Concept Paper: Supporting Safe School Reopening through a COVID-19 Testing Pilot Program in CMSD

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EXECUTIVE SUMMARY

COVID-19 testing is one strategy among numerous mitigation measures recommended by the Centers for Disease Control and Prevention (CDC) to prevent coronavirus transmission in schools. Testing has been shown to reduce COVID-19 infection when paired with strategies like mask-wearing and social distancing. However, it relies on other mitigation strategies, like contact tracing, to ensure efficacy.

Testing can be conducted in school environments for three different purposes, each with different implications for program design:

1. Schools can make tests more easily available to **diagnose** students, families, faculty, and staff with COVID-19 who suspect illness or exposure;
2. Schools can test all or some of the school population to **screen** for COVID-19 among those that do not show symptoms and prevent those who test positive from attending school; and
3. Schools can test a sample of the school population to conduct **surveillance**, that is, to better understand the risk of COVID-19, and make decisions based on such risk.

There are many variables in the design of a testing program, shaped by the purpose of testing (e.g., diagnostic, screening, surveillance). These variables include, but are not limited to: who is

tested, how frequently, with what test, by whom, and in what location. These questions must be explored collaboratively among stakeholders to best balance the needs of the school district and community, and partners' assets and constraints.

- Public health recommendations suggest that older students, faculty, and staff should be prioritized with testing protocols, and they should be tested once or twice a week, respectively.
- Public health guidance and evidence from other school districts indicate the efficiency and cost-effectiveness of the rapid antigen test (with a 15-minute turnaround time) for school-based testing protocols. However, antigen tests are slightly less accurate than molecular tests and may not be appropriate if intended to diagnose COVID-19.
- Other key decisions could remain at the discretion of CMSD leadership in partnership with other stakeholders. Examples include whether individuals can self-test; whether tests occur at a single location or on a single day; whether tests are analyzed in a batch or individually; etc.

There are additional features of any testing protocol that would need to be aligned with legal, regulatory, and public health requirements at state and federal levels. These include, but are not limited to:

- Obtaining consent for those to be tested;
- Obtaining laboratory permits (if needed);
- Sharing test results with appropriate public health authorities, and allowing for contact tracing;
- Notifying COVID-positive individuals, family members, and close contacts of COVID exposure in accordance with privacy and confidentiality laws; and
- Creating and mobilizing, as needed, a positive test plan for COVID-positive individuals and close contacts, including remote learning, isolation, and needed supports.

A pilot program in the remainder of the spring 2021 semester could help build infrastructure that would enable a scalable testing program, if needed, for the 2021-2022 academic year. Partners could consider testing a segment of the school population, such as faculty, staff, and older students—those most at-risk of contracting the coronavirus or becoming severely ill. Partners might also consider sites for the pilot based on neighborhoods most impacted by COVID-19 or existing partnerships with MetroHealth's School Health Program.

There are a variety of state and federal funding opportunities that might be brought to bear to support a testing program; however, pathways for accessing such funding are unclear.

BACKGROUND

This paper is informed by recent guidance from the Centers for Disease Control and Prevention (CDC) on safe school reopening. It draws heavily from *COVID-19 Testing in K-12 Settings: A Playbook for Educators and Leaders*, published by the Rockefeller Foundation and Testing for America in February 2021, which distills findings from school districts throughout the country implementing school-based testing programs and provides a multi-phase plan for designing, implementing, and continuously evaluating testing programs.

The CDC has identified several essential strategies for reducing the risk of COVID-19 transmission in schools, including universal mask-wearing, social distancing, handwashing and other hygiene practices, cleaning and facility maintenance, and contact tracing and isolation post-exposure. **It identifies COVID-19 testing and vaccination as two strategies that offer additional layers of protection.**[i]

Unlike other mitigation strategies, a testing protocol requires the incorporation of other, interrelated elements, such as contact tracing positive test findings. This interdependence is discussed further in the *Testing Protocols and Procedures* section.

