

Maine Pooled PCR Testing Guidance for K-12 Schools May 7, 2021

Maine Department of Health and Human Services (DHHS) and Department of Education (DOE) has implemented a pooled PCR testing program, which is available to any K-12 school administrative unit, public or private, starting in May 2021. Pooled PCR testing is a more efficient way to test large groups of students and staff in schools on a weekly basis. Pooled testing involves collecting swabs from small groups of students, usually students in a class cohort or homeroom, placing the swabs in a common test tube, mixing several test samples together in a "batch" or "pool" and then testing the pooled sample with a PCR test for detection of SARS-CoV-2. If a pool results are positive, the individuals in that pool will need to be tested using a rapid antigen test called BinaxNOW. The positive individual(s) would then be sent home to begin their isolation period.

This document provides detailed information on Maine's Pooled PCR Testing Program and the process schools and districts need to follow to participate.

After careful review of this guidance document, all public School Administrative Units (SAUs) and private schools in Maine that are interested in participating in the state-funded pooled testing program must complete an [Authorized School Application](#). DHHS and DOE will review the SAU application form and, upon approval, connect the SAU with the Testing Service Provider to begin the onboarding process. Schools may apply and enroll in the testing program on a rolling basis. Public schools that also run public PreK programs or summer education programming may also extend this program to those students and staff. The program is not open to private PreK only programs.

Required Steps to Participate in Pooled PCR Testing Program:

1. *Authorized School Application:* For Pooled Testing all participating SAUs and private schools must complete an [Authorized School Application](#), which includes an attestation to the understanding of the [Statement of Assurances](#).
 - a. This application includes detailed information about the specific public or private schools participating in the initiative, including the number of students/staff to be tested and preferences about the operations of the program at each school (sample collection location, need for on-site support or other services, etc.).
 - b. Please note, SAUs and private schools with multiple schools should fill out one application for the entire SAU or private school and indicate specifics about the participating schools within the form. Locations can be added later if schools want to begin with a pilot site.
2. *Statement of Assurances:* To support the effective administration of this program, as well as the safe administration of pooled testing, SAUs and private schools must agree to a series of

assurances before they are authorized to access the pooled testing program. The appropriate signatory must be an individual with the authority to agree to the terms outlined in the *Statement of Assurances*, such as the superintendent or executive director. The *Statement of Assurances* provides an overview of the responsibilities of the SAUs or private schools, and the requirements for the pooled testing program. Noncompliance with the assurances may result in the termination of services. SAUs and private schools will be asked to review and document their understanding in their Authorized School application. The document can be found on the [DOE COVID-19 Toolkit](#) or with the direct link here: [Statement of Assurances](#).

3. *Abbott BinaxNOW preconditions*: All participating SAUs and private schools must have a plan in place for follow-up testing if a positive pool is identified. The expectation is for each SAU or private school to provide Abbott BinaxNOW follow-up testing. The following steps should be completed prior to starting pooled testing, as BinaxNOW testing will be an important component of the program when an SAU or private school is informed of a positive pool.
 - The SAU or private school has either a valid CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. To obtain a CLIA Certificate of Waiver, organizations must complete an application ([CLIA Waiver Application Form](#)) and upon approval will be invoiced a \$180 fee. More information on applying for a CLIA Certificate is available on the [CMS CLIA website](#). SAU/school instructions are located at: [CLIA Waiver Instructions](#)
 - The SAU or private school must complete the BinaxNOW online training modules to ensure the test is used consistent with the manufacturer's instructions. That training is available at: [Abbott BinaxNOW Online Training](#)
 - The SAU or private school must immediately report all results—positive and negative—to the Maine Center for Disease Control and Prevention (CDC) by enrolling in and using the Maine CDC Point-of-Care Test Reporting System: The REDCap electronic reporting portal. The facility must report all negative, positive, and inconclusive test results within 24 hours.
 - The SAU or private school must have a way to contact each person with test results. At a minimum, positive results should be relayed by telephone or in person. Negative results could be shared by email or text message.

Preconditions for Pooled Testing:

All participating SAUs and private schools must complete the following three preconditions before testing begins.

