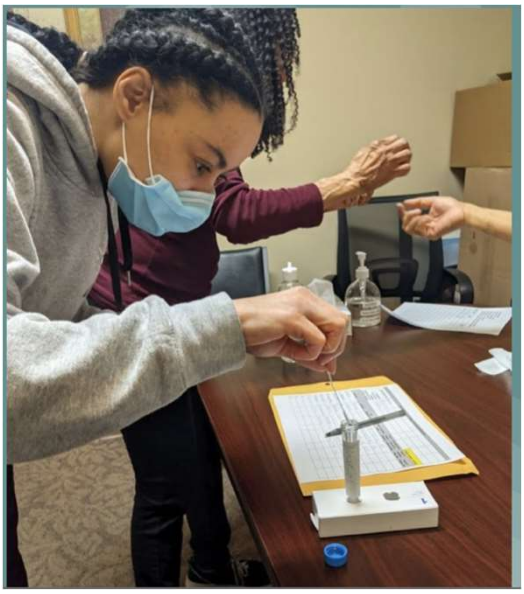
SURVEY #3
→ Post-Pilot Survey of students & families, plus staff

"TEST THE NEST" COVID-19 Testing Pilot: *How Pooled Testing Works*



EPS Learning Model enrollment data as of 2/2/2021

"TEST THE NEST" COVID-19 Testing Pilot: *Pooled Testing Sample Collection*



"TEST THE NEST" COVID-19 Pooled Testing Pilot: *Q&A (Draft 3.3.21)*

What is pooled testing?
Pooled testing is a cost-effective and time-efficient way to test for COVID-19 by reducing the number of tests and supplies needed giving us the ability to process many individuals quickly. It works by 'batching' a group (approx. 10) of individual nasal swab samples into a single test tube to submit for processing.

The expectation is that most pools will have negative results allowing for most pools of students to be quickly cleared. If a pool does return with a positive test, it means one or more students in the pool has COVID-19.

Who is eligible to participate in the EPS COVID-19 Testing Pilot?
All secondary students (grades 6-12) who are currently enrolled in the hybrid/in-person learning model for EPS are eligible to participate. Participation opportunities may expand dependent on testing capacity and availability of other resources.

Do all students have to participate in this study?
No. We hope that all students will take part in this program due to the benefits it will provide to all, but the Testing Pilot is **100% optional for all students**. We know the more students that participate, the more of a "bubble" we create which ultimately keeps our nest safer and our schools open.

What happens if a student agrees to participate in testing, but changes their mind later?
Any student can stop participation in the Testing Pilot at any time without penalty.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

How often and when are students tested?
Students will be tested 1x each week (either Monday or Thursday before school) through the end of the school year (no testing at EPS from March 29-April 2/Spring Break).

How long will this testing be available at EPS?
The Testing Pilot will begin in March and continue through the end of the 2020-21 school year.

Is there a cost for students to participate?
No. There is no participation fee for students to participate in the Testing Pilot.

Will students know who else is in their pool sample?
No. The pooled testing collection process will be randomized for students, so students will not have any confirmation of who is in the sample pool with them.

Who will administer the in-school sample collection for students?
Students will receive training for how to self-administer their own test in the presence of a qualified and trained collection volunteer observer. The student will drop their own nasal swab into the test tube container. No one else will handle their test swab.

How are the 'pooled sample groups' processed?
The district's pooled tests will be processed in labs at OPTUM, a UHG business, located just a few miles down the road from Edina. Processing will occur as soon as sample pools are received at the lab in order to have results before the end of the school day.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

How long will it take to receive results from in-school COVID-19 pool testing?
Fast results are an important piece to making this Testing Pilot effective. Participants will receive same-day results of pooled testing before the end of the school day.

How many students are tested in a pool?
Student samples are pooled and composed of approximately 10 students.

How do students sign-up to participate?
Student registration for the Testing Pilot program will be available through the Infinite Campus portal. All students will need to be registered online before participating. A parental consent waiver will need to be signed as part of student registration.

