



BUSINESS ASSOCIATE AGREEMENT for COVID-19 Testing Services for K-12 Schools

v.08.01.2021

This Agreement is made effective by _____ on and between the client _____, hereinafter referred to as "Covered Entity", and Bluewater Toxicology, LLC dba Bluewater Diagnostic Laboratory (Bluewater Dx), and its affiliated entities, hereinafter referred to as "Business Associate", (individually, a "Party" and collectively, the "Parties").

Business Associate has been approved by the Kentucky Department of Public Health as a Laboratory Service Provider for Coronavirus Disease 2019 (COVID-19) Polymerase Chain Reaction (PCR) diagnostic testing for students in kindergarten through grade 12 (K-12 school districts) and private/charter schools within Kentucky. COVID-19 testing supports safe, in-person instruction, and provides another layer of prevention to protect students, teachers, and staff and slow the spread of SARS-CoV-2, the virus that causes COVID-19.

K-12 School COVID-19 Testing Program is a voluntary program paid for by federal grant funding and offered by the Kentucky Department for Public Health (KDPH) in partnership with the Center for Disease Control (CDC) for Kentucky K-12 schools who wish to participate in school-based COVID-19 screening testing for teachers, staff and students to assist schools in reopening safely for in-person instruction. All charges or billing incurred through this agreement shall be submitted to the Kentucky Department of Public Health (or other appropriate state agency). The Covered Entity, its students, teachers or staff shall NOT be billed or charged by the Business Associate for any COVID-19 testing conducted pursuant to this agreement.

SCOPE OF WORK

Business Associate will support the Covered Entity in the testing program it chooses for its school(s): Testing will be limited to staff and students of Covered Entity to include school district employees and staff (contracted or otherwise) to include but not limited to bus drivers, maintenance, office staff or as determined by the school administrator.

1. Business Associate shall provide testing for K-12 students and staff consistent with the terms outlined in the Addendum which outlines type of testing to be employed, frequency of testing, and population to be tested.
2. Business Associate shall provide or ensure all necessary resources to provide COVID-19 diagnostic testing to the Covered Entity to include:
3. Collaboration to obtain and maintain records of consent from students/guardians and staff who are tested;
4. Onsite personnel, such as a testing coordinator, sample collector(s), and/or other additional staff needed to implement test programs;
5. Provision of all necessary equipment, barriers, signage, etc. necessary to provide the testing service;
6. Logistical and operation support;
7. Provision of own Personal Protective Equipment (PPE) to perform specimen collection or testing;
8. Provision for all supplies necessary for the collection, storage, shipping, and testing of specimens (collection devices, coolers, shippers, lab kits, reagents, consumables, etc.);
9. Provision for specimen collection; and
10. Provision of an online, secure, The Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliant patient portal to students/guardians and staff to access test results.
11. Assurance that clinical personnel supplied will be required to demonstrate the necessary qualifications to perform any medical services required under the contract.
12. Business associate shall ensure all workers who perform these services on Covered Entity property shall have background checks done prior to commencing any work. The Business Associate shall be responsible for all fees associated with obtaining background checks. A copy of each background check shall be supplied to the Covered Entity's school administrator upon request. No Business Associate employee shall be assigned or allowed on the Covered Entity's property who is a registered sex offender or who is otherwise prohibited by law from being on school district property.





13. Business Associate shall maintain HIPAA compliant unique patient identifier as it relates to all test results, negative, positive or indeterminate, completed Centers for Disease Control (CDC) and DPH required forms. DPH reserves the right to review and audit file.
14. Provision of testing with an approved Centers for Disease Control (CDC) test. CDC recommends collecting and testing upper respiratory tract specimens (nasopharyngeal swab or US Food and Drug Administration (FDA)-approved saliva swab). Any additional specimen collection method explicitly approved by the FDA requires submitting supporting documentation.
15. Allowable testing includes FDA authorized or approved SARS-CoV-2 PCR, nucleic acid amplification (NAAT), and antigen testing.
16. Guidance and training as requested based upon CDC recommendations.