1. *Obtain Consent from Individuals to be Tested and to Report Follow-Up Test Results to Maine CDC.*

Consent is required for an individual to participate in pooled testing and follow-up testing

and to report all test results to the Maine CDC. Individuals must agree to all terms to be tested.

SAUs and private schools must make advance preparations to obtain consent from individuals to: (a) administer pooled testing; (b) administer follow-up testing, and (c) share individual test results with the Maine CDC via REDCap. All three components of consent are included in the single pooled testing consent form provided by the Service Testing Provider; individuals who do not provide all three components of consent cannot participate in the pooled testing program.

SAUs and private schools that use sample consent forms provided by DOE for pooled testing and follow-up testing do not have to separately complete the consent required for the Abbott BinaxNOW testing program. The sample consent forms for pooled and follow-up testing can be found on the [DOE COVID-19 Toolkit](#) Pooled Testing Section.

2. *Follow-Up Testing*

SAUs and private schools must have a process in place to individually test students and staff in positive pools with a diagnostic test for COVID-19. The test must have FDA Emergency Use Authorization. The Abbott BinaxNOW rapid point-of-care antigen test will be the primary tool for individual follow-up testing. SAUs and private schools that are not already enrolled in the Abbott BinaxNOW initiative for follow-up testing should complete the registration application process prior to starting the program.

3. *Review the State of Maine Standing Order for Testing*

Tests for COVID-19 must be ordered by a physician. On June 8, 2020, Maine CDC issued a Standing Order (“Order”) that authorizes any health care provider or other trained personnel at a health care facility or medically-supervised COVID-19 collection site (collectively, “collection site”) in the state to collect and submit for laboratory analysis specimens to be tested using a SARS-CoV-2 PCR molecular test for any individual in accordance with the conditions of the Order. This Order was revised on June 18, 2020 to clarify language regarding specimen collection protocols. This Order was also revised September 22, 2020 to allow any individual in Maine who is at least 12 months of age or older to receive testing. The Order was revised on December 8, 2020 to change the quarantine requirement from 14 days to 10 days. [Read the Standing Order \(PDF\)](#). The DHHS Standing Order is not meant to replace existing patient-provider relationships or provider-laboratory relationships.

4. *Ensure all staff complete training requirements*

All staff administering Abbott BinaxNOW test kits within an SAU or private school must complete all Abbott BinaxNOW training modules. The Abbott BinaxNOW training modules can be found [here](#).

All follow-up test results should be entered in REDCap as tests are performed, and by no later than the end of the day the test was performed. This will ensure all results are reported to the Maine CDC.

In addition to reporting of all tests results to the Maine CDC, SAUs and private school staff must report follow-up test results to the individual who was tested or, if the individual is a student, to the person who consented to the testing (i.e., the student's parent/guardian). Additionally, district and school staff must notify DOE of positive follow-up test [results](#).

5. *Maintain Adequate Supply of Personal Protective Equipment:*

All staff administering pooled testing must wear appropriate personal protective equipment (PPE) when conducting tests and handling patient specimens. When collecting a specimen from another individual, the following PPE is required:

- Surgical mask or N95 mask
- Eye protection
- Gloves
- Gown, when collecting specimens

For personnel observing the self-administration of specimen collection, the following PPE is required:

- Surgical mask
- Gloves, if collecting sealed tubes.

Refer to [DOE Personal Protective Equipment](#) guidance document. The DOE PPE Distribution will continue through School Year 2021-22. SAUs should follow the instructions for ordering.