Widespread testing may be a valuable component of school-reopening strategies for the following reasons:

- **Reducing COVID-19 transmission.** Research from the Rockefeller Foundation indicates that weekly school-based testing programs can reduce COVID-19 infections by 50% when combined with masking and distancing.[ii]
- **Increased confidence in reopening.** In a RAND survey of nearly 1,000 former public school teachers, roughly half who quit teaching due to COVID-19 reported that they would be willing to return if there were widespread vaccination or regular COVID-19 testing.[iii] In RAND's survey with Wellesley Public Schools in Massachusetts in fall 2020, only 12% of staff and 39% of parents reported feeling "mostly comfortable" or "very comfortable" returning to school without baseline COVID-19 testing. With baseline testing, 82% of staff and 87% of parents reported feeling reassured about the safety of returning to school.[iv] While the needs and experiences of parents and faculty in every school district are different, these data point to testing as one of a number of strategies to increase comfort in reopening.
- **Lack of widespread vaccination.** While vaccination is a key intervention to prevent COVID-19 illness at a population level, not all individuals impacted by school reopening have access to vaccination yet, like students or their family members. Moreover, challenges with vaccine accessibility and hesitancy have meant that not all faculty and staff who are eligible for the COVID-19 vaccine have been immunized.

- **Equity considerations.** School-based testing programs, whether through on-site provision or referrals to clinical partners, provide families the opportunity to access COVID-19 tests that may be otherwise difficult to access. Schools, as trusted community settings, could be critical testing sites—along with faith-based organizations and community health centers—for Cleveland residents who have been disproportionately burdened by COVID-19, especially people of color.

While the CDC does not identify asymptomatic testing as necessary in all instances, it identifies numerous reasons for which school-based testing might be beneficial, as schools are workplaces where "continuity of operations is a high priority" and where faculty, staff, and students may be in close contact.[v]

Importantly, school-based testing has been identified as one of the numerous tools needed to reduce COVID-19 transmission while risk of transmission remains high. As community spread of COVID-19 decreases, CDC guidelines suggest that testing may be scaled back in frequency or all together. **However, at this time of moderate to high levels of community transmission, the CDC encourages at least weekly testing of students, faculty, and staff if a testing program is adopted.**[vi]

TESTING TYPES

Testing for COVID-19 can be employed for one of three purposes—diagnosis, screening, or surveillance—each of which requiring different programmatic considerations.[vii]

Diagnostic testing, most commonly deployed throughout the pandemic, is used for individuals experiencing symptoms of COVID-19 or who otherwise suspect infection based on exposure. If individuals are able to access diagnostic testing, they can determine whether they need to isolate and encourage their contacts to do the same. Without access to diagnostic testing, individuals run the risk of exposing themselves and others to the virus if undetected. In communities facing challenges accessing diagnostic tests in clinical or community-based settings, schools have become sites of diagnostic testing (e.g., Los Angeles Unified School District).[viii]

Screening testing refers to testing that is "intended to identify infected individuals without symptoms (or prior to development of symptoms) who may be contagious so that measures can be taken to prevent further transmission."[ix] Asymptomatic testing is critical to preventing outbreaks because, according to the CDC, **at least half of infections are likely contracted from someone that is asymptomatic or pre-symptomatic**.[x] With school-based screening, routine testing can be used to determine whether students, faculty, and staff are able to continue to attend school safely.

Surveillance testing refers to testing at a group level to determine the prevalence of COVID-19 within that group. Its purpose is not explicitly to isolate or treat individuals, but rather to make decisions depending on COVID-19 risk to that population. For instance, surveillance testing that

determines the positivity rate of COVID-19 illness in school populations has been used in states like New York to determine if schools should remain open.[xi]

Screening testing has been previously discussed as the primary purpose of a testing program implemented in the Cleveland Metropolitan School District (CMSD). This does not preclude the District from offering diagnostic testing to individuals experiencing symptoms, and CMSD and partners will likely want to consider how to make diagnostic testing more readily available to the school population. A focus on screening also does not necessarily preclude the use of surveillance testing to guide school procedures moving forward.