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RECITALS

Business Associate performs services for Covered Entity pursuant to the following written or oral agreement – Client Service Agreement dated _____ (the “Service Agreement”). Covered Entity is subject to the privacy, security, enforcement and breach regulations promulgated under the Health Insurance Portability & Accountability Act of 1996 and the Health Information Technology for Economic & Clinical Health Act, as such regulations may be amended from time to time (collectively, “HIPAA”). Business Associate is subject to the HIPAA Security Rule (45 CFR Part 164 Subpart C) and certain provisions of the HIPAA Privacy Rule (45 CFR Part 160 and 164 Subpart E).

Covered Entity may disclose protected health information to Business Associate. “Protected health information” is demographic information collected from a patient which (a) is created or received by Covered Entity (b) relates to the past, present or future physical or mental health condition, the provision of health care or the past, present or future payment for the provision of health care of a patient, and (c) identifies the patient, or the information can be used to identify the patient. Protected health information includes information that is transmitted, maintained, or received electronically or in any other form.

Demographic information that identifies the patient or that could be used to identify a patient includes: name, street address, city, county, precinct, zip code, birth date, admission date, discharge date, date of death, telephone number, fax number, email address, social security number, medical record number, health plan beneficiary number, account number, certificate/license numbers, vehicle identifier and serial number, and full face photographic images and any comparable images.

Covered Entity wishes to obtain satisfactory assurances from Business Associate that Business Associate will safeguard protected health information from misuse and unauthorized disclosure and that Business Associate will assist Covered Entity in complying with other requirements related to protected health information.

Business Associate may use and disclose protected health information it receives from Covered Entity strictly for the following purposes and only to the extent necessary for Business Associate to perform its obligations under the Agreement: To perform its duties and obligations under the Service Agreement; To conduct Business Associate’s health care operations, including conducting quality assessment and improvement activities, reviewing competence and qualifications of health care providers, conducting business management, administration, compliance, planning, and development activities, to perform data aggregation and data analysis services using de-identified data, performing customer service functions, and resolving internal grievances; and To provide data aggregation and data analysis services to Covered Entity (if applicable).



Business Associate may not use or further disclose protected health information to another person or entity, including any subcontractor of Business Associate (each, a "Subcontractor"), unless the Subcontractor enters into a written agreement with Business Associate that imposes the same obligations on Subcontractor as are imposed on Business Associate under this Agreement. Business Associate may not copy, duplicate, or otherwise reproduce any part of the information except as required to perform services for Covered Entity in accordance with the Service Agreement. Business Associate shall comply with HIPAA to the extent that HIPAA applies to business associates. Additionally, Business Associate shall comply with the HIPAA Privacy Rule to the extent that Business Associate is carrying out any of Covered Entity's obligations under the HIPAA Privacy Rule. Business Associate shall comply with the minimum necessary standard under the HIPAA Privacy Rule and shall use reasonable efforts to limit the protected health information to the minimum necessary to accomplish the intended purpose whenever using or disclosing protected health information or requesting protected health information (PHI) from Covered Entity, unless otherwise permitted under the HIPAA Privacy Rule. Business Associate shall not sell PHI and shall not receive direct or indirect remuneration in exchange for the disclosure of PHI unless Covered Entity gives prior approval and Covered Entity or Business Associate obtains an authorization from each individual whose PHI is subject to a sale.

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Business Associate shall comply with the HIPAA Security Rule. Business Associate will use appropriate administrative, technical, and physical safeguards to prevent the intentional or unintentional use or disclosure of electronic protected health information ("ePHI"). Such safeguards shall include the development, implementation and enforcement of policies and procedures regarding maintaining the privacy of patient information; use of fax coversheets and standardized email closings which state that the information is intended only for the addressee and that unintended recipients should promptly destroy the information and notify the sender; and the use of data encryption to protect information stored on computers or transmitted electronically. If protected health information is transmitted, maintained or received electronically, Business Associate will use such safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of such information, including access controls, workstation security, integrity controls, data backup and storage, and encryption. Business Associate shall utilize encryption software that will render protected health information "secure" in accordance with standards published by the Secretary of the Department of Health and Human Services (the "Secretary").

