

# Implementation and Performance of a Point-of-Care COVID-19 Test Program in 4000 California Schools

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**Objective** To evaluate the feasibility and accuracy of an unprecedented COVID-19 antigen testing program in schools, which required a healthcare provider order, laboratory director, a Clinical Laboratory Improvement Amendments certificate of waiver, as well as training of school personnel.

**Study design** Descriptive report of a point-of-care, school-based antigen testing program in California from August 1st, 2021 through May 30, 2022, in which participants grades K-12 self-swabbed and school personnel performed testing. Participants included 944 009 students, personnel, and community members from 4022 California kindergarten through high schools. Outcomes measured include sensitivity and specificity (with polymerase chain reaction [PCR] as comparator) of the Abbott BinaxNOW antigen test, number of tests performed, and active infections identified.

**Results** Of 102 022 paired PCR/antigen tests, the overall sensitivity and specificity for the antigen test was 81.2% (95% CI: 80.5%-81.8%) and 99.6% (95% CI: 99.5%-99.6%), respectively, using cycle threshold values <30. During January through March 2022, the highest prevalence period, the positive predictive value of antigen testing was 94.7% and the negative predictive value was 94.2%. Overall, 4022 school sites were enrolled and 3 987 840 million antigen tests were performed on 944 009 individuals. A total of 162 927 positive antigen tests were reported in 135 163 individuals (14.3% of persons tested).

**Conclusions** Rapidly implementing a school-based testing program in thousands of schools is feasible. Self-swabbing and testing by school personnel can yield accurate results. On-site COVID-19 testing is no longer necessary in schools, but this model provides a framework for future infectious disease threats. (*J Pediatr* 2024;274:114178).

ore than 150 countries initiated school closures as a strategy for reducing SARS-CoV-2 spread early in the COVID-19 pandemic. Although most schools offered remote learning, lack of in-person instruction resulted in academic losses and other negative, unintended consequences. Further, school closures disproportionately impacted children from underserved communities. <sup>2,3,6</sup>

Both the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics recommended layered mitigation measures to decrease the risk of COVID-19 infections during resumption of in-person instruction. School-based testing can facilitate safe in-person learning as it can both confirm symptomatic cases and identify asymptomatic infections. Strong evidence for testing utility was provided by Young et al, who demonstrated that frequent testing of COVID-19 exposed students was a safe alternative to home quarantine, thereby keeping students in school. However, there has been limited experience with school-based testing as well as reliability of testing performed by nonmedical, school personnel.

Testing using point-of-care antigen tests requires adhering to state and federal regulations and obtaining a Clinical Laboratory Improvement Amendments (CLIA) waiver certification. Over-the-counter (OTC) SARS-CoV-2 antigen tests

CLIA Clinical Laboratory Improvement Amendments
CDPH California Department of Public Health
CDC Centers for Disease Control and Prevention

Ct Cycle Threshold

K-12 Kindergarten through high schools

NPV Negative predictive value

OTC Over-the-counter

PCR Reverse transcriptase polymerase chain reaction

PPV Positive predictive value

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0022-3476/\$ - see front matter. Published by Elsevier Inc https://doi.org/10.1016/j.jpeds.2024.114178 were not widely available until the Spring of 2022, and importantly, when antigen testing is performed on someone other than oneself or by a legal guardian, a CLIA waiver is required. In January 2021, the California Department of Public Health (CDPH) with the Public Health Institute, initiated a pilot program in selected schools that serve kindergarten through high schools grade 12 (K-12) to determine the optimal approach to implementing professional, on-site antigen testing in schools. By May 2021, in partnership with educational leaders and the PHI, CDPH developed a scalable, comprehensive antigen testing program to support school operations for the 2021-22 school years.

In the fall of 2021, when many schools in California began reopening, CDPH offered schools a choice of the following no-cost, voluntary, testing programs: (1) antigen testing program; (2) reverse transcriptase polymerase chain reaction (PCR) program; or (3) pooled PCR program. This report summarizes the results of the CDPH School Antigen Testing Program, herein after referred to as Antigen Program, to describe the feasibility, scalability, and effectiveness of the program. This report also illustrates the ease and utility of self-swabbing by participants, describes demographic participant characteristics and demonstrates antigen test performance for different variants.

## **Methods**

#### **Setting and Participants**

Public, private and charter K-12 schools in California were invited to participate in the Antigen Program. Los Angeles County received separate federal funding to create its own program and during the transition period, a few Los Angeles County schools participated in the CDPH Antigen Program. The CDPH recommended, but did not require, school-based COVID-19 testing in California.

