

Connecting schools with the nation's leading testing companies to safely reopen

*Last updated on 4/19/2021* 







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### **CONTEXT**

The K-12 National Testing Action Program (NTAP) is a plan to provide free Covid-19 testing for K-12 public schools to enable safe in-person learning



#### **Situation**

- Due to Covid-19, a majority of US K-12 public schools are operating remotely or in hybrid learning
- Online learning is not an adequate replacement for in-person school and is creating large education and socialization gaps



#### **Complication**

- Teachers, students and communities may fear the spread of Covid-19 in schools
- Schools are not fully equipped to provide necessary mitigation measures including testing
- While testing capacity exists, labs do not have a clear signal on how to make capacity readily available to schools
- The value of testing is getting lost amid the focus on vaccination



#### Question

- How do we safely and sustainably re-open the nation's K-12 public schools as quickly as possible?
- How do we make testing free, easy and widely available for schools?



#### **Answer**

- **1. Mitigation** Implement full safety and mitigation activities
- **2. Vaccination** Encourage as many vaccinations as possible
- **3. Confirmation** Use regular testing to provide information and confidence that other measures are working

# K-12 NATIONAL TESTING ACTION PROGRAM (NTAP) SUMMARY (1 OF 2)

#### The school changes stemming from the Covid-19 pandemic have significant impacts:

- Student learning, as well as mental and physical health, particularly for underserved populations
- Parent economic security, particularly for women
- Teacher well-being, including where they focus their money, time, and mental health
- The national economy, including billions of dollars of projected losses

#### K-12 testing programs can help reopen schools:

- Testing programs work to quickly identify positive cases for isolation, keeping school infection rates well below their local community. Schools are the safest place for kids and adults and are safer than the grocery store
- Logistics are feasible for public schools, both large and small. Testing protocols become second nature within weeks
- Testing dramatically increases confidence in re-opening for teachers and parents. We have seen confidence grow from about 20% to over 80%
- Federal actions provide funding & demonstrate the importance of testing as the "missing link" to re-open schools and get all students back for in-person learning

#### Re-opening schools safely this spring requires:

- 1. Safety and mitigation measures (masking, distancing, cohorting, etc.)
- 2. Teacher and staff vaccination
- 3. Regular and reliable testing of students and adults



# K-12 NATIONAL TESTING ACTION PROGRAM (NTAP) SUMMARY (2 OF 2)

#### Testing protocols are critical to program success:

- Step 1 PCR (pooling or individual) or antigen (point of care or central lab) tests with either anterior nasal swabs or saliva
  - Screening testing frequency is often once per week for students and up to twice per week for teachers and staff
- Step 2 Follow-up diagnostic PCR or antigen tests for individuals in positive pools
- Optional but recommended Step 0 Test all participants as program begins

#### NTAP implementation and logistics requires diligent planning and partnership:

- Labs provide lab testing and logistics (including information systems) to schools and parents
  - Capacity for schools must be guaranteed and must not be reduced
  - School testing capacity must not reduce testing capacity or increase Turn Around Time for the general public
- All results must be returned to schools and test takers in 24 hours or fewer
- Costs for tests and additional test-related costs at each school are reimbursed by the state from their allocation of the \$10 billion federal allocation of the American Rescue Plan Act for school testing

#### K-12 NTAP compilation team includes:

- Representatives from the nation's largest labs and test manufacturers with deep experience in Covid-19 testing for schools
- Representatives from the world's largest lab supply manufacturers with deep experience in manufacturing and distribution
- Representatives from information service providers
- In addition, the team met with school superintendents, principals, teachers and parents to inform the plan FOUNDATION



### FOUNDING PARTNER ACKNOWLEDGEMENTS















































## **IMPACT OF SCHOOL CHANGES ON STUDENTS**

#### Impact on learning:

- 25% decrease in post-educational learning potential among ninth graders in poorest communities
- Returning students expected to have only 63-68% and 37-50% annual learning gains in reading and math respectively

#### Food insecurity and mental health:

- 169.6M school meals missed weekly impacting student nutrition & food security
- 24% increase in emergency department visits related to mental health for children aged 5-11 and 31% increase among adolescents aged 12-17

Minority Populations



In Washington D.C., the number of Black and Latino children who met literacy benchmarks dropped by 12-14% compared to white students, whose numbers dropped by 6%



Black and Latino students could experience learning losses equivalent to 9-10 months as a result of the pandemic

## **IMPACT OF SCHOOL CHANGES ON PARENTS**





do not have access to regular caregivers, and their return to work is dependent on in-person schooling for their children



4 in 10 parents

say they have less job security due to the pandemic and fear being penalized because they have childcare responsibilities



4x more women

compared to men left the workforce as the new school year began due to students at home

## **IMPACT OF SCHOOL CHANGES ON TEACHERS**



#### 3 in 4 teachers

are working more hours during Covid-19 than before; of these, nearly one in 5 were working more than 15 hours more per week during Covid-19



#### 3 in 4 teachers

report their school or district does not provide adequate access to counselors and mental health support for both students and teachers



#### 9 in 10 teachers

felt their expertise was not appropriately tapped by decisionmakers in the transition to distance and hybrid learning; nearly half of these expert teachers said their expertise was not tapped at all



#### 1 in 3 teachers

report spending more out-ofpocket money teaching under Covid-19 than before; onequarter are spending more than \$500 more than before

### IMPACT OF SCHOOL CHANGES ON ECONOMY



#### \$2.5 trillion

estimated **cost in future earnings** in the US of four months of lost education – equivalent to 12.7% annual GDP



### \$350 billion

of **lost revenue** and growth could be reversed with the opening of schools, according to some estimates



#### 13.8 million

Years of Life Lost (YLL) may be associated with the school closures during the Covid-19 pandemic



### \$64.5 billion per year

in **lost wages** and economic activity from women leaving the labor force and/or reducing working hours to assume caretaking responsibilities

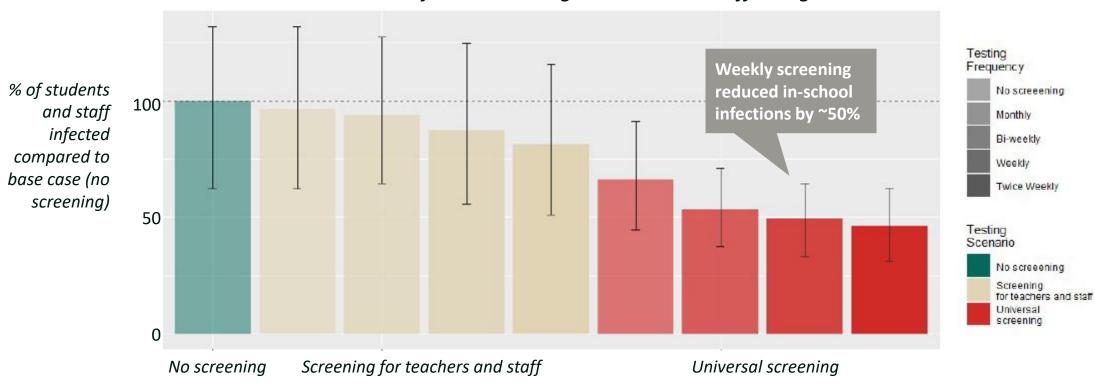
## SUCCESSFUL PROGRAMS: TESTING WORKS TO KEEP SCHOOLS SAFER



## REGULAR TESTING IN SCHOOLS CAN REDUCE INFECTION

Evidence from Mathematica, supported by The Rockefeller Foundation, found that weekly testing of all students, teachers and staff can reduce in-school infections by an estimated 50%

#### Cumulative COVID-19 infections among students and staff in high schools



## SCHOOL PREVALENCE RATES ARE 10X LOWER THAN COMMUNITY RATES

Aggregate data across multiple schools and their contiguous communities shows average school positivity is 0.25% to 0.5% while surrounding community positivity is ~ 7.23%\*



0.53%
positivity
rate in K-12
schools

5.60% positivity rate in community



0.5% 4%positivityrate among rate acrossteachers the state

CDC and others support a return to in-person schooling, citing low prevalence rate in schools as a key part of the justification

Disclaimer: It is important to note that community testing is an opt-in process, and the actual community positivity may be different \*Calculated by aggregating data collected by Ginkgo, CiC Health and JCM Analytics

## TESTING BRINGS STUDENT, PARENT AND TEACHER CONFIDENCE

"I feel more safe now knowing solid facts about who has it and that the people who have it are not at school. So, it's keeping everything safer." - Parent

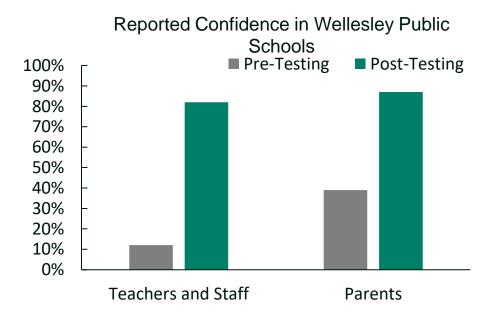
Participants strongly supported the use of testing to confidently return to in-person learning