TESTING DESIGN

The District, its clinical partners, funders, and key community stakeholders, must collaboratively decide on the **testing program design**, based on testing type (i.e., diagnostic, screening, surveillance). Design factors are determined by community risk, the District's needs, partners' collective assets, and constraints. The following can help guide decision-making.[xii]

- Which testing strategy is most appropriate based on CMSD's objectives—diagnostic, screening, or surveillance?
- What intensity of testing is needed to match the level of COVID-19 transmission risk within the school community?
- How frequently can and should individuals be tested?
- How many individuals can and should be tested, and which groups should be prioritized?
- Which type of COVID-19 test (i.e., rapid antigen or molecular) should be used, and should testing utilize individual or pooled samples?
- Should individuals self-test?
- Where could tests be administered or collected—home, school, external testing sites, or a combination? Would testing occur at one or multiple sites?

The *Appendix* provides considerations in answering each of these questions—balancing cost, feasibility, acceptability, and efficiency. These considerations are based upon those surfaced by the CDC and the Rockefeller Foundation's *Playbook on School COVID Testing* and are rooted in the scientific evidence and lessons learned by school districts implementing testing programs throughout the country.

TESTING PROTOCOLS and PROCEDURES

Once partners decide on the objectives of and general approach to testing, there are **procedural decisions** to be made, encompassing logistics, compliance, follow-up, communication, and beyond. Much of the protocol relates to legal, regulatory, and public health requirements of COVID-19

testing and disclosure. These requirements exist regardless of the testing approach chosen; however, they may vary based on testing design.

Considerations for conducting a testing program in line with legal, regulatory, and public health requirements include:[xiii]

- Ensuring clear and widespread communication of the testing program and related procedures among school stakeholders, including parents, students, faculty, school-based health care professionals, staff, and administrators.
- Ensuring compliance with state and federal laws for specimen collection, data management, and test reporting.
- Establishing reporting procedures for all tests administered to state and local public health authorities, as mandated by the CARES Act.
- Ensuring efficient and confidential health information exchange between school, clinical, laboratory, and public health agency partners.
- Ensuring compliance with regulatory certification regarding specimen collection and analysis (e.g., Certified Laboratory Improvement Amendment [CLIA] certificate of waiver), if needed.
- Understanding the activities school staff, including school-based health care professionals, are permitted to conduct by law, compared to clinical and laboratory partners.
- Capturing consent or assent of minor students (via parents), adult students, and faculty and staff.
- Creating a **positive COVID-19 test response plan**, which would include:
    - Providing access to molecular (e.g., PCR) testing to confirm diagnosis, if partners choose to use rapid antigen tests;
    - Communicating positive test results to COVID-positive individuals and families, as well as close contacts in the school environment, in compliance with HIPAA, FERPA, and ADA privacy and confidentiality requirements;
    - Communicating positive test results to state and local public health authorities;
    - Conducting contact tracing to determine school-based exposures, as a complement to public health authority activities; and
    - Ensuring isolation of COVID-positive individuals and close contacts, including virtual education contingency plans and supports (e.g., housing alternatives, food, basic needs) to assist those isolating.
- Offering diagnostic tests or referral to diagnostic testing for those exhibiting COVID-19 symptoms or demonstrating risk of exposure.

These legal, regulatory, and public health requirements are specific to COVID-19 testing, yet they do not encompass all logistical and operational considerations in standing up such a program. Additional considerations include personnel to conduct testing, testing vendor identification, test procurement, facility operation, and equipment and supplies (e.g., personal protective equipment).

PROGRAM PLANNING

Given the complexities of successfully conducting a school-based COVID-19 testing program, CMSD and partners should identify a team of stakeholders to advise on program design and coordinate various aspects of the program. Significant and diverse resources also need to be brought to bear, including financial resources, staff resources, material resources (e.g., tests, PPE, laboratory equipment), and intellectual resources (e.g., legal expertise).

The *Playbook on School COVID-19 Testing* identifies a **testing task force** as a critical entity for program planning, implementation, and oversight. The purpose of the task force is to ensure compliance with local and federal public health regulations, feasible implementation with limited resources, and widespread communication and acceptability among school stakeholders, including parents, students, and faculty/staff. The task force serves as the "nerve center" of the testing apparatus—serving as the face of the program and managing the planning, implementation, and communications.