The Antigen Program allowed schools to test students, school personnel, and school-associated community members (eg, volunteers or siblings). Schools could test members from the school community for any indication, examples including on-campus visitors, and family members of exposed or confirmed cases in staff and students. In limited circumstances, when a licensed healthcare provider was available and with an additional consent, samples could be collected from the youngest participants (2 years through 4 years, 9 months). Individuals younger than 2 years were generally excluded; however, exceptions were made for sibling close contacts.

#### **Program Implementation**

The pilot testing program in January 2021-May 2021 identified several components needed for rapid and effective program implementation: a streamlined statewide CLIA waiver for regulatory compliance to meet state and federal requirements, in-depth training for schools on testing methodologies, specimen collection options, and finally, a mechanism for enrolling participants and for reporting test results to health departments and to participants.

## **State Regulatory Oversight and Accountability**

The Antigen Program provided schools a test order from a health care provider (the State Epidemiologist), oversight from a statewide laboratory director who met California state requirements, use of a CLIA certificate of waiver, professional antigen tests, and access to a digital enrollment reporting platform. To enroll, each school district or school was required to (1) participate in CDPH virtual antigen testing training; (2) utilize CDPH-developed consents for testing (>12 years of age and for the legal guardians of younger students); and (3) use the digital platform for reporting to health department and participants.

## **School-Personnel Training and Roles**

Testing teams were comprised primarily of nonmedical CDPH-trained school personnel, such as registrars, principals, administrators, and teachers. The CDPH virtual training included instruction on the science of lateral flow tests, laboratory techniques and running the test, personal protective equipment requirements, and quality control protocols. Schools were sent Abbot BinaxNOW testing kits, each including 40 test cards, swabs, and one positive control swab. Additional positive control swabs were sent to large training groups. Participants were required to perform positive and negative controls on video during the training, pass the competency quiz and review the CDPH K-12 School Antigen Playbook. Optional, weekly, virtual "Frequently Asked Questions" sessions were available to address questions from school personnel. <sup>10</sup>

For a limited subset of schools, CDPH contracted with testing vendors using federal grant funds earmarked for school testing to provide personnel to support on-site testing. These included schools that served communities with greater uninsured and underinsured populations as determined by a set of equity metrics including percent free lunch eligible students, Healthy Places Index and rurality. Vendors were monitored by number of tests completed and by school district satisfaction surveys. In some cases of public health response, vendors working with health departments were used at schools experiencing outbreaks. In these scenarios, additional voluntary testing was available to school and school community members.

#### **Test Collection**

Abbott BinaxNow professional antigen tests were used at schools. Early in each school's Antigen Program, we encouraged testers to send confirmatory PCR testing that required a second self-swab for both positive (all tests) and negative tests (a random sampling of those who were exposed or symptomatic) to provide information on the quality of antigen testing for the first few weeks of testing. We also encouraged sending PCR tests when there was any uncertainty around antigen results. Samples were sent via delivery services or a state-funded drop box service to the laboratory.

The CDPH's Valencia Branch Laboratory performed PCR testing from September 2021-May 2022. In May 2022, molecular tests (both PCR and reverse transcriptase

loop-mediated isothermal amplification tests) were then performed by the CDPH laboratory network coordinated by Color Health, Inc.

Nasal swabs were collected either by a licensed healthcare professional or by the participant. Since most schools did not have healthcare professionals on site, most children aged 4 years and 9 months and older utilized a self-swabbing method for both antigen, and when needed, PCR sample collection. We developed a video with young children demonstrating self-swabbing that was shared widely. 11

Testing practices (ie, frequency, reason for testing such as surveillance or symptomatic testing, when to send PCR test) varied widely across schools. Schools variably documented the presence or absence of symptoms. Specific state, local health, and school district testing guidance changed over time.

## **Electronic Data Reporting**

Schools that participated in the Antigen Program reported test results, both positive and negative, to their respective local health departments and to CDPH via the digital platform, Primary Diagnostics. This platform was customized from an existing platform to meet both State regulations and our programs particular needs. Results were reported from electronic devices (eg, tablet, smart phone or laptop) in real-time. Schools were encouraged to upload a photograph of individual antigen cards into the digital platform for quality control purposes.

Our data include antigen test results from August 1, 2021 to May 30, 2022 reported through the digital platform. Demographic information, including date of birth, race/ethnicity, and sex were self-reported by participants during program enrollment.