Why do I need to sign a waiver and what permissions does that give?
The required waiver is needed to confirm the student's voluntary participation in the Testing Pilot. It gives EPS and UHG permission to conduct surveillance pooled testing that includes individual sample collection from students on-site at EPS and testing for COVID-19 detection within the pool at UHG.

Do I need to register my student every week?
No. Students register for the entire duration of the Testing Pilot (approx.10 weeks). Parents will only need to sign the waiver once when they pre-register their student. That one-time waiver signature is good for the entirety of the Testing Pilot for the student.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

Why is the Testing Pilot offered to secondary students but not elementary students?
Secondary students were a good fit for the testing pilot for several reasons including a match with our partner UnitedHealth Group and their research efforts, overall testing capacity availability and ease of self-collection samples by older students.

What happens if my student's testing pool comes back with a negative result?
Cartwheels! If a pool is negative (normal), all students/families are notified the same day the student tested (before the end of the school day).

What happens if my student's testing pool comes back with a positive result?
If a student's testing pool is positive, all students in that pool will be contacted by the Health Services staff the same day the student tested (before the end of the school day) and be removed from the classroom. Each student/family will need to have an individual diagnostic test to determine the positive case in the pool. All students in a positive pool would need to follow MDH protocol for quarantine until results from the diagnostic test are confirmed.

Students have two choices for a diagnostic confirmatory test:

1) *Student retests immediately at their school site with an individual UHG diagnostic test for no charge.*
    a) Upon notification, students head to the school testing location and repeat simple nasal swab collection twice, (one sample used for the student's individual diagnostic test and one blind sample for UHG research). **Individual diagnostic results expected by the very next morning (12 hours), if not before.**
    OR
1) *Student obtains an individual diagnostic test independent of EPS and UHG.*
    a) Upon confirmation of a negative result, students may return to school.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

What happens if my student's diagnostic test is negative?
If a student's diagnostic test is negative, they should return to school the next day. If student chooses to do a diagnostic test independent of Testing Pilot, results of the test will need to be shared with Health Services for a return to in-person school.

What happens if my student receives a positive COVID diagnostic result?
If the student's diagnostic test is positive, they will be notified by UHG should follow the COVID-19 quarantine protocol. Your school's Health Services staff would work with students and families to determine a return-to-school date for your student. The district would conduct contract tracing to determine if anyone was in close contact with a student testing positive, and would advise students or staff of close contact protocol. *Please note, students in the same testing pooled sample are not considered close contacts.*

Do students still need to complete the MDH recommended at-home COVID-19 Symptom Screening if they are in this Pilot Testing program?
Yes. All students attending hybrid/in-person learning, whether they are participants in the Testing Pilot or not, will need to remain vigilant and follow the at-home COVID Screening process found here (link). The it is an important COVID-19 prevention measure that helps to mitigate spread of the virus.

If a student is showing any symptoms of COVID, can they still participate in on-site pool testing that day?
No. The COVID-19 testing pilot works to identify *asymptomatic* cases of COVID to help keep our schools open for in-person learning. Including symptomatic students in a pool will decrease the efficiency of pooled testing and cause more positive pools. If any student is showing any symptoms of COVID, the student will need to follow MDH protocols and **not** participate in the Testing Pilot until they are cleared for a return to school.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

If this testing pilot detects asymptomatic cases, does that mean EPS will have to move to a distance learning model?
No. In fact, the opposite is true. The Testing Pilot is a surveillance program that pulls positive cases from the student school community and gives us important information on COVID prevalence in our buildings. This testing method adds an important additional layer to EPS' comprehensive mitigation strategy to help keep schools open for in-person learning. The district will, however, follow contact tracing protocols to determine if any students or staff were in close contact with a student who returns a positive test and would advise students or staff of close contact protocol.

Will UHG collect data about my student?
No. Student privacy is of utmost importance to EPS. No individual or personal data of students will be shared with UHG through the surveillance pooled testing process. All samples collected and tested at UHG will be unidentifiable.

