

Maine's K-12 Pooled PCR Testing Program: Frequently Asked Questions

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Program Eligibility

1. How do we apply to be part of the pooled testing program?

School Administrative Units (SAUs), as well as approved special education schools, and private schools should submit an [Authorized School Application](#) to be included in the pooled testing program. Once application materials are submitted, Maine Department of Health and Human Services (DHHS) and Department of Education (DOE) will connect the unit or school with the testing service provider. DHHS and DOE will review applications on a rolling basis. More information about the application, can be found on the Pooled Testing section of the [DOE COVID-19 Toolkit](#).

2. Which schools are eligible for this program?

SAUs or private schools, providing any type of in-person instruction, such as full-in person or hybrid instructional models or in-person services for high needs students, can participate in this initiative. In addition, SAUs and private schools that are currently in a remote instructional model but intend to use this program as an opportunity to return to in-person learning are also invited to participate. Public schools that offer PreK programs may include that population in the testing program. K-12 private schools are also able to participate in the program; however, private PreK programs are not able to participate currently. There is no minimum number of participants required at a school site.

3. Does the entire SAU or Private school need to participate?

SAUs and private schools are strongly encouraged to involve all students and staff in pooled testing, excluding any individuals who may opt out. However, SAUs and private schools may choose to launch this program with a smaller subset of schools, grades, students, or staff and scale up to a school-wide or unit-wide model at a future date. If SAUs and private schools choose to only involve staff in a pool, however, they are limited to a maximum of 5 individual staff samples per pool and must have BinaxNOW tests available for immediate Follow Up Testing.

4. If an SAU or Private school is not signed up for Abbott BinaxNOW, can they still participate?

Abbott BinaxNOW is required for follow-up testing on the individuals within positive pools and is a core component of the program. The state will cover the costs associated with using Abbott BinaxNOW for follow-up testing, including providing the tests to administer, the platform for reporting and if needed, and clinical and/or administrative support needed to administer the tests. SAUs not currently using Abbott BinaxNOW can obtain tests by following the guidance document and taking necessary steps required, including securing a CLIA Waiver, completing the online training modules and enrolling in REDCap, the online reporting platform. [DOE BinaxNOW Information](#).

5. Can staff and students be required to participate in pooled testing?

No. Participation in pooled testing is voluntary. Students who do not participate cannot be barred from in-person learning opportunities solely because they do not participate, however those not participating in the program who are identified as close contacts will need to quarantine and be out of school for that period of time.

6. If we have a SAU-run PreK program, are we able to include our PreK teachers and students in pooled testing?

Yes. All public-school staff and students, including public PreK teachers and students, can be included.

7. What staff are eligible to participate in the pooled testing program?

All SAU and private school employees or individuals employed by the organization are eligible to participate in the pooled testing program, including those that may already be vaccinated. Additionally, contracted staff such as bus drivers, are also eligible for participation. At this time, staff that work outside of the school are not eligible to participate.

8. Does an SAU or Private school need to have an electronic health record system to participate?

No, an SAU or private school does not need to have an electronic health record system to participate. The Pooled Testing Provider will provide all necessary technology platforms for Pooled PCR Testing and the state will provide access to REDCap to report all BinaxNOW Follow-Up Testing.

Program Costs and Vendors

9. Will the state cover courier costs? Yes. Funding will cover pooled testing processing services (e.g., test kits), transportation (e.g., courier and shipping costs), and additional logistical supports (e.g., specimen collection and site administration).

10. Is there funding available to cover the administration and record keeping associated with testing, or is funding just to pay for testing of pooled samples?

Funding does not currently cover pooled testing administration and record keeping by a school/unit employee. Funding from DHHS for pooled testing covers three areas:

- a. **Onsite specimen collection and testing coordination support:** Staff contracted through the vendor to assist with implementation, on-the-ground operations, and/or specimen collection (if requested and available).
- b. **Pooled testing processing services:** test kits for pooled testing, vendor administrative fees, and BinaxNOW follow-up tests.
- c. **Specimen transportation:** either courier or shipping from test collection site (e.g., school) to laboratory.

Program Validity

11. Is the Abbott BinaxNOW accurate enough to be used as a follow up to the pooled test, especially for asymptomatic children?

Yes. The Maine Center for Disease Control (ME CDC) endorses its use in follow-up testing. No test is 100% accurate. BinaxNOW tests are effective at picking up those individuals with high viral loads (assumed to be most infectious) and are adequate for this purpose. Anyone who develops symptoms consistent with COVID-19 should get tested, even if they have recently received a negative result.