#### **Variant Predominance**

SARS-CoV-2 variant predominance was defined as >50% of positive samples belonging to a single SARS-CoV-2 variant in California. Delta variant predominated in California May 20, 2021 to December 12, 2021; Omicron predominated after December 20, 2021.<sup>13</sup>

#### **Data Analysis**

We described antigen testing volume and participants by age, sex, race/ethnicity, rural-urban classification, and district/school type (public, private, charter). We analyzed and mapped regional testing rates among participating public school students with population denominator data from the California Department of Education (charter and private schools were excluded due to lack of denominator data available). Geographical boundaries were defined by California Regional Public Health Office Regions. Using data from the California Health and Human Services Open Data Portal, we compared weekly, statewide PCR percent positivity with the Antigen Program's test positivity from August 2021 to May 2022.

We assessed antigen test sensitivity and specificity using paired antigen/PCR results. Results were included in the

analysis if a PCR sample was collected within 2 days of the antigen sample. We stratified antigen test performance by age of participants, SARS-CoV-2 variant predominance (ie, Delta or Omicron) and by cycle threshold (Ct) value. The Ct threshold value <30 was chosen due to the correlation of higher viral loads and greater infectiousness. 17 Positive PCR results included 2 Ct values; one from the nucleocapsid genetic target and a second from the open reading frame genetic target. Because these targets are very similar, we averaged the 2 Ct values for each positive PCR result for inclusion in the analysis. 18 We excluded PCR results if one of the 2 Ct values was zero. In calculating the positive predictive value (PPV) and negative predictive value (NPV), we excluded community participants from the overall prevalence calculations as they were not defined as the population of interest for our study.

We analyzed data using SAS, version 9.4 (SAS Institute Inc, http://www.sas.com). Sensitivity and specificity estimates, including large-sample 95% confidence intervals (95% CIs), were generated using SAS/STAT 15.1 analytical products. We mapped geographic testing data with ArcMap, version 10.8.1 (Esri).

This Antigen Program received a nonresearch determination from the California Committee for the Protection of Human Subjects. We followed the SQUIRE 2.0 reporting guidelines.<sup>19</sup>

## Results

## **Testing Program Impact**

From August 2021 to May 2022, the Antigen Program was implemented in 907 school districts, charter and private schools, leading to COVID-19 testing performance at 4022 unique school sites throughout California; 2712 of these sites were enrolled within a 3-month period. More than 300 virtual training sessions over Zoom were conducted with approximately 6000 school personnel members. Sites included 3232 (80.4%) public schools, 560 (13.9%) private schools, and 230 (5.7%) charter schools distributed throughout California. Among enrolled school districts, 241 districts received additional state support to provide personnel for testing as determined by equity metrics. Of California's 57 counties, only one small rural county was not represented in our program. We observed the highest antigen testing rate in the Northern California region and the lowest rate in the San Joaquin Valley region with 2813 tests per 1000 students and with 582 tests performed per 1000 students, respectively. Testing rates differed over time because of viral prevalence and program enrollment; however, regional differences were similar throughout the Program (Figure 1).

Antigen results were reported for 944 009 individuals, including 705 435 (74.7%) students, 197 842 (21.0%) school personnel, and 40 732 (4.3%) community members. Of 3 987 840 antigen tests performed, most (2 848 216; 71.4%) were performed on students, 1 081 650 (27.1%) on school personnel, and 57 974 (1.5%) on community members.

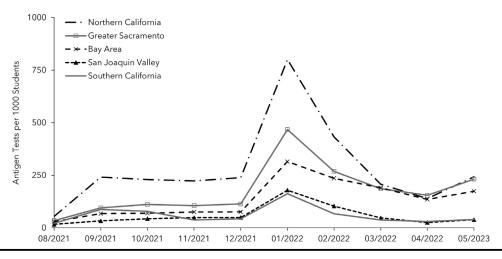


Figure 1. Monthly antigen tests performed per 1000 Public School students by California Local Health Officer Regions, August 2021-May 2022. California Local Health Officer Regions include Northern California, Greater Sacramento, Bay Area, San Joaquin Valley, and Southern California. Los Angeles was excluded from numerator and denominator of this calculation.

The median number of tests performed per participant was 2 (IQR: 1-4); 42.7% (402 746) of participants were tested once; 34.1% (321 529) were tested 2-4 times and 23.3% (219 734) were tested 5 or more times.

