

Even as we receive encouraging news of vaccine progress, we face the grim reality of continued outbreaks and shutdowns this winter and spring while we wait for widespread vaccination. Frequent testing will be needed to continue to monitor the prevalence of COVID-19 and break chains of transmission for months after a vaccine is introduced.

The closing of K12 schools has been a particular pain point for communities across the country. Despite heroic efforts to enable in-person learning, schools have faced repeated cycles of reopenings, outbreaks, and closures. Various techniques to test teachers or students have been utilized alongside social distancing and sanitation measures, but costs have been prohibitive, preventing most schools from being able to implement routine testing despite well established benefits of using testing to detect asymptomatic and pre-symptomatic cases. With recent advances in testing options, weekly testing for all students, teachers, and staff could now be possible, and can empower schools with data to support their reopening and complement other mitigation strategies.

K12 testing needs

Routine testing is a <u>highly effective</u> tool in preventing and controlling outbreaks. During the fall semester, many colleges and universities across the country used routine, twice-weekly testing of students and staff, keeping outbreaks at bay and positivity rates well below 1%. In order for K12 schools to also realize these benefits from testing, practical, sustainable testing strategies must meet several requirements.

Cost

• First, testing must be affordable. The majority of molecular tests such as PCR currently available charge insurers or governments upwards of \$100 per test, a number that would devastate school budgets if multiplied across all students and teachers each week. More affordable options, including lab tests as low as \$6 and antigen tests as low as \$15, that are becoming widely available are far more practical.

Logistics

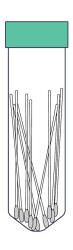
Second, testing must be accessible. Testing must be easy for schools to administer across
different age groups and abilities and not present technical or logistical challenges. Logistics,
oversight requirements, and training must be straightforward and as simple as possible.
Plans, results, and public health guidance must be well vetted and well communicated to
administrators, teachers, families, and students.

Scale

• Finally, testing must be scalable. School nurses or other administrators must be able to easily handle tests for hundreds of individuals per day. Laboratories across the country must be able to support the demand nationwide K12 testing will produce.

Pooling makes it possible

Given the enormous challenges of scaling affordable testing capacity and enabling logistics of in-school testing, the only way to implement widespread testing in K12 schools nationwide is through classroom pooling.



Classroom pooling (also sometimes referred to as source pooling or swab pooling) is a method of molecular testing (e.g. PCR) that combines many individual tests together at the school into one tube that is run together as a single test. This method can provide affordable and logistically simple options for routine testing in schools. Unlike lab pooling, where samples are diluted when they are mixed together at the lab, classroom pooling makes it possible for every student in a classroom to be tested together, from 5 to 25 swabs.

As a public health tool, classroom pooling can provide valuable data for school decision making. In younger grades especially, where students typically remain in the same classroom and interact only with members of their classroom cohort, knowing

of any positive cases at a classroom level can inform action to help prevent further spread. For the same reason, teachers could also be included in the student pools in these grades, while in higher grades it may be preferable to test them separately. Public health testing should not be used for individual clinical decision making. However, public health officials can use this information to recommend follow up action, including quarantine or follow up testing with diagnostic PCR or rapid antigen tests.

How classroom pooling works:

- 1. Lower nasal (anterior nares) swabs can be collected from every student in a given classroom into a single large tube by a school nurse or other test administrator. Kids as young as first grade have been able to successfully self-administer the swab with observation by a testing administrator in our early pilots; younger children can be swabbed by a nurse.
- 2. This tube is then sent to the lab and all the swabs tested together in a single test. This method does not report individual test results—a positive result in a pooled sample indicates that there is at least one case in the classroom.
- 3. Because a fixed volume of liquid is added to the swabs together (as opposed to media pooling, which mixes liquid from individual samples in the lab), classroom pooling retains most of the sensitivity of an individual test while dramatically reducing costs and increasing throughput. We estimate that pooling could enable per-person costs of \$6 or less.





4. Students from classrooms with positive pool results can be individually tested using \$15 rapid antigen such as the Abbott BinaxNOW or other individual testing options (e.g. local clinics, testing sites, or vendors providing testing options).