How are the surveys for students and families being used?
There will be a total of three (3) surveys conducted throughout the Testing Pilot. All of the surveys are blind and 100% optional for participants. They will be distributed to eligible secondary students to capture data and metrics surrounding the COVID Testing Pilot.

What are the costs to EPS for this pilot?
EPS has committed up to $45,000 in funds to cover testing materials at-cost (PPE, swabs, test tubes) for up to 3,500 individual participants per week. (approx. 45,000 tests).

Isn't there free testing already available through the state/MDH?
Yes, but remembering to order the at home kit or physically going to a testing site is challenging for busy families. Also, the turnaround time for the state/MDH test of 1-2 days once the test is received for processing which is not ideal. By bringing testing to the school grounds, students will have an extremely convenient way to test with fast turnaround times.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

How sensitive is this test?
The test is considered to have >95% accuracy. It is a RT-PCR test using the same method of detection as most hospital reference labs or mail-in tests. Validation work performed for FDA Emergency Use Authorization as well as independent analysis shows that the test performs as well as other PCR tests. All tests, including reference lab PCR tests, have the risk of reporting positive results when they are in fact negative (false positive) as well as reporting a negative result when the person is actually infected (false negative).

What COVID-19 mitigation protocols will be used during the testing process to keep students and staff safe?
Students will maintain a distance of 6 feet as they wait their turn to conduct their COVID test. The nasal swab will be dropped into the pool sample container available in the testing space. Hand sanitizer will be available as they exit the testing space. Students will be the only person handling their own test swab.

Why is this method being used?
Testing is a critical mitigation strategy for identification of COVID-19-infected people without symptoms. Research has shown that around 40-50% of people infected with COVID-19 do not develop symptoms.* Testing needs to be frequent, sustainable, accurate, and convenient. Current lab-based PCR (the most sensitive and reliable) testing is expensive and logistically complex. The PCR test used for this Testing Pilot is the gold standard, providing results quickly and allowing for more individuals to be tested efficiently and effectively at one time.

How is information about the student participants being protected?
Your data will not be identifiable in the Testing Pilot that will be stored or shared as research.
Identifiers will only be used for EPS to immediately respond to any positive pool test results to ensure that we identify participants in a positive pool to prevent further transmission.

"TEST THE NEST" COVID-19 Testing Pilot: *Q&A* *(Draft 3.3.21)*

What if I am injured because of taking part in this study?
Any individual who is injured or gets sick as a result of study participation should call a doctor immediately. Insurance may be billed for the care needed. UHG R&D will pay any charges that are not covered by an insurance policy or the government, provided the injury was not due to an underlying illness or condition and was not caused by the individual or some other third party. If an individual tests positive for COVID-19, UHG R&D will not cover any health expenses associated with treatment for COVID-19. No other payment is routinely available from the study doctor or UHG R&D.

Who reviews this UHG COVID-19 Testing Pilot for Edina Public Schools program?
The study is reviewed and approved by a human subjects institutional review board (IRB) to ensure safety and data integrity.

What happens to samples collected for this study?
Individual's pooled study samples will not be saved or used for any other purpose than testing. Swabs that are reserved for research (which are only taken when there is a positive pool) will be de-identified and used for other COVID-19 research by UHG.

**https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/expanded-screening-testing.html

"TEST THE NEST" COVID-19 Testing Pilot: *Proposed Next Steps*

LAUNCH COVID TESTING PILOT: PROJECT TEST THE NEST
→ Testing begins roll out for all registered students at all secondary sites by **March 15**

MARCH

Thursday, March 4
Special School Board Meeting: *Board approval of testing pilot agreement*

Monday, March 8
School Board Meeting: *Board approval of testing pilot protocol, consent and assent*

Tuesday, March 9 Friday, March 12
- *Communication begins to EPS families, FAQ, registration opens for students, testing pilot survey #1.*
- *Volunteer training.*
- *Logistics and operations with UHG.*
- *Small-scale testing trial run at each secondary site.*

Monday, March 15
Launch COVID Pooled Testing Pilot for students
- Mondays, EHS (50%) & VVMS
- Thursdays, EHS (50%) & SVMS