The largest proportion (n = 311793; 44.2%) of participants were children between 5 and 10 years of age. Most student participants were from public school districts in urban settings (Table I). Test positivity across all sites ranged from a low of 0.6% during the week ending October 2, 2021 to a high of 12.1% the week ending January 22, 2022, (Figure 2) during the California Omicron surge. From August 2021 from May 2022, 162 927 positive antigen tests were reported in 135 163 individuals (14.3% of persons tested). Of the COVID-19 positives, 93 083 (68.9%) were students, 33 758 (25.0%) were school personnel and 8322 (6.2%) were community members. Among positive antigen tests, 91 141 (67.4%) occurred in January 2022. When community members were tested, which included family members of positive cases in school, their rate of test positivity was often higher (Supplemental Figure 1, online; available at www.jpeds.com).

#### Point-of-Care Antigen Test Performance

From August 2021 from May 2022, schools performed 106 622 paired antigen/PCR tests. Using PCR as the comparator, antigen test sensitivity and specificity was 66.9% (95% CI: 66.2%-67.6%) and 99.6% (95% CI: 99.5%-99.6%), respectively (**Table II**), and were relatively constant across age groups. Antigen test sensitivity increased to 81.2% (95% CI: 80.5%-81.8%) across 102 023 PCR paired tests when PCR Ct values <30. Sensitivity was 70.6% (95% CI: 69.2%-72.0%) during Delta variant predominance and decreased to 65.9% (95% CI: 65.1%-66.7%) during Omicron variant predominance. Modest differences were noted in antigen sensitivity with PCR Ct values <30 during Delta and Omicron variant predominance (**Table II**). Concordant antigen-PCR results

had a median PCR Ct value of 19.3 (IQR: 16.4-22.6) compared with discordant antigen-PCR results which had a median PCR Ct value of 30.5 (IQR 25.9-34.4) (Figure 3). During January-March 2022, the highest prevalence period, PPV was 94.7% and the NPV was 94.2% (Supplemental Table 1, online; available at www.jpeds.com). The cost to administer this program was approximately \$2.85 per antigen test, excluding the cost of personnel (Supplemental Table 2, online; available at www.jpeds.com).

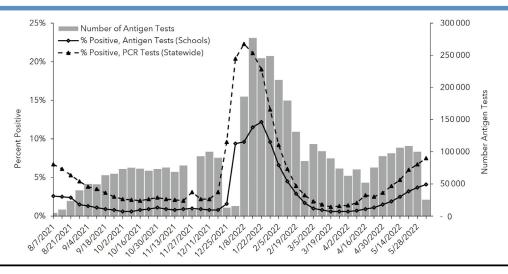
## **Discussion**

The Antigen Program resulted in rapid implementation, large-volume capability, professional on-site SARS-CoV-2 testing in California school communities during the 2021-2022 school years. By providing schools with essential resources such as training, technical assistance, and regulatory support, thousands of K-12 schools were able to quickly adopt and effectively implement professional, on-site antigen testing. Equity was a core rationale for the inception of this program, as access to healthcare often is limited in resource poor areas. By encouraging all schools to participate and providing additional personnel support for the most vulnerable school populations, we enhanced access to communities with fewer testing options. The Antigen Program was far reaching, serving a racially and ethnically diverse group of students, school personnel and community members throughout California. As the Delta variant surged in the Fall of 2021, the demand for testing was high and over 60% of schools enrolled within a 3-month period.<sup>20</sup> Approximately one-third of schools in California (4000 school sites) participated in the voluntary program. Despite the unprecedented nature of this program, test results were reliable, with specificity approaching 100% and high sensitivity in individuals with high viral loads. A decrease in test sensitivity was

Table I. Characteristics of student and staff participants and distribution of rapid antigen tests performed during California school antigen testing program, August 2021-May 2022