Business Associate shall report to Covered Entity as soon as possible, but in no event later than 10 days after Business Associate becomes aware of (a) any use or disclosure of PHI not permitted under this Agreement or the Service Agreement, (b) any security incident, or (c) any acquisition, access, use, or disclosure of unsecured PHI (an "Incident"), whether or not the Business Associate believes that it qualifies as a "breach" under HIPAA. Business Associate shall, at the direction of Covered Entity, cooperate and assist in investigating the Incident, performing a risk assessment, determining whether the Incident is reportable, making the necessary reports to individuals, the media and the government, and taking steps to minimize any adverse consequences resulting from the Incident. With respect to any breach of unsecured PHI, Business Associate shall provide the following information to Covered Entity: (a) a brief description of the Incident; (b) a description of the nature and extent of the PHI involved in the Incident and the likelihood of re-identification; (c) the individual who impermissibly used the PHI or received the PHI; (d) whether the PHI was actually acquired or viewed or if only the opportunity to do so existed; and (e) a description of Business Associate's actions to mitigate the consequences of the Incident and to prevent further such incidents.

Business Associate shall take appropriate disciplinary action against any of its employees that were involved in the Incident. Except as directed by Covered Entity or required by law, the Business Associate shall not directly report the Incident to the Secretary, the media or any individual and shall keep the matter strictly confidential. Business Associate shall be solely responsible for its own costs and fees related to investigating and/or responding to its potential HIPAA violations and, if necessary, providing appropriate notice to individuals, the government and/or the media (as required).



Business Associate shall make protected health information available, or assist Covered Entity in making protected health information available to patients in accordance with federal law, including (a) permitting a patient to inspect and obtain a copy of his or her protected health information, (b) providing an accounting of disclosures, (c) permitting a patient to request an amendment to protected health information, and (d) permitting a patient to restrict the use and disclosure of his or her protected health information.

Covered Entity shall not knowingly agree to additional restrictions or requirements that materially affect Business Associate's ability to perform or costs of performance. Business Associate may either terminate this Agreement (as well as underlying Service Agreement) if the Covered Entity agrees to such additional restrictions or requirements or the Parties can agree Business Associate may recover costs associated with such additional restrictions or requirements.

Business Associate shall make its internal practices, books and records relating to the use and disclosure of protected health information available to the Secretary for purposes of determining compliance with federal law during the term of the Agreement and for a period of five years after termination of the Agreement. By complying with this provision, Covered Entity or Business Associate shall not be deemed to have waived any attorney-client, accountant client or other privilege. If Business Associate breaches a material term of this Business Associate Agreement, Covered Entity may terminate the Agreement (defined above). Upon termination of the Agreement for any reason, this Business Associate Agreement shall automatically terminate, and Business Associate shall return, destroy or permanently delete any protected health information it has received or created on behalf of Covered Entity. If return or destruction is not feasible, Business Associate shall continue to safeguard protected health information as required by this Agreement and shall no longer use or disclose the information.

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Business Associate shall defend and indemnify Covered Entity and hold Covered Entity and its employees, officers, directors, managers, members, and affiliates harmless from and against any and all claims, demands, actions, costs, expenses and liabilities, including any costs related to Covered Entity's obligations to investigate and/or respond to potential HIPAA violations and, if necessary, to provide written notice to individuals, the government, or the media for reportable breaches and establishing a toll-free telephone number, as required by HIPAA, and reasonable attorneys' fees, which may arise in connection with the failure by Business Associate or its employees or agents to perform any of their obligations in accordance with this Agreement.

Business Associate shall provide to Covered Entity verification of professional liability and general liability coverage in the minimum amount of One Million Dollars (\$1,000,000) per occurrence, and which meets the requirement of state and federal law, listing Business Associate as insureds and also naming Covered Entity as an additional insured and certificate holder. Business Associate shall notify Covered Entity immediately if insurance coverage is canceled for any reason.

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Business Associate is an independent contractor of Covered Entity. Covered Entity and Business Associate shall not by virtue of this Agreement be deemed to be creating any agency, partnership, employment, or joint venture relationship. Business Associate may not bind Covered Entity nor incur obligations for or on behalf of Covered Entity.

The Covered Entity, its students, teachers or staff shall NOT be billed or charged by the Business Associate for any COVID-19 testing conducted pursuant to this agreement.

The Covered Entity may terminate this agreement with thirty (30) days' written notice to the Business Associate.

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This Agreement shall be binding upon the parties hereto and their respective legal representatives, successors, and assigns.



This Agreement shall be governed by, and construed in accordance with, all appropriate state and federal laws.

This Agreement may not be assigned by Business Associate, nor may Business Associate delegate his, her, or its duties hereunder, without the express prior written consent of Covered Entity. This Agreement may not be amended except by an instrument in writing signed by Covered Entity and Business Associate.