Feasibility

Cost

• Using the estimate of \$6 per student, testing all 53 million K12 students in the US once per week through pooled molecular testing with 25 students per pool would cost \$318M per week. Given today's high daily incidence rates, up to 5% of pools could be expected to have a positive case. Using \$15 rapid antigen tests to test all individuals in positive pools would cost an additional \$40M per week. Over a 16 week semester, pooled molecular testing and LFA reflex testing of positive pools would cost a total of \$5.7B nationwide.

Logistics

• Testing all K12 students across the country will require testing to be set up in each of the 13,000 US school districts. Each of these will need to receive documentation, training, kits, and access to a portal to track tests and receive results. Using one tube per class dramatically reduces strain on supply chains, simplifies logistics, and streamlines the onsite testing process. During pilot studies, it was possible for a teacher to observe several students at a time as they self-administered swabs and placed them into the sample collection tube. Repeating this process for a whole class took about 12 minutes.

Scale

• Using pooled molecular testing with 25 individuals per pool, testing all students once per week would require 510,000 pooled molecular tests and 25,000 rapid antigen tests per day. Current national capacity is approximately 3.3 million laboratory molecular tests and 3.1 million rapid antigen tests per day. This means the capacity to test every single K12 student already exists and can be activated through classroom pooling.

Any lab that is currently processing molecular tests for SARS-CoV-2 can be validated to run these pooled tests according to <u>FDA guidelines</u> for source or swab pooling, so school districts can partner with the lab provider closest to them without the need to create new laboratory infrastructure.

Routine nationwide K12 testing thus can be facilitated through the development of a coordinated network of laboratories. Many laboratories currently running molecular tests will be able to perform the intermediate step of transferring the pooled sample from the large tube themselves, while others will require a different lab to do this step for them. Testing capacity is unevenly spread across the country, with far fewer laboratories in rural areas. A network that coordinates between private sector, academic, and public laboratories to bridge these gaps would be highly impactful.

Case studies

Several pilot studies of classroom pooling methods have been run by different labs and organizations, including Concentric by Ginkgo. In December, we ran a pilot classroom testing program that included schools in Massachusetts, Louisiana, and Rhode Island to validate the operational logistics of testing inside schools using this model. Of note, pilots in Louisiana and Rhode Island were conducted entirely remotely; Ginkgo employees trained schools to run the program without having to be on site.

Salem, Massachusetts:

Sixth and eighth grade classrooms at Collins Middle School enrolled in the pilot. Parents were briefed and their concerns were addressed before they provided consent for each student. In each classroom, students self-swabbed with lower nasal swabs and deposited their swab into a single collection tube. Turnaround time for test results was between two and three days after the samples reached the lab, and we continue to work with a network of labs to further decrease turnaround time for pooled test results.

• Administrator's feedback:

"The Ginkgo student-administered COVID testing is an easy process for my scholars. [Our] Middle School and Ginkgo were able to collaborate to roll out an engaging orientation for our scholars. As the partnership grows and we reflect on this process we will have our scholars learn and be an active participant in the community fight of the spread of COVID-19."- Matt Condon, Principal

• Teacher's feedback:

"I think it's such a quick process that I would love to see it continue on in the next few months because we don't really know and can't really control things that are happening outside of our building. So as the process continues, I think, as students continue to get tested, we can be more proactive about what is happening and what we can control to make sure that everyone's as safe as possible." - Victoria Tran, 6th Grade ELA Teacher

• Student's feedback:

When asked: "now that you've seen your classmate do this, will you take part in this process next time?" The majority of students raised their hands and said yes.

"The test was not bad at all. It just tickles." -6th grader

Opportunities

As vaccines are deployed, routine testing will still be essential to keeping schools open and preventing unnecessary spread. Deploying such a system supports in-person education, which has massive benefits for students, families, and the broader economy. Testing programs at this level can also contribute to community-wide public health, providing information about infection rates in a large segment of the population. Classroom pooling makes this possible with low costs, feasible logistics, and massive scale.