**UNITEDHEALTH GROUP** 

SURVEY RESULTS (% agree/strongly agree)	Parents	Students	Staff
Testing students, staff and teachers on a regular basis is important to ensure that school can remain open and the WIS community can be as safe as possible	91.8	95.1	92.6
Post-launch: I am open to being part of a pooled testing protocol once or twice a week, with an individual confirmatory test required if the pool is positive	90.3	93.4	98.8
I feel that students or teachers who refuse to be tested individually or as part of a pool on a frequent basis should not be allowed to attend in person classes	80.4	83.13	74.1

Baseline testing increased confidence of safety of in-person learning



## **SUCCESSFUL K-12 TESTING:** MASSACHUSETTS SCHOOLS (1 OF 2)

#### **Program overview:**

- Weekly testing for every classroom across the state (900K+ students)
- Students and staff self-swab with a lower nasal swab
- 10+ swabs pooled together and run using an accurate molecular test
- Samples processes at local and regional labs
- Follow-up testing for individuals in positive pools using Abbot BinaxNOW

#### **Initial data:**

154

school districts have rolled out testing



940 or 50% of public schools participating



~13,000 tests in first week of testing



### THE Massachusetts Program



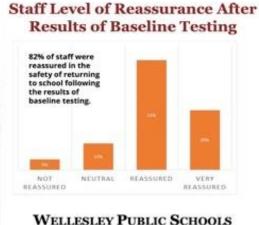
The Boston Blobe

Baker announces coronavirus pool testing to be made available to all Massachusetts public schools



By James Vainis Globe Staff, Updated January 8, 2021, 133 p.m.





#### **Boston Herald**

Massachusetts teachers unions laud Charlie Baker's new coronavirus pool testing program for schools





# **SUCCESSFUL K-12 TESTING:** MASSACHUSETTS SCHOOLS (2 OF 2)

Pooled testing in Massachusetts, a collaborative effort between the Massachusetts Department of Public Health and the Department of Elementary and Secondary Education with implementation support from the Shah Family Foundation, is the first statewide pooled testing effort to offer weekly testing to all students, teachers and staff in public schools. The program launched in January and schools are already testing students

#### **Pooled testing offering:**

- The tests are front-end or onsite pooling of swabs where roughly 10 swabs are put into one tube and sent to the lab for less than \$5/swab
- Rapid antigen tests are provided free to schools to do follow-up tests of positive pools
- Vendors also provide individual PCR tests for follow-up testing for \$26.50-\$85
- The state is paying for the first phase of the program through March 28 for any interested district. To continue programs, districts may use other federal funds

#### **Operationalizing school testing:**

- Most schools are administering the program themselves using nurses and other school staff to administer program and observe tests
- Some larger school districts are contracting with ambulance companies or bringing in nursing students to help with program administration

#### **Key partners:**





Implementation support



- More districts, including more urban districts, are returning to inperson learning with testing
- Early data indicate that positivity rates in schools are lower than community rates
- Pooled testing is more doable & manageable than some might realize – it is very possible to implement the initiative within all kinds of districts
- It's essential for the state to establish critical components of this
  initiative including funding, a state contract list, and regulatory
  enablement but districts need to have the ability to adapt the
  model to reflect the strengths & challenges of local contexts
- It's very important to aggregate resources, examples and tools to streamline the process for everyone (e.g., common consent form in multiple languages, Covid Ed Testing website)
- High quality parent engagement is crucial
- It is vital to have good vendor and inter-governmental partners

### **SUCCESSFUL K-12 TESTING:** NYC PUBLIC SCHOOLS

In September, BioReference embarked on a journey in collaboration with New York City Health and Hospitals to bring school back and help keep teachers and students safe throughout the school year



64 BioReference teams in the field

**200** Schools per day

**1200** Total schools

TAT <38 hours

209,790 students and staff tested to date

.47% positivity























- -Turn-key operation that includes a pre-accessioning process, onboarding, training, scheduling, consent, collection and timely TAT
- -PCR lab-based testing
- -Multiple daily communications with city and school command center
- -Minimal disruptions in schools including normalizing testing for younger students
- -Daily analytics of results



## **SUCCESSFUL K-12 TESTING:** DISTRICT OF COLUMBIA SCHOOLS

#### **Current status:**

All students and staff tested weekly



**7.3 people** in the average pool





Over 605 samples from students and staff tested each event



**2 positive pools** (1 faculty, 1 kindergarten) to date



#### **Key learnings**

- Pooling in a pod is the most cost-effective and sustainable method for testing
- Staff and older students can self-swab
- Transparent communication to parents, staff and students about importance of testing (in multiple languages) is critical
- Pooling-specific, cloud-based information management system should be used to effectively track data
- Clear standard operating procedures and setting up a governance structure is critical for success
- A list of FAQs should be created and updated as necessary to address staff and family concerns

**UNITEDHEALTH GROUP** 

### **SUCCESSFUL K-12 TESTING: BALTIMORE CITY SCHOOLS**

Baltimore City Schools have been utilizing weekly testing with different systems for elementary, middle and high schools





Baltimore City Schools To Offer Weekly COVID-19 Testing For Students, Staff

By Kelsey Kushner February 24, 2021 at 11:15 pm

Filed Under: Baltimore, Baltimore City Public Schools, Baltimore News, Coronavirus Outbreak in Maryland: WJZ Complete Coverage, COVID



#### Baltimore City Schools re-open with voluntary inperson learning

by Rachel Aragon | Monday, March 1st 2021

#### **Current status:**

- ~10K students and staff tested
- **750**+ pools
- 78 schools (soon to be 110)

#### **Elementary and middle schools:**

- Students and staff self-collect with lower nasal swabs
- 5-25 individuals pooled together
- Samples processed at local or regional lab
- Results ~24 hours from when samples arrive at the lab
- If a positive result, classrooms will quarantine for 2 weeks and follow up with individual PCR tests

#### **Common characteristics:**

- Weekly testing
- Parent consent is required for inperson learning, which includes Covid-19 screening/testing

#### High schools:

- Students and staff self-collect individual saliva samples
- Samples processed at a mobile lab in DC
- Results ~8 hrs from when samples arrive at the lab
- Individuals and close contacts will quarantine for 2 weeks if a positive result

## SUCCESSFUL K-12 TESTING: ORONO DISTRICT, MINNESOTA

3,065 students and staff



Average test results within 12 hours



1,000 SalivaDirect tests/week



Average test price: \$20



- Saliva Direct is working with Orono school district. Low test price has allowed the district to test a larger number of faculty and parents
- Even with testing just once per week, the sensitivity of PCR test has enabled multiple infections to be detected prior to symptom onset, likely preventing further spread
- Fast test turnaround time enabled the school district to remain open daily for in-person learning, even when the state was experiencing a surge in cases
- Conversely, other test strategies, which required tests to be mailed, were unable to prevent outbreaks, nearly leading to a cancellation of school sports



### **SUCCESSFUL K-12 TESTING:** DELAWARE PUBLIC SCHOOLS

School testing in Delaware, a collaborative effort between the Delaware Health and Social Services and Department of Education, has successfully demonstrated a scalable, in-person, low-resource program utilizing BD antigen tests. This program started in a handful of public charter schools and has quickly expanded across the state with buy-in from parents, staff and administrators



#### **Current status:**

**75+** public schools participating

**33%** of schools in Delaware

**5,000+** students and staff tested

#### **Easy to implement:**

- Flexible program implemented by school staff. Estimated need for 2-3 FTE / 1,000 people
- Automated results reporting expected to simplify workflow further

#### **Return to school:**

- Positive cases have been identified without impacting school opening
- Schools see parents switching back from virtual to in-person education





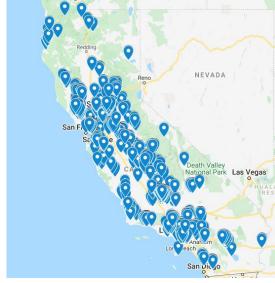


- Prioritizing **communication** to all stakeholders throughout the process is key
- Students can be introduced to swabbing in a drivethrough environment with parents nearby
- Focusing on logistics is crucial. Walk-up service may work well for older students, while classroom service may fit for cohorted and youngest students
- **Self-swabbing** under observation with oldest students improves throughput and logistics
- Clear guidance on obtaining consent and addressing legal requirements early is critical
- Continuous feedback from all stakeholders can make the program sustainable
- Objective assessment of test results minimizes staff confusion and improve logistics
- Reporting and documentation is a significant resource challenge. Automating reporting may save 2 FTE time

## **SUCCESSFUL K-12 TESTING: CALIFORNIA SCHOOLS**

A collaboration between Color and Perkin Elmer to provide access to high-quality, fast PCR testing for public and private schools throughout California started with a focus on testing staff and has expanded to include students and student athletes. The program led by the California Department of Public Health has supported statewide onboarding for all school districts and standardized a scalable model across diverse populations