Characteristic	Students		Staff	
	N (%) (n = 705 435)	Tests, N (%) (n = 2 848 216)	N (%) (n = 197 842)	Tests, N (%) (n = 1 081 650)
Age				
0-4 years (Preschool)	11 072 (1.6)	26 788 (0.9)	-	-
5-10 years (Elementary)	311 793 (44.2)	1 324 025 (46.5)	-	-
11-14 years (Middle)	224 710 (31.9)	910 861 (32.0)	-	-
15-18 years (High)	157 860 (22.4)	586 542 (20.6)	-	-
19-49 years	- ' '	<u>-</u> ' ' '	138 279 (69.9)	743 810 (68.8)
50-64 years	-	-	51 915 (26.2)	297 993 (27.5)
65+ years	-	-	7648 (3.9)	39 847 (3.7)
Gender			, ,	,
Female	311 010 (44.1)	1 282 890 (45.0)	136 480 (69.0)	768 794 (71.1)
Male	327 977 (46.5)	1 349 663 (47.4)	47 847 (24.2)	238 715 (22.1)
Non-Binary	2559 (0.4)	11 286 (0.4)	652 (0.3)	4373 (0.4)
Transgender Female	122 (0.0)	518 (0.0)	20 (0.0)	126 (0.0)
Transgender Male	410 (0.1)	1483 (0.1)	47 (0.0)	259 (0.0)
Other	446 (0.1)	1978 (0.1)	137 (0.1)	837 (0.1)
Did Not Disclose	62 911 (8.9)	200 428 (7.0)	12 659 (6.4)	68 546 (6.3)
Race/Ethnicity	` ,	` '	` ,	, ,
Native American/Alaskan	4090 (0.6)	22 994 (0.8)	980 (0.5)	6839 (0.6)
Asian	54 421 (7.7)	264 492 (9.3)	11 503 (5.9)	57 586 (5.3)
Black	29 669 (4.2)	147 772 (5.2)	9045 (4.6)	52 243 (4.8)
Hispanic All Races	279 400 (39.6)	1 046 472 (36.7)	63 493 (32.1)	320 132 (29.6)
Multi-Race Non-Hispanic	37 295 (5.3)	205 501 (7.2)	5565 (2.8)	31 088 (2.9)
Native Hawaiian/Pacific Islander	2336 (0.3)	12 132 (0.4)	597 (0.3)	2792 (0.3)
Other	82 866 (11.8)	268 648 (9.4)	12 775 (6.5)	52 057 (4.8)
White	148 527 (21.1)	645 600 (22.7)	73 071 (36.9)	431 901 (39.9)
Did Not Disclose	66 831 (9.5)	234 605 (8.2)	20 813 (10.5)	127 012 (11.7)
Population Density				
Urban	462 171 (65.5)	2 057 585 (72.2)	135 990 (68.7)	723 246 (66.9)
Suburban	174 670 (24.8)	460 129 (16.2)	42 452 (21.5)	230 886 (21.4)
Rural	68 594 (9.7)	330 502 (11.6)	19 400 (9.8)	127 518 (11.8)
District/School Type	. ,	• •		, ,
Public	607 716 (86.2)	2 349 570 (82.5)	169 190 (85.5)	925 514 (85.6)
Private	54 826 (7.8)	285 804 (10.0)	17 418 (8.8)	103 196 (9.5)
Charter	36 586 (5.2)	199 700 (7.0)	7851 (4.0)	46 710 (4.3)
Public Health Response*	6307 (0.9)	13 142 (0.5)	3383 (1.7)	6230 (0.6)

<sup>\*</sup>Refers to ad hoc testing performed by Public Health Departments at school sites to contain an active COVID-19 outbreak.



**Figure 2.** School antigen program test volume and positivity compared with California Health and Human Services Statewide PCR Positivity, August 2021-May 2022 by week. Weekly California PCR percent positivity from the California Health and Human Services open data portal.

Table II. Sensitivity and specificity of antigen tests with PCR as comparator by Participant age, SARS-CoV-2 variant predominance and cycle threshold (CT) value in the California School antigen testing program, August 2021-May 2022