12. Is pooled testing an effective strategy in areas where COVID prevalence is high?

Yes. Pooled testing is an effective tool to identify positive cases without the logistical and financial burden of regular individual testing. In communities with high COVID prevalence, which is defined for schools in Maine as color coded yellow or red, it is strongly suggested that SAUs and private

schools start with pools smaller than 10 to minimize the number of positive pools returned.

13. Is pooled testing an effective strategy in areas with low transmission rates?

Yes. Pooled testing is an effective strategy in areas with low transmission. With lower COVID-19 rates, there may be fewer follow-up tests. This can increase staff and community confidence in returning to school while incurring much lower costs than individual testing.

14. How has the state reviewed the laboratories used in the Pooled Testing Program?

All laboratories allowed to process samples under the state-contracted Pooled Testing Providers have undergone a technical review of their pooling strategy and supplementary data by the ME CDC, DHHS, and DOE.

15. Does the state allow different standards for test performance (sensitivity) for surveillance testing versus diagnostic testing?

It would not be the state's intention to purposefully accept a lower sensitivity for surveillance tests versus diagnostic tests. Rather, our shared goal is to select tests that are sensitive and specific enough to identify cases within the testing algorithm(s) of this program.

Testing Process Coordination

16. How many staff are needed to carry out the collection and processing of tests?

In most cases, DHHS expects that pooled testing can be conducted with existing staff, although pooled testing providers are able to coordinate additional staff to help implement the program and collect samples as part of Level II services (funded by the state, if needed and available). SAUs and private schools are welcome to collaborate with neighboring schools to share services or coordinate specific tasks. If additional staff are requested, this may delay the start of pool testing in an SAU or private school.

17. Who administers the Abbott BinaxNOW tests and Pooled Tests?

The Emergency Use Authorization (EUA) received for the Abbott BinaxNOW test allows it to be administered by a variety of trained professionals, including, though not limited to, school nurses.

All staff administering Abbott BinaxNOW test kits within a school or unit must complete all Abbott BinaxNOW training modules. The Abbott BinaxNOW training modules can be found [here](#). These modules provide a detailed step-by-step guide to the test process. The modules should be completed in their entirety prior to staff performing test on individuals.

Similarly, pooled testing is administered at the school level either by trained school staff, including, though not limited to, school nurses, or onsite test specimen collectors. For staff and for students in grades 2 and up, the test may be conducted by self-collection and observed by trained staff. There are instances of children younger than second grade who are able to self-collect; however, this is following a period of instruction and hand-over-hand guidance. The Pooled Testing Services Providers will provide the training for staff administering or observing specimen collection.

18. What is needed to transport tests to the lab?

Samples are transported by FedEx to the laboratory for processing. In instances where FedEx cannot meet the required shipping timeline, a courier will be arranged to transport the samples to the laboratory. There is no risk in transmission while transporting test samples as all samples are sealed.

There are no complex requirements for transportation, such as refrigeration.

19. How long will it take to receive pooled test results?

In almost all cases, it will take 24-48 hours to received pooled test results. As a reminder, staff and students do not need to quarantine while awaiting pooled test results and should be in school unless they become symptomatic.

20. Should SAUs and Private schools participating in Maine’s pooled testing program provide accommodations for students with disabilities who opt-in to the program?

Yes. SAUs and private schools participating in the pooled testing program must ensure that students with disabilities are provided an equal opportunity to participate in a pool and to benefit from the services offered. Some of these students will need accommodations to participate effectively in the testing program. Participating SAUs and private schools must ensure that personnel responsible for implementation of the on-site testing are provided training necessary to accommodate students with disabilities. They should work with the pooled service testing provider to provide social stories, video preparation, visual aids, imitative models, scripts, desensitization, appropriate reinforcers, administration of the test with a staff member familiar with the student, and/or other accommodations and supports necessary to ensure equitable opportunities to participate. Parents/guardians of students with disabilities, as all students, should be informed that for any reason they may opt-out of the voluntary testing program or revoke consent at any time

Testing Strategy

21. What test pool sizes, composition, and frequency are recommended?

Appropriate pool size should be determined by several factors including vendor and community/school prevalence. 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, such as schools in counties categorized as yellow or red, or schools who are seeing a high share of positive pools in previous weeks, should lower their pool size to 10 or fewer. The pool size should not be lower than 5.

It is highly recommended for health, as well as administrative reasons, that “membership” within a given pool remain as constant as possible. Teachers, where possible, should be pooled with their students (as a positive pooled result on a pool full of teachers may cause staffing issues while all teachers in the pool are individually re-tested). If SAUs or schools choose to only involve staff in a pool, however, they are limited to a maximum of 5 tests per pool and must have BinaxNOW tests available for immediate follow up testing.

Pool testing should be done on individuals once per week.