Map of CA K-12 schools testing

10,000+

Schools eligible for program

1,600+

**School staff trained** 

50,000+

K12 tests in less than 6 weeks

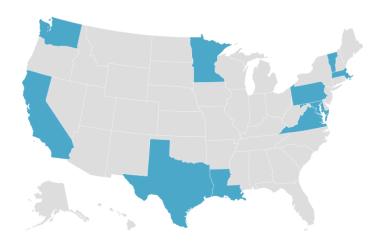
- Standardized, state-level onboarding of over 1,000 districts helps provide clean, school-level data to the state for public health planning and interventions
- Creating plug-and-play processes such as pre-assembled testing kits significantly reduces errors during sample collection and increases scalability
- One-time consent and HIPAA authorization early is critical to streamline testing processes
- In-house staff can be trained at scale to support sample collection and program administration when coupled with easy-to-use software and centralized support infrastructure
- Clear funding models help improve access for underserved populations
- In addition to capacity requirements, key pieces of successful implementation also include coordinated onboarding, shipping and information management between testing partners
- Simplified logistics and consistent, easy-to-understand processes has supported effective use of time and resources and increased time spent in the classroom in K-12 California schools



## **SUCCESSFUL K-12 TESTING:** NATIONWIDE PILOT WITH PCR POOLING

**Current status** of Concentric by Gingko's pilot of **pooled testing** in over 130 schools across 11 states:

- <15 minutes to run a full-classroom collection</li>
- 1000+ classrooms tested
- 10,000+ students and educators tested
- 32 positive individuals identified and isolated to reduce transmission



## Kids feel empowered to self-swab, help their community, and teach others

Swabs go "Boogers down".

YORK ACADEMY

You only have to go up to the squishy part of your nose.

PARK STREET SCHOOL

We have a jingle - "1, 2, 3, 4 - switch it over, do 4 more"

SHARON PUBLIC SCHOOLS

It's a free chance to pick your nose, and no one is going to yell at you.

SHARON PUBLIC SCHOOLS

- Clear communication increases confidence among students, parents, teachers and administrators
- Streamlined and human-readable consent forms are vital for ensuring parent buy-in
- Build infrastructure (including registration portals) that can scale
- Streamlining school onboarding virtually (via a website and videos) enables rapid scale
- Minimized disruption to classroom is needed for adoption (<15 minutes and self-collection)
- Pod-pooling approach can work in a wide range of schools (multiple states, low-income areas, minority communities, etc.)



## **SUCCESSFUL K-12 TESTING:** CROSS-CITY LEARNING GROUP PILOT SITES

The Cross-City Learning Group was formed through The Rockefeller Foundation's partnerships with HHS, Duke-Margolis Center for Health Policy, Johns Hopkins University, Mathematica and six cities/states willing to pilot testing programs



Washington D.C.

8 learning hubs



Tulsa

70 schools



**Rhode Island** 

78 schools and learning education agencies



Louisville

12 regional testing sites



**New Orleans** 

45 schools



**Los Angeles** 

60
Parks and Recreation centers

- Engaging early with district administrators and local partners can help gain their buy-in and support for identifying resources
- Clear communications, delivered by trusted leaders in the community, are needed to build community members' understanding of the program and encourage participation
- The testing approach should be designed using both evidencebased guidance and on-theground knowledge of what will be acceptable to students, parents, teachers and staff





## WHAT IS THE VISION: K-12 NATIONAL TESTING ACTION PROGRAM

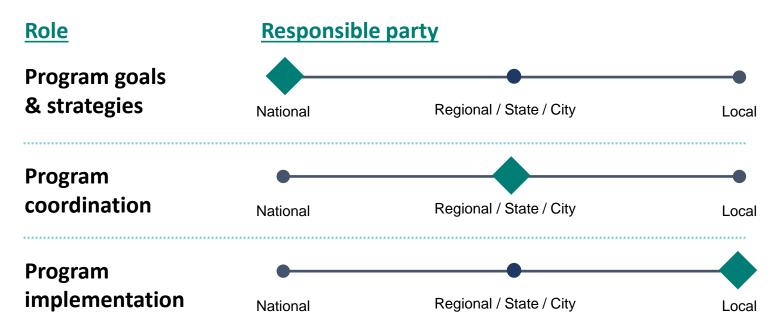
Testing is the missing link to K-12 schools reopening safely in-person this spring

#### Thus, the K-12 National Testing Action Program focuses on:

- A. Free and easy testing for schools, kids and parents
- B. **Reliable and predictable testing** availability for schools
- C. No reduction of **testing availability** anywhere in the country
- D. Public and private **resources mobilized** and coordinated for sustainable capacity
- E. A maximum **24-hour turnaround time** for results
- F. Simple procurement, funding and implementation processes, including results reporting
- G. Ability to **adapt and improve**, keeping pace with scientific advances

## **HOW DOES IT WORK:** NATIONAL, REGIONAL AND LOCAL COLLABORATION

The K-12 National Testing Action Program is designed to be **federally guided**, **state/regionally coordinated**, **and locally implemented at the school /district level**, all with the aim to **support the safe reopening of 100% of K-12 schools** 



## K-12 NTAP will provide enough support to test:

- 100% of willing students weekly (per appropriate consent/assent)
- 100% of willing teachers and all staff up to twice weekly

"Everything should be made as simple as possible but no simpler" - Albert Einstein

## **KEY REQUIREMENTS FOR SUCCESSFUL K-12 TESTING**

Key requirements for successful testing programs

#### **Easy**

Testing an entire classroom should take minimal time (e.g., ~12 minutes). Testing must be easy for students as young as kindergarten to do. Logistics should be streamlined and should not burden school staff

#### **Effective**

Testing should be accurate and give school communities data that provides them with confidence to maintain in-person learning

#### **Accessible**

Testing should be easy to access for every school and should be easily scalable to cover entire school districts

#### **Affordable**

The cost of testing should allow for every student to be tested every week. Federal funding may be leveraged to cover costs

## **HOW TO CHOOSE A TEST:** STEPS IN THE TESTING PROTOCOL

A strong testing protocol consists of three steps:

#### Step 0

#### **Initiation testing**

(if possible)

When program begins — especially for schools in high prevalence areas — all students, teachers and staff should be tested individually or in small pods before regular weekly testing begins\*

#### Step 1

#### **Asymptomatic screening**

Pooled PCR tests or antigen tests administered weekly to students and twice-weekly to teachers and staff

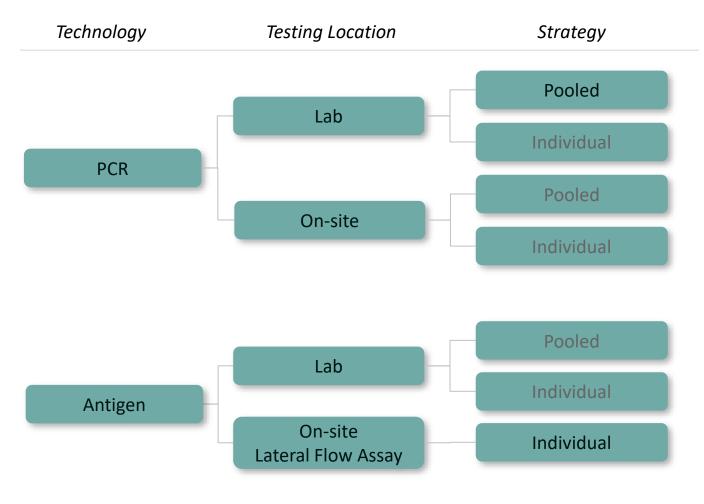
#### Step 2

## Positive pool follow-up testing as required

For individuals in positive pools, provide individual PCR or antigen diagnostic tests – via at-home, onsite, clinic, lab or pharmacy testing

\*While Step 0 is not discussed in further detail here, it is possible to leverage similar testing strategies to those described for steps 1 and 2. The purpose of Step 0 is to identify infected individuals before regular testing begins, which will make it easier to identify new cases moving forward

# **HOW TO CHOOSE A TEST:** ASYMPTOMATIC SCREENING OPTIONS (STEP 1)



Multiple testing technologies and systems will be needed to collectively meet school demand and diversify the supply chain. Common types of testing include:

**PCR testing** is a strong option for routine screening testing. PCR testing can be done individually or in pools where multiple samples are tested together "as one." Samples are typically collected at the school and sent to a lab for processing. Data management handled by test provider.

Antigen testing is another strong option for routine screening testing, potentially with serial testing or for diagnostic testing for a positive pool deconvolution. Samples are collected at the school and tested on-site for fastest results or in a central lab for results returned in 24 hours. Data management is handled by test provider.