Task force roles could include: school district coordinator, school site coordinator, testing coordinator, COVID-19 testing ambassador, communications lead, vendor management lead, facilities management lead, evaluation lead, and information technology lead. Please consult the *Playbook* for example descriptions of the roles, responsibilities, and example staff members for these partners.

The *Playbook* also underscores the need for partnerships because of the complex logistical and regulatory requirements of testing. Partners are critical to inform testing design, tailor testing to the District's needs, and secure additional staffing and financial resources. Partners might include local public health authorities, local or state government, health care providers, test vendors, clinical/laboratory entities, parents' associations, teacher and staff unions, and community members. Local public health authorities are particularly important to ensure compliance with state and federal laws and requirements for specimen collection and reporting. Community partners also play a key role in offering perspectives that are especially sensitive to needs of parents and families.

POTENTIAL SOURCES OF SUPPORT

Funding sources for screening or surveillance testing programs are varied and unclear. Because either of these testing objectives imply administration to *asymptomatic* individuals, rather than those who have a demonstrated risk of COVID exposure, insurance does not reimburse for the cost of the test procurement and administration.

It may be possible to utilize public sector COVID-19 relief funds to support school-based asymptomatic testing programs through three pathways, each with various direct or indirect limitations:

1.) **Education stabilization funding.** The Elementary and Secondary School Education Relief (ESSER) Fund appropriation, through the CARES Act and the introduced American Rescue Plan, appears flexible in its permissible uses (e.g., preparedness and coordination with public health authorities).[xiv,xv] Some state education agencies (e.g., Wisconsin, Minnesota) have issued guidance that directly or indirectly permits support for school-based testing.[xvi,xvii] State and local education authorities can then deploy funds for testing programs at their discretion. However, school districts undoubtedly grapple with competing priorities as funding is needed to support a host of mitigation measures in place for safe school operation.
2.) **Testing supplies.** COVID-19 tests purchased by the federal government have been distributed to states for allocation. There is no restriction on distributing tests for testing in school-based settings, and federal Department of Health and Human Service and Department of Defense grants have provided testing in school settings (e.g., North Carolina).[xviii] However, to our knowledge, the use of these testing supplies appears limited to diagnostic purposes.
3.) **Other stimulus funds.** Funding in related agencies (e.g., health, economic development) might be applied to a school-based, screening testing program more flexibly through grant opportunities. However, these funding opportunities are not clearly delineated in federal stimulus policies and might require intensive advocacy at state and local levels of government.

While public sector dollars will need to be brought to bear to support a testing program at scale, models of school testing around the country have also utilized philanthropic and private sector support, especially in start-up.[xix]

PILOT PROGRAM CONSIDERATIONS

A pilot program launched during the spring 2021 semester could build necessary infrastructure to enable a scalable testing program, as needed, for the 2021-2022 academic year. CMSD, MetroHealth, and community stakeholders are best equipped to determine which segment of the school population should be involved in such a pilot based on community needs, the District's plan for reopening, and MetroHealth's and CMSD's existing school-based health infrastructure.

Per public health guidance, individuals prioritized for testing might be those most at-risk of contracting or becoming ill from the virus (e.g., faculty, staff, older students, student athletes, students with disabilities).[xx] Pilot schools could be selected based on location in neighborhoods most impacted by COVID-19 and/or by participation in MetroHealth's School Health Program. For instance, Garret Morgan High School is located in one of the two Cleveland ZIP codes reporting over 100 COVID-19 cases in the last 14 days (as of March 2, 2021),[xxi] and it is a participating MetroHealth school-based clinic site. The number of schools (and associated students, faculty, and staff) to be involved in a pilot testing program might be determined by the capacity of MetroHealth and CMSD Nursing & Health Services staff and MetroHealth's laboratories.

APPENDIX: CONSIDERATIONS FOR TESTING DESIGN[xxii]

Which testing strategy makes sense based on the school's objectives—diagnostic, screening, or surveillance?