Characteristics	Paired Tests, N	Sensitivity (95% CI)	Specificity (95% CI)
Age			
All age groups	106 622	66.9 (66.2-67.6)	99.6 (99.5-99.6)
0-4 years	2450	67.1 (62.2-72.0)	99.2 (98.8-99.6)
5-10 years	40 632	67.9 (66.6-69.2)	99.6 (99.5-99.6)
11-14	17 799	68.8 (67.2-70.4)	99.5 (99.4-99.6)
15-18	11 892	67.9 (65.9-69.9)	99.7 (99.6-99.8)
Adults 19+	33 849	65.2 (64.1-66.3)	99.6 (99.5-99.7)
Age and Variant Predominance		(* * * * * * * * * * * * * * * * * * *	,
Delta*			
All age groups	55 972	70.7 (69.3-72.1)	99.7 (99.6-99.7)
0-4 years	1429	55.1 (44.1-66.2)	99.0 (98.4-99.5)
5-10 years	25 788	69.2 (66.8-71.6)	99.6 (99.6-99.7)
≥11 years	28 755	71.9 (70.2-73.7)	99.8 (99.7-99.8)
Omicron*		,	,
All age groups	50 650	65.9 (65.1-66.7)	99.4 (99.3-99.5)
0-4 years	1021	70.6 (65.2-75.9)	99.6 (99.1-99.9)
5-10 years	14 844	67.4 (65.9-69.0)	99.4 (99.2-99.5)
≥11 years	34 785	65.2 (64.3-66.1)	99.4 (99.3-99.5)
Age and CT Value <30		,	,
All age groups	102 023	81.2 (80.5-81.8)	99.6 (99.5-99.6)
0-4 years	2350	81.8 (77.1-86.6)	99.2 (98.8-99.6)
5-10 years	39 469	83.3 (82.1-84.5)	99.6 (99.5-99.6)
≥11 years	60 204	80.3 (79.5-81.1)	99.6 (99.5-99.7)
Age, Variant Predominance and CT Value <30		,	,
Delta*			
All age groups	55 230	85.9 (84.7-87.1)	99.7 (99.6-99.7)
0-4 years	1406	76.4 (65.1-87.6)	99.0 (98.4-99.5)
5-10 years	25 506	86.0 (84.0-88.1)	99.6 (99.6-99.7)
≥11 years	28 318	86.0 (84.5-87.5)	99.8 (99.7-99.8)
Omicron*		,	,
All age groups	46 793	79.7 (78.9-80.5)	99.4 (99.3-99.5)
0-4 years	944	83.3 (78.1-88.5)	99.6 (99.1-99.9)
5-10 years	13 963	82.2 (80.8-83.6)	99.4 (99.2-99.5)
≥11 years	31 886	78.6 (77.7-79.6)	99.4 (99.3-99.5)

\*Delta variant predominance in California was during 08/01/2021-12/20/2021; Omicron predominance includes tests with a date of 12/21/2021 or later.

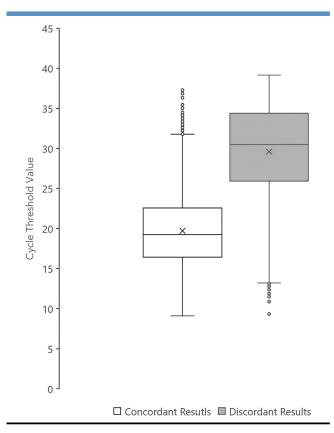
observed, however, during the Omicron variant surge, which also corresponded with the highest test-positivity rate of over 12.5%. Ultimately, over 150 000 active infections were identified, allowing for immediate exclusion of students and school personnel and initiation of rapid contact investigation potentially reducing new infections and preventing outbreaks. 9,21-23

The goal of school-based testing was to reduce transmission of COVID-19 while preserving in-person instruction. Rapid detection of infectious persons through antigen testing increasingly became the preferred modality of COVID-19 testing in K-12 settings. While PCR is highly sensitive and unlikely to miss infected individuals, PCR testing can lead to exclusion of individuals whose initial infectious period was weeks prior to testing. <sup>24,25</sup> Furthermore, PCR testing is performed off-site with turnaround times of at least 1-3 days. <sup>26</sup> Schools that opted for the Antigen Program benefited from the real-time isolation of infectious individuals with high viral loads, as well as enabling rapid contact tracing. <sup>17,27-29</sup>

The use of nonmedical, nonlaboratory personnel for widescale testing in schools was unprecedented. As we learned in our pilot phase, school personnel were initially wary about performing testing, as most did not have a healthcare or laboratory background. To address this, we required testers to participate in a rigorous web-based training and to pass a competency quiz. As a result, test performance within our program as measured by over 81 000 paired tests, was on-par with those found in health care and community settings with similar sensitivities (around 60% overall, 80% using Ct <30) and specificities (99%).  $^{30-33}$  Specificity throughout the study remained high; however, in the setting of low prevalence, even a relatively high specificity could result in false-positive results.  $^{34}$ 

Heavy reliance on self-swabbing for specimen collection in schools also was unprecedented. At the time we started the Antigen Program there were limited data on the effectiveness of this sampling strategy with just a single study of 163 children. Anticipating the need for cultural change, we created and widely distributed an age-appropriate educational video demonstrating self-swabbing by children. The sampling technique in our cohort was effective and, remarkably, over 40 000 participants were 5 years of age or younger. The success of self-swabbing subsequently has been reported by others. 36-38

An uncertainty we faced during our program was how emerging variants would affect the accuracy of antigen testing. Published literature suggested similar performance when comparing Delta vs Omicron viruses. <sup>39-41</sup> However, we found