# **HOW TO CHOOSE A TEST:** FOLLOW-UP TESTING OPTIONS (STEP 2)

#### **Step 2 testing options:**

#### Follow-up test:



- Same Sample Reflex: Test provider can deconvolute a positive PCR pool directly with the initial saliva or nasal swab, most commonly with lab-pooling where part of each sample may be available for retest.
- New Sample Reflex: A new sample from those in the positive pool is collected and then retested with:
  - On site Rapid antigen (serially) or PCR test
  - Lab based antigen or PCR test



**Pre-paid coupon:** Can be redeemed at a local retail pharmacy, clinic, testing lab or public health or university lab to get confirmatory test to obtain proof of a negative result to return to school



**At-home kit:** Can be used to self-collect a nasal swab or saliva sample and ship it back to a lab for testing. A prepaid shipping label will be provided

#### Benefits of the K-12 NTAP program

- ✓ Provides schools and families the flexibility to choose the right test option and location for them
- ✓ Improves equity and access to confirmatory testing
- ✓ Quickly allows students to get the confirmatory results required to return to school
- ✓ Optimizes use of **local testing resources** based on availability and preference
- ✓ No cost to families or schools

### **PCR POOLING:** THE EVOLUTION OF PCR TESTING

#### The path from individual to pooled testing: what we've learned

Colleges and universities demonstrate effectiveness of testing, infection control and isolation measures by creating subcommunities with lower Covid-19 prevalence and test positivity rates than the surrounding communities

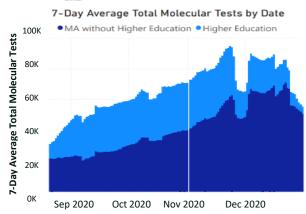
Tufts University implemented a regimented individual PCR testing strategy in partnership with the Broad Institute to obtain community prevalence data across campus sites in multiple municipalities

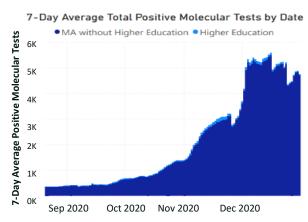
High costs limit the accessibility of repeated individual PCR testing for K-12 communities Tufts University designed a study of pooled testing to evaluate the specificity and sensitivity of a pooled assay, which provides great confidence in identifying all positive individuals using pooling. Pooling becomes more popular in K-12 schools

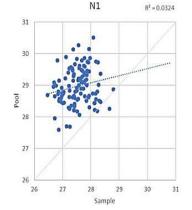
While sample dilution was an upfront concern for pooling, as it could result in false negatives, pilot results from 1576 individuals (students, staff, faculty, etc.) showed 100% congruence between pooled and individual results, no false negative results, and slightly elevated CT-values

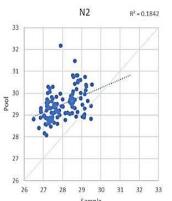


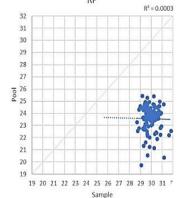
Massachusetts Department of Public Health COVID-19 Dashboard- Sunday, January 03, 2021
All Molecular COVID-19 Tests Associated with Higher Education Testing











Data Sources: COVID-19 Data provided by the Bureau of Infectious Disease and Laboratory Sciences; Tables & Figures created by the Office of Population Health. Note: All data are current as of 11:59 PM on 1/2/21. Due to lag in reporting by labs, counts for most recent dates are likely to be incomplete. This includes individuals who have had more than one molecular test

Ct results comparing pool Cts (y-axis) with the Ct value of the corresponding single positive sample (x-axis). Each graph represents a different probe; N1 and N2 detect regions of SARS-CoV-2 virus RNA while RP represents host genetic material abundance. Blue line: trendline of data; grey line: y=x bisector.

### **PCR POD POOLING:** HOW IT WORKS

#### **Classroom pooling**

All students and teachers in a pod **swab their noses** with short swabs (think: cotton swabs). Swabs are placed in one tube (this is the "pooling" step). This pool is then run as a single test at a local lab.

Key benefit: groups of 25 people can be tested using one test. For a school of 500, only 20 tubes must be collected and managed, instead of 500 when testing individually.

Only positive pools result in further action. Next steps are decided by the school.

#### STEP 1 - Pods self-swab

Individuals in a pod (e.g., classroom) self-swab and place swabs into a single tube. Takes minutes to complete for an entire pod



#### STEP 2 - Test the pools

Each tube is then run using one test at a local lab, and the classroom is provided with one result



#### STEP 3 - Get results

Results can be used by schools to make more informed decisions, detect the virus earlier, and mitigate spread



## PCR POD POOLING: TESTING OPTIONS FOLLOWING A POSITIVE POOL

#### What happens if there's a positive pool?

The solution will look a little different for each school based on unique circumstances. However, K-12 NTAP recommends all follow-up testing be fully funded to ensure equitable access and fast results, with no additional administrative or billing burden.

**⋈** 

#### Approaches for follow-up testing:

#### School-based testing (preferred option)

Rapid antigen tests or on-site collection for labbased nasal or saliva tests administered at school

#### Pre-paid coupon

Coupon redeemable at local pharmacies, clinics, testing labs or hospitals to obtain proof of negative result to return to school

#### At-home testing

Self-collected nasal or saliva sample sent to labs for testing using pre-paid shipping

#### **Community-based testing**

Tests administered at pharmacies, clinics, doctor's offices, community centers or other publicly accessible sites

### **PCR IN-LAB POOLING:** HOW IT WORKS

#### In-lab pooling

All students and teachers **swab their noses** with short swabs (think: cotton swabs) or **produce saliva samples** samples in individual tubes. Tubes are sent to the lab where part of each sample is combined with other samples to form a pool. This pool is then run as a single test at a local lab.

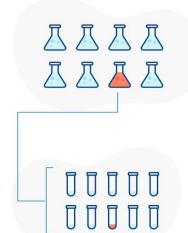
**Key benefits**: school can benefit from the efficiency of pooled testing without the need for separate follow-up sample collection. It also allows for the use of tests with at-home sample collection options, which can minimize the operational burden on schools

## Three step laboratory process ≤





2 Pools are tested



For positive pools, remaining parts of samples are individually tested



### **PCR POOLING: SENSITIVITY**

Studies comparing the sensitivity of pooled versus individual tests confirm that **PCR pooling is more than sufficient** for asymptomatic screening tests and has **similar sensitivity to individual testing.** In April 2021, the FDA recommended that best practice for the use of antigen tests is serial testing – two tests within 24 to 36 hours.



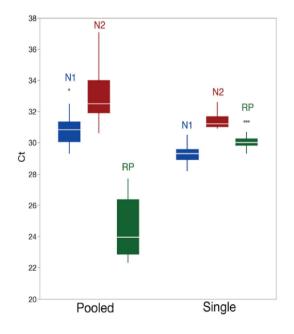
A study conducted by *The Broad Institute* found comparable levels of detection when samples are pooled or individually tested

**Results show** that the sensitivity was comparable for pooled and individual/single samples

#### Notes on the graph:

- 10 samples were pooled together to compare sensitivity N1
  and N2 samples look for Covid-19 virus genome and RP
  samples look for human genome (control)
- A lower Ct value means a higher amount of virus genome is present
- The RP Ct is significantly lower in the pool as expected since human genomic material is present on both positive and negative swabs

### Pooled vs individual testing sensitivity



#### **UNITEDHEALTH GROUP**

A study by the *UnitedHealth Group* showed pooled testing had comparable performance to individual PCR testing

**Results show** that up to 15 samples could be pooled together to reduce costs and supplies while maintaining accuracy of results

### **RAPID ANTIGEN:** HOW IT WORKS

#### Rapid antigen testing

**Students and teachers have their noses swabbed** with short swabs. Each swab is applied to a test card or cassette and allowed to run for the appropriate amount of time.

**Each person tested has their own test**. For a school of 500, a total of 500 tests are needed to test everyone. In April 2021, the FDA recommended that best practice for the use of antigen tests is serial testing – two tests within 24 to 36 hours.

Once the necessary time has elapsed, trained staff interpret and record each result. Positive results are communicated to the individuals and families.

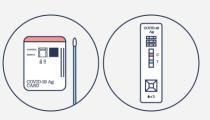
#### STEP 1 - Individuals swabbed

Individuals are swabbed either by a trained staff member or a healthcare professional



#### STEP 2 - Test each swab

Each swab is applied to a test card or cassette by a trained staff member or healthcare professional



#### STEP 3 - Get results

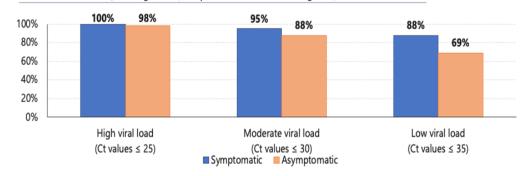
Results are interpreted and recorded by a trained staff member or healthcare professional. They can be used to make more informed decisions, detect the virus, and mitigate spread



### **RAPID ANTIGEN: USE FOR POOL DECONVOLUTION**

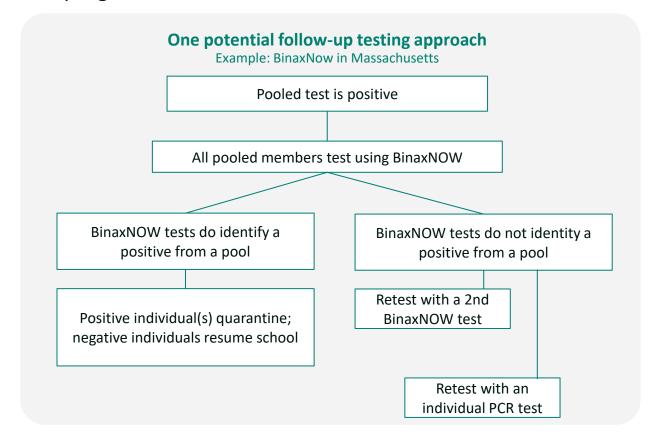
Given the speed, accuracy, price and widespread availability, some schools are using **rapid antigen testing as a way for recommended follow-up testing** to support the pooled test program

### Percentage of positive PCR tests accompanied by a positive BinaxNOW test, by viral load All other results were false negatives (PCR positive & BinaxNOW negative)



When compared to PCR tests, BinaxNOW is **accurate in detecting COVID-19 in children** with moderate to high viral loads, even if they are asymptomatic.