The following graphic from the *Playbook on School Testing* explains the differences in testing design based on objectives.

OBJECTIVE	DESCRIPTION	PRIORITY CHARACTERISTICS	HOW TO DEPLOY
Clinical Diagnostic	Diagnosing symptomatic individuals or close contacts of those infected for individual clinical decision-making.	Highly accurate and timely results for appropriate clinical treatment (if required) and effective isolation and contact tracing.	**Circumstances:** If an individual presents with symptoms, or has been in close contact of someone who has received a positive test result. **Timeframe:** As soon as possible after symptom development or five to seven days after close contact exposure.
Screening	Routine testing of individuals without symptoms or any reason to suspect exposure. The objective is to reduce transmission by identifying potentially infected individuals faster to protect public health.	For regular routine screening, frequency of retesting and time to results is more important than highly accurate tests; confirmatory tests may be needed for individual clinical decision-making.	**Circumstances:** In a high to moderate risk setting based on risk assessment. **Frequency:** At least once weekly testing with rapid turn-around of results for the entire population (some percentage of the population may not opt-in to testing, which will reduce the effectiveness of this method to break chains of transmission).
Determining Prevalence/ Surveillance	Understanding prevalence in a community to inform workplace, local, or regional policies; individual results are not returned.	Frequency and time to results should be appropriate to allow timely decision-making and course adjustment.	**Circumstances:** In a moderate to low community prevalence. **Frequency:** Once weekly testing or less of a population or a sufficient sample of the population; sample size should be determined based on risk assessment and testing resources in partnership with local health officials.

Even if a testing strategy focuses on asymptomatic individuals, the District **must also** establish pathways for diagnostic testing for students, faculty, and staff with symptoms or risk of exposure.

As an example, a New Orleans school established a partnership with a local hospital to grant priority access to students and staff for diagnostic testing.

What intensity of testing is needed to match the level of COVID-19 transmission risk among the school community?

Knowing that a testing program requires significant investment of staff and financial resources, the appropriate testing program for a given district will be one that calibrates the intensity of testing with COVID-19 risk. The *Playbook* provides a three-pronged approach to assessing risk that includes (1) the likelihood of introducing infection (e.g., the extent of COVID spread in the community); (2) the risk of in-school transmission and outbreak (e.g., the relative strength or weakness of mitigation measures); and (3) the severity of consequences of infection (e.g., families' (in)ability to isolate, risk to family members).

The *Playbook* also provides a risk assessment tool developed by the Duke-Margolis Center for Health Policy and Johns Hopkins Center for Health Security available to assess risk in these three domains.

If CMSD were to identify relatively low risks, testing could be conducted less frequently, with longer turnaround time, and with a random subset of students, faculty, and staff. An assessment indicating higher risk, on the other hand, would indicate the need for testing more frequently, with quicker turnaround, and of as much of the school population as possible.

How frequently can and should individuals be tested?

Schools with testing programs vary in testing frequency, ranging from weekly or biweekly, to bimonthly or intermittently. The CDC recommends that students be tested once per week and faculty and staff tested twice per week during periods of high transmission risk if schools adopt screening testing programs. Frequency can be reduced to weekly tests for faculty and staff and no tests for students in the presence of low community spread and strong mitigation strategies.

How many individuals can and should be tested, and which groups should be prioritized?

If the District identifies the purpose of testing as screening for and disrupting COVID infection, it would be ideal to test as many students, faculty, and staff as possible. This is in comparison to testing for surveillance purposes, which could be accomplished through a random sample of the school population. However, a full-scale screening program would be challenging to implement without a pilot at a smaller scale, given the logistical constraints of standing up and operating a testing program.

The CDC encourages schools to prioritize faculty and staff, given their greater risk of COVID illness and morbidity than students, and high school and middle school students, given their twofold higher incidence of COVID-19 compared to elementary school students. These older groups are more likely

to be able to conduct self-tests in ways that can reduce staffing needs. The CDC also poses options for prioritization by ZIP code, based on highest rates of COVID positivity.