Any and all notices, consents or other communications by one party intended for the other shall be deemed to have been properly given if in writing and personally delivered, transmitted by electronic means, or deposited in the United States, postpaid, to the addresses or numbers set forth below the signatures of the parties.

No waiver of a breach of any provision of this Agreement shall be construed to be a waiver of any breach of any other provision. No delay in acting with regard to any breach of any provision of this Agreement shall be construed as a waiver of such breach.

This Agreement constitutes the entire understanding and agreement of the parties with respect to its subject matter and, other than amendments necessary to accommodate changes to HIPAA, cannot be changed or modified except by another agreement in writing signed by the parties.

COVERED ENTITY

Client:

Address:

City:

State:

Zip Code:

Signed by (Print):

Title:

Signature:

Date:

BUSINESS ASSOCIATE

Bluewater Toxicology, LLC dba Bluewater Diagnostic Laboratory

221 S. Bardstown Rd.

Mt. Washington, KY 40047-7248

Signed by: Troy Pitcock, VP of Administration

Signature:

Date:

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BLUEWATER Dx

Addendum

This Addendum to the Business Associates Agreement (hereinafter referred to as the "Addendum") is entered into as of _____ by and between client _____, hereinafter referred to as "**Covered Entity**", and Bluewater Toxicology, LLC dba Bluewater Diagnostic Laboratory (Bluewater Dx), and its affiliated entities, hereinafter referred to as "**Business Associate**", (individually, a "Party" and collectively, the "Parties"), both of whom agree to be bound both by this Addendum and the BAA to which it pertains.

Through this Addendum, the Parties wish to specify the **scope of testing services** to be performed by the Business Associate.

School District:

Address:

City:

State:

Zip:

Phone:

Fax:

School Administrator Name:

Title:

Email:

Nurse / COVID-19 Surveillance Coordinator:

Title:

Email:

DESIRED COVID-19 TESTING SERVICES FOR ALL NAMED SCHOOLS IN DISTRICT

Type of testing desired:

☐ Symptomatic

☐ Screening

☐ Outbreak

Collection method:

☐ Nasopharyngeal

☐ Nasopharyngeal

☐ Nasopharyngeal

☐ Oropharyngeal

☐ Oropharyngeal

☐ Oropharyngeal

☐ Oral Rinse

☐ Oral Rinse

☐ Oral Rinse

☐ Rapid (not PCR)

Testing Location:

☐ Nurse's Office

☐ Nurse's Office

☐ Nurse's Office

☐ Classroom

☐ Classroom

☐ Classroom



- ☐ On-Campus Drive-Up
- ☐ Off-Campus at designated
- ☐ BWDx Location (VIP)

☐ On-Campus Drive-Up

☐ On-Campus Drive-Up



Collection to be performed by:

- ☐ Bluewater Dx Associates
- ☐ School Nurse

- ☐ Bluewater Dx Associates
- ☐ School Nurse

- ☐ Bluewater Dx Associates
- ☐ School Nurse

Population to be tested:

- ☐ Teachers and other staff
- ☐ All students
- ☐ Opt-in students only

- ☐ Entire school
- ☐ Opt-in students only
- ☐ Athletes
- ☐ Scheduled outings/trips
- ☐ % of student population
- ☐ Other school group

To be determined at time of outbreak.

Frequency:

As needed

☐ **Antibody testing desired.** Covered Entity wishes to make antibody testing available to interested teachers, staff, and students. The prepay cost to the client (Covered Entity or individual) is \$53.10 as this testing is not covered by the state of Kentucky or the DPH.

Notes: _____

Registration: All test participants will register for testing using a toll-free number unique to the school or district. (Parents should register minor children.)

District Schools: Please attach a list of all schools within Covered Entity's district. Include points of contact at each.

Results: Test results will be available 24-48 hours after sample collection. (In some cases, same-day results may be available in some areas of Kentucky).

Parents will receive a text message containing a secure link to their child's test results in real time.

Test results will be sent to the state of Kentucky per Business Associates contract with the Kentucky DPH.

Cost: Business Associate will directly bill the state of Kentucky per its contract for all state-approved forms of testing.

COVERED ENTITY

BUSINESS ASSOCIATE



Signature

Date

Printed Name

Signature

Date

Troy Pitcock, VP of Administration
Printed Name