These children are the most likely to be highly contagious and transmit the disease.



### **LAB-BASED ANTIGEN:** HOW IT WORKS

#### **Lab-based antigen testing**

Students and teachers have their noses swabbed with cotton swabs. Each swab is placed in a tube and a pretreatment solution is applied to the sample. The tube is then sent to a laboratory, where they place it on a high-speed automated lab instrument.

**Each person tested has their own test.** For a school of 500, a total of 500 tests are needed to test everyone. After samples are collected, they are sent to the lab for analysis. Lab-based antigen tests are high-throughput with hundreds of results per hour.

Results are interpreted and can be reported same day to the school by the laboratory as positive or negative.

Positive results are then communicated to the individuals and families. Follow-up testing is not required.

#### **STEP 1 - Individuals swabbed**

Individuals are swabbed either by a trained staff member or a healthcare professional

#### STEP 2 - Test each swab

Each swab is inserted into a tube by a trained staff member or healthcare professional. A pre-treatment solution is applied to the sample to inactivate the virus. This helps to protect the healthcare professional.

#### **STEP 3 - Get results**

Results are interpreted, recorded and reported to the school by the laboratory. The results can be used to detect the virus, make informed decisions (e.g., about student/staff quarantine) and mitigate spread. The laboratory reports can help the schools satisfy their reporting requirement to the authorities.

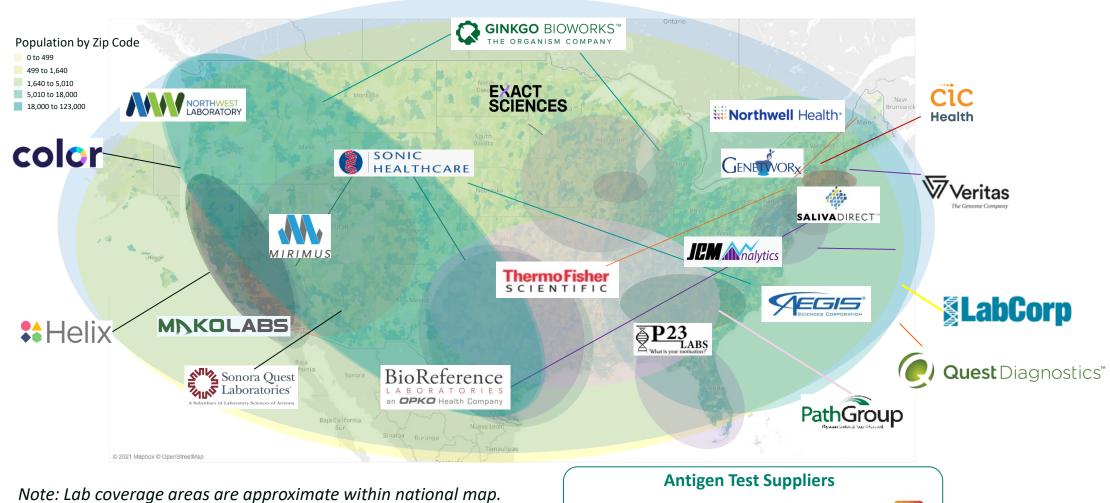






Test Result: Negative

# WHO PROVIDES TESTING: TESTING FOOTPRINT FOR SCALING K-12 TESTING



Note: Lab coverage areas are approximate within national map.

Additional coverage possible through public health and university labs



### WHAT WILL IT COST: ALL-IN COST ESTIMATES AND **ASSUMPTIONS**

#### **ALL-IN COST PARAMETERS**

#### \$30 per person for Step 1: asymptomatic testing

\$10-15 per person: pooled PCR or antigen tests \$15-20 per person: school administrative costs

#### \$60 per person for Step 2: positive pool follow up

\$40-50 per person: individual PCR or antigen tests \$5-10 per person: school administrative costs

#### **ASSUMPTIONS**

Per person testing costs, including school administrative costs, are estimated from current operations in school testing programs

Assumption that ~1% of pools are positive and require deconvolution / Step 2 testing

Note: These numbers are included as an illustration of current market conditions. As more testing vendors enter this market, we expect the resulting competition will drive prices down.

# K-12 NATIONAL TESTING ACTION PROGRAM: IMPLEMENTATION LOGISTICS



### MINIMUM STANDARDS FOR PROGRAM SUCCESS

#### **STANDARDS FOR SUCCESS**

A. School and community alignment and engagement

- D. Resources to administer and process tests efficiently and effectively
- G. Regulatory support

B. 'Right test, right place, right time'

- E. Clear public health guidance and resources for every stage of the process
- H. Ensuring equity and broad access

C. Necessary supply of tests, supplies and other resources

F. Reporting and data systems

Minimum standards help ensure quality testing programs are available to all students, teachers and all staff, while still allowing the schools flexibility to design and customize their programs based on their unique context and needs

# PROGRAM MINIMUM STANDARDS (1 OF 2)

#### A. School and community alignment, engagement and education

 School committees, superintendents, teachers, unions and families should understand the goals of the testing program and how it helps to safely and sustainably reopen

#### B. "Right test, right place, right time" (pooling or individual testing strategy)

- A standardized menu of testing protocols and workflows should be designed for schools that offer 24-hour results to test takers
- Testing programs should screen students and staff at a frequency that prevents outbreaks and enables the quarantining of individuals who
  test positive

#### C. Necessary supply of tests, supplies and other resources

- A stable and reliable supply of tests with a consistent process and result reporting should be available
- Fulfilling school demand nationally requires multiple types and sources of tests

#### D. Resources to administer testing programs efficiently and effectively

- Testing service providers should manage procurement, contracting and onboarding with individual districts and schools
- Testing playbooks and toolkits can explain how to roll out and manage a testing program at the district or school level
- Testing lead or coordinator should be appointed for each school; potentially a school nurse, school administrator, district administrator, or USPHS Commissioned Corps

#### E. Clear public health guidance and educational resources for every stage of the process

- Easy-to-understand rationale for and explanation of testing protocol is critical
- Situations that necessitate confirmatory tests require some guidance
- There should be an explanation of how schools and families should react to a positive case in school or in household
- Protocol for quarantine and return-to-school should be published

### PROGRAM MINIMUM STANDARDS (1 OF 2)

#### F. Reporting and data systems

- Aggregate pool results should be reported to school, parents and student; tracking should be facilitated by online secure software products
- Any positive individual diagnostic results whether antigen or molecular -- should be reported to local public health authorities per existing public health laws and facilitated by HIPPA-compliant software products
- Test results are intended to keep school open and are not aimed at individual diagnostics

#### **G.** Regulatory support

- Standard consent for adults and students is necessary, including release of personal health data as appropriate
- An important and reasonable option is to have schools designated as CLIA sites for appropriate testing
- It can be useful to have a standing physician order to authorize individual diagnostic tests under school testing protocol

#### H. Ensuring equity and broad access

- All schools and districts are encouraged to participate in program
- Testing programs should be offered at no cost to schools or participants or families
- State and local customization can provide varying levels of support for school districts with differing needs
- Test demand forecast can be created on objective factors (# students, ages, geographic densities et. al.)

# WHAT DO SCHOOLS DO: RUBBER HITS THE ROAD — OPERATION OVERVIEW

There are 4 key steps to executing K-12 NTAP, but each component within the key steps must be designed and executed based on individual needs of the school

#### **Key steps** 1) Coordination & administration 2) Testing modality selection 3) Facility set-up 4) Results reporting Choose testing partner(s) Establish key positions & roles Set-up on-site, centralized, Decide reporting strategy Hire, train and build partnerships with • Finalize protocols for Step 1 decentralized or other Establish procedures for Asymptomatic Screening and physical models local public health officials reporting positive results and Create a communication plan for Step 2 Follow-up Testing for confirmatory testing updates and changes to the process positive pools Receive authorization and registration • **Decide on Initiation Testing** for testing

Considerations for tailoring design and execution





Student population needs (age, special needs, etc.)