Virtually all schools implementing screening testing programs have done so through an opt-in model, rather than required testing. While the Equal Employment Opportunity Commission (EEOC) permits mandatory COVID testing, it is largely viewed as unethical to mandate these tests.

Which type of COVID test (i.e., molecular or rapid antigen) should be used, and should testing be individual or pooled samples?

For COVID-19 tests that detect active infection (rather than past infection), there are two types: molecular tests (i.e., PCR) or antigen tests (also known as "rapid tests"). They have tradeoffs in accuracy and speed of detection, as exemplified in the figure below. They also differ in price, personnel needed, and mode of specimen collection (e.g., nasal swab, saliva).

TABLE 6 **Summary of Test Type Considerations**

	TEST TYPE		
	PCR		ANTIGEN
FACTOR	INDIVIDUAL PROCESSING	POOLED PROCESSING	INDIVIDUAL PROCESSING
Sample Type	Anterior nasal swab, saliva	Anterior nasal swab, saliva	Anterior nasal swab, saliva
Accuracy	Generally high (but can vary by test*)	Slightly less sensitive than individual PCR for detecting low viral loads, depending upon pool size*	Less capable of detecting low viral loads*
Personnel Needed	Moderate if administrator collected; fewer if self-collected	Moderate if administrator collected. Fewer if self-collected, but pool deconvolution or matrix testing required for positive results	Moderate if administrator collected. Fewer if self-collected. Additional may be needed to load instruments and read and report results
Cost	Highest $25 to $100+ *** per person (lab fee), plus $15 to $20 per person for test administration	Lower $10 to $25 per person (lab fee), plus $15 to $20 per person for test administration Deconvolution/reflex tests may have additional costs.	Lower $5 to $25 per person (test cost), plus $15 to $20 per person for test administration Some tests require purchase of an instrument. Confirmatory tests for positive results, if needed, are additional cost.
Turnaround Time	Generally, 24 to 48 hours**	24 to 48 hours (initial test); possible 24 to 48 additional hours (reflex test)	15 to 30 minutes
Confirmatory Test	Generally not needed	Deconvolution or reflex testing required for positive pools	Confirmatory test recommended for positive tests

* Ask to see real-world performance data for the specific test being used
** Turnaround time could be subject to change based upon demand and capacity. Schools should be aware of this and monitor accordingly. Prices vary and will change as the market evolves.
*** Cost estimates based on input from experts at Health Catalyst

Based on experiences from schools across the country, **the *Playbook* recommends use of the antigen test, given its relatively low cost and quick turnaround time**. In light of limited accuracy, it recommends follow-up, confirmatory molecular (i.e., PCR) tests for those who test positive using the antigen test.

Pooling is a strategy often employed by schools to reduce administrative burden and cost by testing multiple samples simultaneously. When a sample within the pool tests positive, this method requires retesting of all individuals in the pool. Therefore, the pooling method is only advantageous if there is (1) relatively low COVID-19 prevalence in the community and (2) the existence of natural pods of individuals (e.g., homerooms, sports teams) that would be considered close contacts to be tested and potentially isolated anyways in the case of a positive result.

Does it make sense for individuals to self-test? Where could tests be administered and/or collected -- home, school, external testing sites, or a combination? Should testing be done at one or multiple sites?

Both molecular and antigen testing provide opportunity for tests to be self-administered, reducing staffing burden. However, the District would need to seek regulatory clarification as to whether or not subjects can administer the test without the presence of a trained observer, which would dictate whether or not it would be possible to administer these tests at home rather than school. It also appears that health care professionals are required for processing and analyzing test results.[xxiii,xxiv] Self-testing is recommended for staff and older students, whereas a professionally administered test is recommended for younger students.

Testing sites thus may include school, home, or external testing site. For school and external testing sites, the District and its clinical partners may choose to employ a centralized or decentralized point(s) of test administration and/or collection. This would be dependent on staffing resources, (in)efficiencies created through centralization, etc. If the District opts to administer or process tests on-site, it will need to obtain a Clinical Laboratory Improvement Amendment (CLIA) certificate of waiver.

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