22. Should individuals who have previously tested positive for COVID-19 be included in pools? No, individuals who have previously tested positive (on an individual, not pooled, test) in the past 90 days should be excluded. After 90 days, they should be included again in the pools.

23. Should vaccinated staff participate in pooled testing?

We encourage teachers and staff to participate in the testing even if they have already been fully vaccinated, though it is not required. There are several reasons why vaccinated staff should participate in pooled testing, including:

- While each vaccine authorized by the FDA is effective at preventing symptomatic infection, no vaccine is 100% effective. Vaccinated individuals may still get COVID-19 and transmit it to others.
- Evidence suggests that fully vaccinated people are less likely to have asymptomatic infection and potentially less likely to transmit SARS-CoV-2 to others, but further investigation is ongoing.
- Teachers can model good practices for students to encourage participation.

24. If a fully vaccinated individual is part of a positive pool, do they need to have a negative test before returning to school/work?

No. As with all individuals in a positive pool, a fully vaccinated individual who is part of a positive pool should follow DHHS/DOE's recommended protocols, which includes receiving a follow-up/reflex test (either BinaxNOW) but it is not necessary for that person to stay out of work (i.e., quarantine) before taking the follow up test.

Testing Operations

25. How will training be conducted?

The Pooled Testing Provider will provide training to staff to administer tests as well as how to observe sample collection. This training will also include information on how to track samples in each pool, use the software, and deliver samples to the laboratory.

26. Can tests be given at home?

At this time, the pooled testing options associated with this initiative cannot be conducted at home. Pooled tests should occur in school and be administered or supervised by trained staff.

27. Do students and staff need to quarantine until the pool test results are returned?

Pooled testing provides surveillance testing capabilities to schools, meaning that students and staff participating in the pooled PCR testing program do not have to quarantine if they have been identified as a close contact. These individuals should remain in school and continue to participate in the weekly pooled PCR testing program. However, any unvaccinated student or staff member not participating in pooled PCR testing Program or unwilling to get follow-up BinaxNOW testing as part of a positive pool and identified as a close contact of a confirmed case will need to quarantine for 10 days.

28. Do individuals in a positive pool need to quarantine while they are waiting for individual-level results to return?

No. Students who are part of a positive pool do not need to quarantine while they await their follow-up test results, unless they are symptomatic. It is possible that individuals that had COVID-19 (knowingly or unknowingly) but are no longer contagious will cause some pooled tests to come back positive, and every test has a chance of false positives. Symptomatic students should not attend school and follow the school's procedure. If not symptomatic, individuals in a positive pool will return to school for follow-up testing. Individuals who receive positive follow-up individual test results will need to be isolated as defined in the Standard Operating Procedure [Investigating Positive Cases for COVID-19 in Schools](#).

29. What PPE is required for staff administering or observing tests?

Anterior nasal swabs are not considered to be aerosol generating procedures, but PPE is recommended for people administering or observing the tests simply because they have to be so close to the individual being tested. 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.

30. What are the options if BinaxNOW tests for positive pool members are all negative?

All negative BinaxNOW tests likely indicate an individual of lower viral load that is less likely to be infectious. If this occurs, schools will conduct a second BinaxNOW test on all individuals no sooner than the next day, but within 2 days. If those tests are all negative, then the school would proceed with the next round of scheduled pooled PCR testing.

31. What follow-up test options exist for students or staff who live far away from school?

If a student or staff member is in a positive pool, they should return to school as normal to receive follow-up testing. These individuals do not have to quarantine and can ride on buses or take their normal transportation method to school if they are not symptomatic. Symptomatic individuals should follow the guidance outlined in the [Standard Operating Procedure Investigating Positive Cases for COVID-19 in Schools](#). The hope is that this will largely eliminate any difficulties or costs associated with individuals being out of school when a positive pool is identified, as Follow-Up Testing results can be immediately delivered with Abbott BinaxNOW testing.

32. What if I can't conduct follow up testing on every member of a Positive pool?

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.

33. Can BinaxNOW tests be run outside?

BinaxNOW tests cannot be accurately run if the swab or kit is outside of the 59-86-degree range (Fahrenheit). However, the swab can be gathered in colder or warmer temperatures and run once the parts of the test are within that temperature range. When ordering BinaxNOW tests, SAUs and private schools may order additional vials to transport swabs that are collected outside of the temperature range.

34. Who should provide the standing order for Abbott BinaxNOW Follow-Up Testing in schools?

A provider standing order is required for individual Abbott BinaxNOW testing, and any follow up PCR tests administered onsite. 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.