Access to approved contracts and vendors



**Proximity to labs** 



Human and financial resources



Number of students, teachers and staff

### WHAT DO SCHOOLS DO: COORDINATION AND **ADMINISTRATION**

Successful implementation, coordination and administration requires that schools fill staff positions prior to launching K-12 NTAP; schools can choose to hire additional employees, partner with external stakeholders and/or train existing staff for these roles

Positions necessary to implement K-12 NTAP Coordinator(s) Oversee the daily operations and verify authorization/consent and registration **Ushers Logistics Leads** Quality **Communications** Results Test Lead **Administrators Controllers** Manager Direct students. Ship collected teachers and samples to labs Manage safe Ensure all Create and Collect or staff to testing and maintain results are oversee sample testing manage communication promptly locations collection shipping environment and disposal of shared with key s with records stakeholders biohazards stakeholders

Depending on the position being filled and experience of the individual, specific trainings and certifications may be needed

A combination of hiring, training and partnerships can be used for these positions. Options include:



Hire temporary employees



Partner with external stakeholders (e.g., Commissioned Corps or health professionals)



**Train existing staff** 

**Example:** Watertown Public Schools, Broad Institute and CIC Health collaborated to administer individual testing for high-need students



School nurses championed, coordinated and administered testing



School nurses provided in-house training for ancillary support



Cost savings from leveraging in-house resources



# WHAT DO SCHOOLS DO: SETTING UP COLLECTION FACILITIES

To maintain quality and consistency, on-site collection (e.g., at schools, local pop-up labs, etc.) is preferred to at-home collection. School's can tailor their on-site collection set up based on size, resource availability and testing modality

#### **Set-up options**

#### **Centralized (walk-up)**

Examples: Gym, cafeteria

#### When it works well:

- ✓ High-volume testing
- ✓ Limited testers available
- ✓ Test technologies that require more equipment or storage

#### **Challenges:**

✓ Space may already be in use for other school activities and social distancing needs

#### **Decentralized**

**Examples:** Individual classrooms

#### When it works well:

- ✓ Homeroom or pod model
- Minimizes day-to-day disruptions for younger students (more familiar to them)

#### Challenges

- ✓ Staff capacity
- ✓ Transporting PPE and supplies to each location (e.g., hazard waste removal)

#### **Centralized (drive-thru)**

**Examples:** Parking lot, drop-off zones

#### When it works well:

- Areas with high community prevalence (limits potentially infected individuals from entering common areas)
- ✓ For testing one-time visitors, substitute teachers, etc.

#### **Challenges:**

✓ Sufficient physical space may not be available

Example: Washington International School and UnitedHealth Group collaborated to perform weekly pooled rapid testing

- Centralizing sample collection to make it easy was the key to success
- Using a phased approach allowed continuous improvement in sample collection methods

Photo Credit: Natasha Bhalla

#### **Alternative collection approaches**

At-home collection may be used for several reasons including when individuals are showing Covid-19 symptoms or when a school lacks the staff needed to test the volume of students necessary

**Off-premise testing** at pharmacy or other thirdparty location may be used when individuals prefer their primary care provider to testing in school

### WHAT DO SCHOOLS DO: RESULTS REPORTING

Regular and prompt reporting of results to testing participants and their families, schools and school districts and the state and federal government is critical to maintaining safe school environment and overall public health

#### What to report on

#### Results to students, teachers and staff



#### **Test results**

Clearly and promptly provide test results as soon as they are available, including any need for follow-up testing



#### **Quarantine and isolation guidance**

Reshare quarantining and isolation guidelines when positive pools/individual tests are identified



#### School positivity rates and trends

Regularly share updates to the school community on the total number of cases and positivity trends to maintain trust

#### Results to local, state and federal government



#### **Positive cases**

Provide regular updates on the total number cases and positivity trends at school or school district level (according to state and federal guidelines)

#### Tools and technologies to facilitate reporting

- Centralized information platform to store data with the ability to remove PII and aggregate at school district level as needed per FERPA and HIPAA guidelines
- Website and/or text messaging options to share results as soon as they are available
- Inquiry form to get status updates if the test results are not available in the expected timeframe

### **Example: Washington International School and UnitedHealth Group collaborated to perform weekly pooled rapid testing**

- Use cloud-based information management system to track results and communication
- Report results to parents, staff and students within 40 minutes
- Created list of easily accessible FAQs about testing, operations, data security and safety



# SCHOOL OPERATIONS IN ACTION: SCHOOL NURSE PERSPECTIVE

EXAMPLE CASE – while the scenario below focuses on pod pooling, Nurse Jamie could play the coordinator role for any testing program



Nurse Jamie is the head nurse at a high school in a city supporting the school principal and the district superintendent as they adopt the K-12 NTAP. She firmly believes that both students and teachers should be tested regularly if the school is to reopen for in-person learning

**Coordination and test modality** 

Set-up

**Sample collection** 

**Results reporting** 



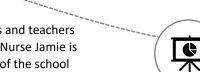
Over the last few weeks, Nurse Jamie (testing coordinator), the district superintendent and the principal have coordinated to obtain consent to test and complete registration to begin testing. They have determined that students, teachers and staff will be tested through pooled sample test



Nurse Jamie, in close collaboration with the other school nurses, helped by hiring additional temporary staff to help with ushering, testing and shipping tasks. She also helped coordinate the set-up of testing booths in the gym for students and a separate area to test teachers and staff. The testing team conducted a dry run of all operation on Sunday before school reopened



It's Monday and students and teachers begin to arrive to school. Nurse Jamie is in the command center of the school making sure that all individuals are getting tested. Once all the test samples are collected, Nurse Jamie checks in with the logistics staff to ensure all samples get shipped promptly to the nearby labs



Nurse Jamie gets to school early on Tuesday and sees an email from the lab saying that one pool in grade 8 tested positive. She immediately sends an email to parents of those in the positive pool. If an onsite rapid testing protocol is set up, she works with each student to be tested.

If not, she send an online voucher to parents to get an individual test for each student



Those who tested negative onsite with a rapid test are back at school. Those who tested with an outside lab confirm their negative (or positive) status with an email to Nurse Jamie. As expected, 7 were negative and 1 was positive. She authorized the 7 to come back to school and shared the update with stakeholders according to their protocol



# SCHOOL OPERATIONS IN ACTION: STUDENT PERSPECTIVE

EXAMPLE CASE – while the scenario below focuses on pod pooling, Molly would have a similar experience with any testing program



Molly's school has worked hard to implement the K-12 NTAP program, which is a national testing strategy that allows teachers and students to safely come back to school in-person. She can hardly contain her excitement to start school this coming week because she will finally be able to see her friends and teachers in-person

Engagement Testing



Over the last few weeks, Molly's parents have been talking with the school about the new testing program to understand all the steps they are taking to safely test Molly and keep her safe when she is in school. They have filled out required consent forms and registered for regular testing It's Monday and when Molly arrives at school with her new rainbow mask, one of the school staff checks her in and directs her to head to the gym with the rest of her homeroom classmates. There are arrows on the ground directing her to one of the several tables that are set up in the gym. She only waits in line for 5 minutes (standing 6 feet apart from her classmates, of course)



When it is her turn, the school nurse watches Molly swab her nose. That took only a minute and wasn't as scary as she thought it would be! Then Molly follows the arrows out of the gym and back to her class for the rest of the day



Molly comes back to school on Tuesday. While her whole class is there, the class next to them is empty because someone in that pod had a positive test. The teacher explains that the students in that pod will be tested again to confirm the positive individual



Results

Molly's parents and all parents are made aware of the positive pool but reminded of schools' low overall prevalence rate. They are also reminded that whenever there is a positive pool, everyone in that pool will be retested either with a rapid test onsite or given a voucher to be tested at a local lab or retail pharmacy



Molly's parent receive another email from the school on Wednesday confirming the Covid-19 positive individuals were successfully identified and asked to continue in-home learning or teaching for at least 2 weeks. For contact tracing purposes, they were also told that Molly was not in contact with the Covid-19 positive individual and should attend school normally

# WHO IS NEEDED: BUILDING CONFIDENCE FOR PARTICIPANTS

Wide-spread adoption and participation relies on building confidence for participants by understanding their priorities and concerns. State and local leadership must proactively reassure and address the concerns of stakeholders

	Superintendents	Teachers and staff	Parents	Students
Priorities and Concerns	<ul> <li>All willing individuals are getting tested</li> <li>Results are obtained quickly</li> <li>Payments and funding vehicles are in place</li> </ul>	<ul> <li>Keeping themselves and students safe</li> <li>Preparing for when someone gets sick in school</li> <li>Missing work when they test positive</li> <li>Data privacy</li> <li>Test collection safety</li> </ul>	<ul> <li>Safety of children</li> <li>Testing without parent/guardian present</li> <li>Perceived cost and time of confirmatory test if applicable</li> <li>Data privacy</li> <li>Test collection safety</li> </ul>	<ul> <li>Fear of getting the swab</li> <li>Test collection safety</li> <li>Stigma or lost school time linked to positive results</li> </ul>
Actions to Build Confidence	<ul> <li>Set frequency and sensitivity standards</li> <li>Provide easy-to-use consent forms</li> <li>Provide central POC to ask questions</li> </ul>	<ul> <li>Provide guidance on isolation and other mitigation strategies</li> <li>Bring in trained people to administer tests</li> <li>Be transparent about data privacy and use</li> </ul>	<ul> <li>Provide information on getting confirmatory tests</li> <li>Make consent forms easy to understand</li> <li>Provide results quickly</li> <li>Be transparent about data privacy and use</li> </ul>	<ul> <li>Make the testing process as easy as possible to reduce stress and anxiety</li> <li>Provide guidance on what do you if you're feeling sick</li> </ul>