Pooled Testing Vendor Information:

Pooled testing Provider	<u>Concentric by Ginkgo</u>
Description	Ginkgo has a plan to provide simple, affordable testing for every school in Maine. This self-swab pooled testing model allows for up to 25 swabs in a single pool and plugs into an integrated online portal where administrators can easily view results across classrooms.
Website	https://www.concentricbyginkgo.com/
Processing Laboratory	Ginkgo Bioworks, Boston MA
Min/Max # of swabs per pool	5-25
Consent Process	Electronic or Paper-based
Technology Platform for Pooled Testing	Does not require personal information for pooled testing
Technology Platform for Follow Up Reporting	Same system for pooled, Abbott BinaxNOW, and follow up PCR testing

Under the state-funded contract, SAUs and private schools will work with a pooled testing provider that will manage the following services:

- *Operations and logistics of pooled testing:* The vendor will procure, supply, and ship to the district the physical materials needed for testing, including swabs, test tubes, label printers, and any other necessary materials.
- *Training:* The vendor will conduct “train the trainer” style training to support SAUs and private schools with launch, including how to collect, store, and label samples, as well as how to use the software associated with pooled testing. Training will also include an overview of the DHHS and DOE approved protocols that schools should follow in the case of a positive pool and the protocols associated with follow-up testing. Training will also include the steps to obtain consent. Each SAU or private school is then responsible for disseminating the training information within their own school communities.
- *Software associated with pooled testing:* The vendor will supply a software platform that schools will use to enter pool information, order supplies, track test results, and centralize other necessary testing information. The platform will return test results within 24-48 hours of the lab receiving the samples.
- *Technical assistance/customer support to district/school personnel:* The vendor will provide customer service solutions for the participating SAU or private school. They will work directly with the testing coordinator or other administrators at the SAU or private school level to troubleshoot on topics including delivery issues, specimen collection, labeling tubes, transporting samples, test results, and training.
- *Transportation of specimen from the school to the laboratory:* The vendor will offer same-day shipping service or courier service to deliver tests to the laboratory. To encourage efficiency, SAUs and private schools in the same geographic location may be encouraged to collaborate on shipping logistics.

For SAUs and private schools that require additional support and capacity to implement pooled testing, the following optional services may be requested from the pooled testing providers. DHHS will endeavor to fulfill requests for these additional services; however, requests for additional support may delay pooled testing implementation.

- *Onsite test specimen collectors:* The vendor may provide the trained professionals to administer the test to students and staff through, for example, a subcontract with an Emergency Medical Technician (EMT) service provider or other health staffing agency.
- *Onsite testing coordinator:* The vendor may provide an individual on an hourly basis to support the onsite management of the pooled testing program.

Overview of Pooled Testing and Protocols

Pooled testing involves mixing several test samples together in a “batch” or “pool” and then testing the pooled sample with a PCR test for detection of SARS-CoV-2.¹ Pooled testing will be administered at school either by trained school staff, including school nurses, or onsite test specimen collectors. For staff and for students in second grade and up, the test can be conducted by self-collection. Younger students may be able to do self-collection with instruction and hand over hand training. Testing for all consenting students and staff members must take place once per week. Collected specimens are delivered to approved laboratories via same-day delivery, and results are returned within 24-48 hours. Please note, results may be returned by the Pooled testing providers’ software platform during non-school hours. It is the expectation that testing coordinator will review results and implement protocols during operating hours.

If a pooled test result is negative, then all individuals within that pool are presumed negative and may remain in school. If a pooled test result is positive, then all individuals in the pool must be retested individually. The Abbott BinaxNOW rapid point-of-care antigen test will be the primary source of this individual follow-up testing. SAUs that are not already enrolled in the Abbott BinaxNOW initiative are required to complete that process prior to starting pooled testing.

Considerations for Pooled Testing:

- Staff and students who are in grades second grade and above are encouraged to self-collect pooled testing samples under appropriate supervision and at the discretion of the trained observer. There are instances of children younger than second grade who are also able to self-collect; however, this is following a period of instruction and hand-over-hand guidance. Self-collection limits the amount of PPE required for testing administrators and enables testing to be done more quickly, reducing the impact on student learning time. Tests must be administered with individuals at least 6 feet apart, as masks will briefly be partially lowered during collection.
- Unvaccinated students and staff participating in the testing program who have been identified as a close contact of a confirmed case, regardless of whether they were a

¹ FDA, Pooled sampled testing and screening for COVID-19, (2020, August 24). Available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19>

member of the identified positive pool, do not need to quarantine so long as they are enrolled in the testing program. These individuals should remain in school and continue to participate in the weekly pooled PCR testing program. However, any unvaccinated student or staff member who is not participating in Maine’s Pooled PCR Testing Program and/or is unwilling to get follow-up BinaxNOW testing as part of a positive pool and is identified as a close contact of a confirmed case will need to quarantine for 10 days.