35. If we use Abbott BinaxNOW for follow-up testing, can we also use it for symptomatic testing?

Yes. Schools may find guidance on the use of BinaxNOW in the school setting [here](#), as well instructions for obtaining consent for symptomatic BinaxNOW testing and ordering additional BinaxNOW tests [here](#). The [sample consent form for BinaxNOW](#) has been updated to include all uses approved for the K-12 setting. Please note, this consent form does not include consent for pooled PCR testing.

36. Is there a statewide CLIA waiver to cover Abbott BinaxNOW testing in the K-12 environment?

No. However, schools and SAUs are now eligible to apply for a CLIA Certificate of Waiver. 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](#) or refer to the [DOE CLIA Waiver Instructions](#).

37. Do you have to reapply for the CLIA waiver if you’ve already gotten a waiver and have been approved for BinaxNOW?

No. If you have already been applied for a CLIA waiver, you do not have to reapply.

38. If Abbott BinaxNOW is used for follow-up testing, will the Abbott BinaxNOW tests continue to be provided free to schools for other use cases as outlined in the ME DHHS BinaxNOW Testing Guidance for Schools?

Yes. The state intends to provide the Abbott BinaxNOW tests for follow-up testing and any of the other approved use cases as outlined in guidance. This is dependent on sufficient supply from Abbott, but currently the state does not foresee any supply constraints.

39. If a school enrolls in this testing program and uses Abbott BinaxNOW for follow-up testing, can they also use them for symptomatic testing if they had not previously signed up for the existing Abbott BinaxNOW DHHS program for children/staff who become symptomatic in school?

Yes. Schools and SAUs can use the Abbott BinaxNOW for either or both purposes (symptomatic testing and follow-up testing for positive pools).

40. Does the state have a required turn-around time for Pooled Testing Program results for vendors who are participating in the pooled testing?

Yes. The Testing Service Provider will be required to deliver pooled testing results to the school by 4:00PM (local time, Augusta, Maine) two calendar days from the date the samples were picked up for shipment from the Authorized School by FedEx or courier. Many times, results will be returned in

approximately 24 hours.

41. Should household members of individuals in a positive pool be considered “possibly exposed” while waiting for follow-up testing to be completed?

No. Members of a positive pool do not have to quarantine prior to receiving the results of their follow-up tests, unless they are symptomatic. Similarly, household contacts of individuals in a positive pool do not need to quarantine, unless the individual is confirmed to have COVID-19 through follow-up testing. Individuals or close contacts of individuals who do receive a positive follow-up test result should follow the [Standard Operating Procedure Investigating Positive Cases for COVID-19 in Schools](#).

42. Can DHHS provide or facilitate N95 respirator fit testing for school nurses?

Annual fit testing is a routine part of using N95 respirators and can be performed by many occupational health providers. During the public health emergency, and with the wide variety of N95 respirators in use, it is not always possible to perform fit testing. Nurses and health care staff are encouraged to conduct a user seal check to determine if the respirator is being properly worn and should be performed with each use. The user seal check procedure is described here: <https://www.cdc.gov/niosh/docs/2018-130/pdfs/2018-130.pdf>

43. For a COVID-19 positive individual, should the pooled test or follow-up test be used to determine the start of the infectious period?

If an asymptomatic individual tests positive for COVID-19, the infectious period is considered to begin 2 days prior to the collection of their positive test. The date of the pooled test should be used to determine the infectious period.

Program Reporting

44. Will positive follow up BinaxNOW tests count toward the state confirmed counts if they are not PCR tested?

Yes. The BinaxNOW test results do count in the total case numbers for Maine. They are counted as probable cases. However, as a reminder, 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.

45. Should SAUs and Private schools report the number of individuals in negative pools to improve the accuracy of the “percent positivity” metrics for each community?

No. At this time, DHHS does not require results of pooled surveillance tests to be reported to the department. Only the individual-level follow-up tests (diagnostic) are required to be reported to the state – all positive, negative, and inconclusive.

46. What if a pool comes back with an “Unusable” or “Indeterminate” result?

An “Invalid” result could mean several different things, ranging from collection errors (e.g. swabs inserted upside-down) to a one-time error at the laboratory. An “Inconclusive” result means that there was an extremely small amount of virus detected by one of the probes at the laboratory but not enough to consider the pool positive. An “unusable” result means that the sample could not be tested

because of a broken tube, inverted swab, or not within the 5-25 swab range. DHHS recommends re-testing as soon as possible in either case - either by re-pooling immediately or by follow up testing the members of the pool individually, according to what is preferable or more viable for your school.

47. Do families need to complete consent forms each week a pooled test is conducted?

No. Staff and parent/guardian consent forms only need to be completed once a year for participation in the program. These forms must provide consent to participate in pooled testing consent for any necessary follow up tests, including administering and reporting Abbott BinaxNOW tests.