<sup>\*</sup>Note: The Testing for America K-12 Playbook provides a tactical communications plan to engage stakeholders including who is responsible for the communication

### LAB & TEST PROVIDER CONTACT INFORMATION (1 OF 3)

NOT EXHAUSTIVE — This contact list of lab and test providers is a tool for schools, districts, and ELC recipients; however, ELC grant recipients are welcome to use any lab or testing provider consistent with their ELC recipient guidelines

General Information					Testing Technology					Experience and Readiness			
Company	HQ	Contact name	E-mail	Geographi c reach		PCR - individual	Antigen without instrument	Antigen with instrument	Central Lab Antigen	Experience with K-12 Testing	Number of schools actively testing today	Own lab or partner lab?	Ready to start testing?
					Yes / No	Yes / No	Yes / No	Yes / No		Yes / No		Own / Partner	Yes / No
Abbott	Chicago, IL	Brian StCyr, Adam Bishop	brian.stcyr@abbott.com; adam.bishop@abbott.com	National	Yes	Yes	Yes	No	No	Yes	26 to 100	Partner	Yes
Aegis Sciences	Nashville, TN	Regina Sweeney	regina.sweeney@aegislabs.com	National	Yes	Yes	No	No	No	Yes	26 to 100	Own	Yes
American Esoteric	Managhia TN	David Smalley,	dlesselles (@e.el.ee.se	TN, MO,	Vaa	Vaa	Vaa	Vaa	Na	Na	N1/A	0	Vaa
Laboratories- Sonic BD (BD Veritor)	Memphis, TN Franklin Lakes, NJ	PhD Jeff Eisinger	dlsmalley@ael.com jeff.eisinger@bd.com	AR, MS National	Yes No	Yes Yes	Yes No	Yes Yes	No No	No Yes	N/A 101 to 250	Own Partner	Yes Yes
Bernhardt Laboratory -	FIGURIUI Lakes, INJ	Jen Lisinger	<u>Jen.eisinger@bd.com</u>	INALIONAL	INO	163	INO	res	INO	165	101 (0 230	raitilei	163
Sonic	Jacksonville, FL	Bruce Walton	bwalton@auroradx.com	FL	Yes	Yes	Yes	Yes	No	Yes	101 to 250	Own	Yes
BioReference Laboratories	Elmwood Park, NJ	Ellen Beausang	ebeausang@bioreference.com	National	Yes	Yes	Yes	Yes	No	Yes	501 to 1500	Own	Yes
CIC Health	Cambridge, MA	Carrie Allen	allen@cic.com	National	Yes	Yes	Yes	Yes	Yes	Yes	1500+	Partner	Yes
Clinical Labs of Hawaii -	cambridge, MA	Carrie Allen	anenie cic.com	Ivacional	163	163	103	163	163	163	13001	1 al tilei	163
Sonic	Honolulu, HI	Michele Cox	michele.cox@hawaiilabs.com	н	Yes	Yes	Yes	Yes	No	Yes	251-500	Own	Yes
Clinical Pathology				TX, LA, OK,									
Laboratories - Sonic	Austin, TX	Tony Jones	tjones@cpllabs.com	NV, NM	Yes	Yes	Yes	Yes	No	No	N/A	Own	Yes
Color	Burlingame, CA	Caroline Savello	caroline@color.com	National	Yes	Yes	Yes	No	No	Yes	1500+	Both	Yes
Eastside Clinical													
Laboratories - Sonic	Providence, RI	Gary Sammarco	gary@esclab.com	RI, MA	Yes	Yes	Yes	Yes	No	Yes	101 to 250	Own	Yes
Exact Sciences	Madison, WI	Melanie Hayward	mhayward@exactsciences.com	Midwest	Yes	Yes	No	No	No	Yes	1 to 25	Own	Yes

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					Yes / No	Yes / No	Yes / No	Yes / No		Yes / No		Own / Partner	Yes / No
GENETWORx	Glen Allen, VA	Maryrose Roberts	mroberts@recoverycoa.com	National	Yes	Yes	Yes	No	No	Yes	1 to 25	Own	Yes
Ginkgo Bioworks	Boston, MA	Matt McKnight	mmcknight@ginkgobioworks.co <u>m</u>	National	Yes	Yes	Yes	No	No	Yes	501 to 1500	Partner	Yes
Helix	San Mateo, CA	Ed MacBean	edgar.macbean@helix.com	National	Yes	Yes	No	No	No	Yes	26 to 100	Own	Yes
JCM Analytics	Durham, NC	Corey Palermo	corey.palermo@jcma-llc.com	National	Yes	Yes	No	No	No	Yes	101 to 250	Partner	Yes
LabCorp	Burlington, NC	Kevin DeAngelo	deangek@labcorp.com	National	Yes	Yes	Yes	Yes	Yes	Yes	N/A	Own	Yes
LumiraDx Ltd	Waltham, MA	Laura Dullanty	laura.dullanty@lumiradx.com	National	No	Yes	No	Yes	No	No	N/A	Partner	Yes
Mako Medical Laboratories	Raleigh, NC	Josh Arant	jarant@makomedical.com	Eastern US	Yes	Yes	Yes	Yes	Yes	Yes	1500+	Own	Yes
Mirimus	Brooklyn, NY	Prem Premsrirut	prem@mirimus.com	National	Yes	Yes	No	No	No	Yes	501 to 1500	Own	Yes
Northwell Health Laboratories	Lake Success, NY	Bridgette Mastaglio	bmastaglio@northwell.edu	NY	Yes	Yes	Yes	Yes	No	Yes	N/A	Own	Yes
Northwest Pathology	Bellingham, WA	Jack Smith	jack.smith@northwestpathology com	Pacific NW	Yes	Yes	No	No	No	Yes	1 to 25	Own	Yes
P23 Labs	Savannah, GA	Angie Crouch	info@p23labs.com	GA, AR	No	Yes	Yes	No	No	Yes	1 to 25	Own	Yes
PathGroup	Brentwood, TN	Richard Halstead; Brent Sower	rhalstead@pathgroup.com; bsower@pathgroup.com	National	Yes	Yes	No	No	No	Yes	1 to 25	Own	Yes

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## LAB & TEST PROVIDER CONTACT INFORMATION (3 OF 3)

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					Yes /			,				Own /	
					No	Yes / No	Yes / No	Yes / No		Yes / No		Partner	Yes / No
			stacia.x.rivello@questdiagnostics	<u>.</u>									
Quest Diagnostics	Secaucus, NJ	Stacia Rivello	<u>com</u>	National	Yes	Yes	Yes	Yes	No	Yes	26 to 100	Own	Yes
		Patrick Sweeney;	patrick.sweeney@quidel.com;										
Quidel	San Diego, CA	Rick Graham	rick.graham@quidel.com	National	Yes	Yes	Yes	Yes	No	Yes	101 to 250	Partner	Yes
SalivaDirect	New Haven, CT	Anne Wyllie	salivadirect@gmail.com	National	No	Yes	No	No	No	Yes	26 to 100	Partner	Yes
Sunrise Medical				NY, CT, DC,									
Laboratories - Sonic	Hicksville, NY	Alan Greenberg	agreenberg@sunriselab.com	MD, VA	Yes	Yes	Yes	Yes	No	Yes	1 to 25	Own	Yes
Seacoast Path /	Exeter, NH /												
Greensboro Path / Lab	Greensboro, NC/			NH, NC,									
Medicine - Sonic	Las Vegas, NV	Bruce Walton	bwalton@auroradx.com	NV	Yes	Yes	Yes	Yes	No	Yes	1 to 25	Own	Yes
Sonora Quest /													
Laboratory Sciences of		Sonya Engle;	sonya.engle@sonoraquest.com;										
Arizona	Phoenix, AZ	Tom Leggett	tom.leggett@sonoraquest.com	Arizona	Yes	Yes	No	No	No	No	N/A	Own	Yes
Thermo Fisher	Waltham, MA	Tim Fenton	tim.fenton@thermofisher.com	National	Yes	Yes	Yes	Yes	No	Yes	1500+	Partner	Yes
Veritas Genetics	Danvers, MA	Mirza Cifric	mcifric@veritasgenetics.com	National	Yes	Yes	No	No	No	Yes	26 to 100	Both	Yes
West Pac Laboratories -	Santa Fe Springs,												
Sonic	CA	Joel Bentz, MD	jbentz@westpaclab.com	CA	Yes	Yes	Yes	Yes	No	Yes	1 to 25	Own	Yes

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# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (1)