**Figure 3.** Box plot of antigen test concordance with paired, positive PCR test results (n = 16 692) among participants in the California School antigen testing program, August 2021-May 2022.

antigen test performance decreased with the Omicron variant. Based on nonoverlapping confidence intervals, tests performed during Omicron predominance had a lower sensitivity than those performed during Delta predominance. The reason for the apparently lower sensitivity during the Omicron wave is unknown but could be due to immune and viral factors such as a lower viral load, higher vaccination coverage, prior infection or may be related to unique factors of our program, such as excess testing volume affecting quality.<sup>42</sup>

There are several limitations to this report. Practices varied across schools as to when confirmatory PCRs were ordered. For example, early in their respective testing programs, some schools ran both PCR and antigen tests on every symptomatic child, some schools confirmed every positive antigen test, whereas other schools only sent PCR on symptomatic exposed people who tested negative by antigen. These variable practices could lead to false negatives or positives. In addition, we were unable to determine how well self-swabbing performed in certain populations as both the antigen and PCR samples were collected by self-swabbing. Children were tested more than adults, which may have led to differences in sampling quality. Finally, participating schools may have had more resources because on-site testing requires

more personnel, which may limit the generalizability of this study. However, schools from almost all settings, rural and urban, and nearly all counties in California were represented. Anecdotally, schools communicated their value of this program, but we were unable to systematically measure the overall program satisfaction. Ideally a comprehensive cost analysis and the impact of transmission would be important for future similar programs.

Point-of-care antigen testing under a centralized model for schools is a powerful and unprecedented strategy to improve testing access for the school community. In California this model resulted in over 4000 participating school sites. A similar approach was used in other community settings in California, including homeless shelters, senior centers, and assisted living facilities.

At the start of the 2022-2023 school years, most K-12 schools transitioned from administering on-site tests at school to distributing OTC tests for home-use. Notwith-standing this transition to OTC, the Antigen Program provides a model for future outbreaks for which OTC tests are not readily accessible. Our program demonstrates that a strong relationship between schools and public health entities can result in rapidly expanding access to testing in school communities. By providing training, technical assistance, and regulatory support, on-site testing is a feasible and accurate way to mitigate disease transmission in K-12 schools. A similar program may be needed for future epidemics or pandemics such as that may occur with a novel influenza virus.

## **CRediT authorship contribution statement**

Chloe Le Marchand: Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Kyle Rizzo: Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. Robert Nakamura: Writing - original draft, Validation, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Lea Bornstein: Writing - original draft, Supervision, Project administration, Methodology, Investigation, Conceptualization. Naomi S. Bardach: Writing – review & editing, Supervision, Project administration, Methodology, Conceptualization. Daniel Pritchard: Writing - review & editing, Resources, Investigation, Data curation. Stefanie Medlin: Writing - review & editing, Resources, Investigation, Data curation. Ayella Ahmed: Writing - review & editing, Resources, Investigation, Data curation. **Megan Cornejo:** Writing – review & editing, Resources, Investigation, Data curation. Lea Moser: Writing – review & editing, Resources, Investigation, Data curation. Omid Bakhtar: Writing - review & editing, Methodology, Conceptualization. Lynn D. Silver: Writing – review & editing, Methodology, Investigation, Funding acquisition, Data curation,

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## **Declaration of Competing Interest**

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The other authors declare no conflicts of interest.

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## References

- UNICEF. COVID-19 and School Closures: one year of education disruption. UNICEF; 2021. Accessed July 24, 2024. https://data.unicef.org/resources/one-year-of-covid-19-and-school-closures/
- Christakis DA, Van Cleve W, Zimmerman FJ. Estimation of US children's educational attainment and years of life lost associated with primary school closures during the coronavirus disease 2019 pandemic. JAMA Netw Open 2020;3:e2028786.
- Hawrilenko M, Kroshus E, Tandon P, Christakis D. The association between school closures and child mental health during COVID-19. JAMA Netw Open 2021;4:e2124092.
- Kroman HTN, O'Keefe B, Repka M. Missing in the Margins 2021: Revisiting the COVID-19 Attendance Crisis. Bellweather Education Partners; 2020. Accessed July 24, 2024. https://bellwether.org/publications/missing-in-the-margins-2021-revisiting-the-covid-19-attendance-crisis/