- All school staff and students who submit consent forms are strongly encouraged to participate in weekly pooled testing. This includes contracted staff such as bus drivers. The only exception is that any individual who has tested positive for COVID-19 in the past 90 days should be excluded from pooled testing. Currently, individuals working outside of the school are not eligible to participate.
- SAUs should determine pool size based on several factors, including current community/school incidence of COVID-19. Because the cost and logistical advantages of pooled testing are dependent upon a relatively low portion of pools being positive, schools in communities with high prevalence, which is defined in Maine as being categorized as yellow or red, or schools that have seen a high share of positive pools in previous weeks, should consider lowering their pool size to at least 10. The pool size should not be lower than 5. The maximum number of swabs per pool is 25.
- “Membership” within a given pool should remain as constant as possible. Teachers should be pooled with their students because a positive result on a pool full of teachers or staff may cause staffing issues while each staff member gets individually re-tested. If districts or schools strongly prefer to create pools comprised exclusively of staff, they are limited to a maximum of 5 swabs per staff-only pool and must have Abbott BinaxNOW tests available for immediate follow-up testing.
- All students and staff participating in the testing program should be tested once a week – no more and no less. Testing all students and staff once per week may require multiple testing days each week.

Protocols and Considerations for Follow-Up Testing using Abbott BinaxNOW:

- Abbott BinaxNOW rapid antigen tests are recommended for the purposes of follow-up testing on positive pools.
- In the case where positive pool results are returned when students are out of school (i.e., weekend or remote days in the hybrid model), asymptomatic pool members may return to the school or a follow-up testing site for the sole purpose of follow-up testing. In the event that not all members of a positive pool are able to receive follow up BinaxNOW tests (e.g. some are on vacation or otherwise absent), schools should proceed with normal follow-up testing protocol with the members of the positive pool that are present. If follow up testing with the BinaxNOW does not identify a positive from among the pool members available, all available members of that pool must be re-tested with a second BinaxNOW no sooner than the next day, but within 2 days. As in other cases, it is not necessary to quarantine/isolate until an individual has received a positive individual test result. Members of a positive pool who are not immediately available for follow up testing with the rest of their pool should receive follow up testing per normal protocol as

soon as it is possible to do so, or alternatively the individual(s) can pursue COVID-19 testing independently and relay test results to the school. A school can accept a negative result as adequate follow up testing.

- Symptomatic individuals should not return to school for any reason, including follow-up testing; instead they should stay home from school and notify the school. Symptomatic individuals should be directed to obtain follow-up testing either by BinaxNOW or PCR testing at a [community test site](#) or medical office.
- In the case of a positive pool where there are no positive cases identified by BinaxNOW upon follow-up testing, all members of the pool can remain in school. Individuals should be tested by another round of BinaxNOW test no sooner than the following day, or within 2 days after the initial negative result. If no positive individuals are identified with the second round of BinaxNOW, then the members of the pool will proceed to the next round of scheduled Pooled PCR testing. Pooled PCR testing is a form of surveillance and two rounds of negative BinaxNOW indicates that the viral load is not detectable, and therefore unlikely to be infectious. All members of the pool should be advised that if they become symptomatic at any point, they should stay home, and speak to a school administrator/nurse, and get COVID-19 testing at a [community testing location](#) or medical office.
- The Federal CDC guidance for opening outbreaks requires a PCR or a NAAT. A school needs 3 PCR/NAAT tests in 14 days from different households to open an outbreak. All positive antigen tests from the 14 days of the 3 PCR/NAAT are probable cases and are counted in the outbreak once it is opened. Antigen tests alone will not open an outbreak based on Federal CDC surveillance guidance. Therefore, we strongly encourage at least the first three positive antigen tests to be sent for confirmatory PCR testing. Schools should identify [places](#) to direct individuals for confirmatory PCR testing within 24-48 hours of the initial BinaxNOW test