I. Test basics		Answer
1 What type(s) of test do	es the vendor provide? (e.g., PCR, Antigen, both)?	
2 Does the vendor offer t	est pooling?	
3 If the vendor offers poo	ling:	
- Is pooling done in the	e classroom as "pod pooling" or in the lab as "lab pooling"?	
- Does vendor offer r	eflex/deconvolution testing to identify those who are positive within a positive pool?	
4 If the vendor offers refl	ex/deconvolution testing:	
- Does reflex/pooling	equire an additional sample to be collected?	
- Where is test done?		
- What is the time from	n sample to result delivered?	
5 What samples are colle	cted (e.g., Saliva, Anterior Nasal Swab (front of nose), Nasopharyngeal (back of nose))?	
6 Is at-home sample coll	ection an option?	
7 What is the reported se	nsitivity of the tests offered? In adults? In children? In symptomatic? In asymptomatic?	
8 What is the reported sp	ecificity of the tests offered? In adults? In children? In symptomatic? In asymptomatic?	
9 What is the vendor's tir	ne-to-results (from sample collection to results reporting)? - Should be less than 24 hours.	
10 Will the vendor guaran	ee a specific time to results for 95% of samples?	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (2)

II. Testing process and related materials	Answer
11 Where are samples collected (in classrooms, entryway or central location like gymnasium)?	71101101
12 On what schedule and how long does vendor estimate it will take to collect samples?	
12 What are the vendor's policies / expectations for who can and cannot self swab?	
13 Where are tests processed - at school or at an outside lab? If at a lab, where is the lab?	
14 Does the vendor provide ready-to-use test kits?	
15 Does the vendor charge for kits ordered or kits processed?	
16 Does the vendor or the school hold the inventory of materials?	
17 If inventory is held at the school, what are the storage requirements?	
25 Does the vendor provide test kit storage materials and equipment that is applicable to the given season and local weather conditions?	
18 Does the vendor support inventory management (e.g., auto-restocking, inventory tracking)?	
19 Does the vendor provide swabs?	
20 Does the vendor provide saliva sample tubes?	
21 Does the vendor provide PPE (e.g., masks, gowns, gloves) for test takers?	
22 Does the vendor provide PPE (e.g., masks, gowns, gloves) for staff?	
23 Does the vendor provide sanitation materials (e.g., hand sanitizer, disinfectant spray)?	
24 Does the vendor provide shipping materials (e.g., packages, envelopes, shipping tape)?	
26 Does the vendor provide other site setup materials (e.g., popup tents, signs, tables, chairs, traffic cones)?	
27 Is biohazard waste generated and if so, does the vendor manage waste disposal?	
28 What IT hardware does the vendor provide?	
-Laptop(s)	
-Harddrive(s)	
-Wifi Modem / Router / Extender	
-Barcode Printer	
-Barcode Scanners	
-Other	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (3)

III. Personnel / workforce	Answer
29 Does the vendor provide a testing program coordinator / leader?	
Does the vendor provide onsite trained staff (e.g., nurses, clinicians) to support sample collection (e.g., swabbing) and results analysis / follow-ups?	
31 Does the vendor provide training for the school's identified testing coordinator?	
32 Does the vendor provide training for school testing staff and personnel? If so, what training(s) does the vendor offer?	
-Registering and Checking-In Individuals	
-Sample Collection	
-Packaging Samples to send to Lab	
-Communications to Positive Cases	
-Contact Tracing	
-Other	
33 Does the vendor provide technical assistance (remote or on-site) for test site staff throughout testing process?	
34 Does the vendor provide personnel to support initial site setup?	
35 Does the vendor take responsibility for contacting positive pool participants?	
36 Does vendor offer follow up counseling / support for any test-positive individuals?	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (4)

IV. Program management and other services	Answer
37 Does the vendor offer a standard menu of testing protocols, or are workflows custom designed for the school?	
Does the vendor support the school with designing and implementing a communications strategy (e.g., materials / instructions for students, faculty, and staff)?	
39 Will samples be moved by the vendor or by an external courier service?	
40 If samples are not moved by the vendor, does the vendor cover shipping costs?	
41 Does the vendor provide testing site design guidance and setup instructions?	
42 Does the vendor support additional follow-up sample collection, if required?	
43 Does the vendor have a protocol for contact tracing?	
44 What quality control processes will be put in place to prevent the mislabeling of samples or other errors?	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (5)

Key questions school administrators should ask when evaluating testing vendor proposals:

V. Data and reporting	Answer
45 Does the vendor provide initial database setup support and collect a census of the school population?	
46 Does the vendor have an integrated technology platform? If so, what capabilities are included?	
-Scheduling test dates / times for individuals	
-Sending test reminders to individuals	
-Managing roster of consenting individuals	
-Registering individuals / check-in	
-Consenting individuals	
-Tracking Samples	
-Documenting results	
-Reporting results to individuals / parents	
-Reporting results to schools	
-Reporting results to public health authorities	
-Inventory management and test kit ordering	
-Other	
Does the vendor provide additional analytical capabilities as part of their IT platform (e.g., population health analytics, surveillance testing and reporting, dashboard, tracking of key metrics)?	
48 What is the vendor's time-to-results (from sample collection to results reporting)?	
49 Will the vendor guarantee a specific time to results for 95% of samples?	

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# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (6)

VI. Legal, medical and regulatory	Answer
Does the vendor have its own consent form (authorization to perform test and share results) or expect school to create or use a state or city approved consent?	
- For parents and guardians	
- For adults, incl. teachers and staff	
51 Does the vendor handle collection of consents and test registration?	
52 Does the vendor have a process for new or additional students / adults to register and consent after the initial start to the program?	
53 How is additional information required for consent collected?	
54 Will school require regulatory approvals to perform sample collection or testing onsite?	
55 Will school need a physician order to authorize individual diagnostic tests under school testing protocol?	
Does vendor offer individual physician authorization for diagnostic tests? Is there an option establish a standing physician order? If so, does the vendor provide the standing order or does the school find the physician?	
57 Does the vendor make recommendations on quarantining and follow-up testing?	
58 Does the vendor carry legal liability insurance?	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (7)

VII. Costs	Answer
59 What is the cost per initial test?	
60 What is the cost per reflex / follow-up test?	
61 Is there a set-up cost / set-up fee?	
62 Is there a monthly fee?	
63 Is an integrated technology platform included in these costs?	
63 Are there a minimum number of tests that must be utilized each week?	
64 Are there any other fees / costs to be paid to the testing vendors?	

# STANDING UP A K-12 TESTING CAPABILITY: VENDOR CHECKLIST (8)

VIII. Testing vendor experience	Answer
Does testing vendor have experience in K-12 school testing? If yes:	
- How many schools, roughly how many students / adults and with what type of testing regime?	
- Are other school clients similar to your school in size, demographics and geography?	
- Does the vendor work with other schools in your region?	
- How long does it take for vendor to set up a new testing program from contract to first test?	
- Does the vendor have capacity to expand to new schools?	

# CDC RECOMMENDS SCREENING TESTING TO REDUCE TRANSMISSION

"Viral testing strategies in partnership with schools should be part of a comprehensive prevention approach. Screening testing is intended to identify infected people without symptoms...to prevent further transmission." – CDC Guidelines

Community transmission	CDC Recommendations for Screening Testing		
	Students	Teachers	Athletics
Low (~30% of states)  In last 7 days, 0-9 new cases per 100K, <5% positive tests	No screening testing	At least once per week	At least once per week
Moderate (~70% of states)  In last 7 days, 10-49 new cases per 100K, 5-7.9% positive tests	At least once per week	At least once per week	At least once per week
Substantial or High (~0% of states)  In last 7 days, 50+ new cases per 100K, 8%+ positive tests	At least once per week	At least once per week	Twice per week for high-risk sports, at least once per week for all others

Given the **CDC recommends screening testing in schools in most instances**, it is critical to establish a program that is **easy to administer** and **requires minimal additional resources** from schools

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### **GUIDING PRINCIPLES FOR K-12 NTAP DEVELOPMENT**

The K-12 NTAP team operates by a set of core principles which have guided the design and implementation of the program:



**Think Big but Design Small** – Standardize guidance to be widely applicable and scalable yet also tailorable for state-level coordination and school or district-level implementation



**Provide Clear, Simple and Realistic Guidelines** – Encourage use and adoption by making the guidelines easy to follow and proactively identifying ways to reduce barriers



**Be Reasonably Comprehensive** – Provide a common platform to understand the minimum requirements for K-12 testing at a broad level to enable the return of in-person learning



**Be Focused** – Prioritize testing solutions and strategies. Other mitigation strategies are assumed but secondary to this program (e.g., vaccine distribution, masking, physical distancing)



**Enable Agility** – Develop a plan that is practical and sustainable, while acknowledging the dynamic environment and likely necessity of real-time adaptation



Build Capacity - Identify ways meet demand for K-12 testing without diminishing existing testing capacity



Minimize Burden – Minimize burden on schools and families throughout the process to increase adoption

# **QUESTIONS AND FOLLOW UP**

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