- Rajmil L, Hjern A, Boran P, Gunnlaugsson G, Kraus de Camargo O, Raman S. Impact of lockdown and school closure on children's health and well-being during the first wave of COVID-19: a narrative review. BMJ Paediatr Open 2021;5:e001043.
- Engzell P, Frey A, Verhagen MD. Learning loss due to school closures during the COVID-19 pandemic. Proc Natl Acad Sci U S A 2021;118:e2022376118.
- CDC. Operational guidance for K-12 schools and early care and education programs to support safe in-person learning. Center for Disease Control; 2021. Accessed July 24, 2024. https://archive.cdc.gov/www\_cdc\_gov/coronavirus/2019-ncov/community/schools-childcare/k-12-childcare-guidance.html
- 8. AAP. COVID-19 guidance for safe schools and promotion of in-person learning. American Academy of Pediatrics; 2021. Accessed July 24, 2024. https://archive.cdc.gov/#/details?url=https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-childcare-guidance.html
- 9. Young BC, Eyre DW, Kendrick S, White C, Smith S, Beveridge G, et al. A cluster randomised trial of the impact of a policy of daily testing for contacts of COVID-19 cases on attendance and COVID-19 transmission in English secondary schools and colleges. medRxiv 2021. https://doi.org/10.1101/2021.07.23.21260992
- CDPH. California K-12 antigen testing program playbook: California Department of Public Health. 2021. Accessed June 1, 2024. https:// www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20 Library/COVID-19/School-Based-Antigen-Testing-Playbook.pdf
- CDPH. COVID-19 testing: Demonstration of self swabbing for students. California Department of Public Health; 2021. Accessed July 24, 2024. https://www.youtube.com/watch?v=DU\_G-D\_sL3I
- 12. Primary. Health. Accessed April 12, 2024. https://primary.health/
- CDPH. California department of public health SARS-CoV-2 variants in California. Accessed September 1, 2022. https://covid19.ca.gov/variants/
- Public Schools and Districts Data Files. In: Education CDo. California Department of Education; 2021. Accessed July 24, 2024. https://www.cde.ca.gov/ds/si/ds/pubschls.asp
- CDPH. Regional public health office. Accessed April 12, 2024. https://www.cdph.ca.gov/Programs/RPHO
- Statewide COVID-19 Cases Deaths Tests. In: Sets COD. California Health and Human Services Open Data Portal; 2021-2022. Accessed July 24, 2024. https://data.chhs.ca.gov/dataset/covid-19-time-seriesmetrics-by-county-and-state/resource/046cdd2b-31e5-4d34-9ed3-b48c dbc4be7a
- 17. Bullard J, Dust K, Funk D, Strong JE, Alexander D, Garnett L, et al. Predicting infectious severe acute respiratory syndrome coronavirus 2 from diagnostic samples. Clin Infect Dis 2020;71:2663-6.
- Sahoo MK, Huang C, Sibai M, Solis D, Pinsky BA. Harmonization of SARS-CoV-2 reverse transcription quantitative PCR tests to the first WHO international standard for SARS-CoV-2 RNA. J Clin Virol 2022;154:105242.
- SQUIRE. SQUIRE 2.0 guidelines. Accessed April 12, 2024. https://www.squire-statement.org/index.cfm?fuseaction=page.viewPage&pageID=471&nodeID=1#notes
- CDPH. California department of public Helath COVID-19 vaccination data. Accessed September 1, 2022. https://www.cdph.ca.gov/Programs/ CID/DCDC/Pages/COVID-Vaccine-Data.aspx
- Mathematica. Implementing routine COVID-19 testing in schools can significantly reduce (and in some cases eliminate) transmission. Mathematica; 2021. Accessed July 24, 2024. https://www.mathematica.org/ news/implementing-routine-covid-19-testing-in-schools-can-significantlyreduce-and-in-some-cases
- 22. Volpp KG, Kraut BH, Ghosh S, Neatherlin J. Minimal SARS-CoV-2 transmission after implementation of a comprehensive mitigation strategy at a school New Jersey, August 20-November 27, 2020. MMWR Morb Mortal Wkly Rep 2021;70:377-81.
- 23. Lanier WA, Babitz KD, Collingwood A, Graul MF, Dickson S, Cunningham L, et al. COVID-19 testing to Sustain in-person instruction and extracurricular activities in high schools Utah, November 2020-March 2021. MMWR Morb Mortal Wkly Rep 2021;70:785-91.
- 24. Piralla A, Ricchi M, Cusi MG, Prati P, Vicari N, Scarsi G, et al. Residual SARS-CoV-2 RNA in nasal swabs of convalescent COVID-19

patients: is prolonged quarantine always justified? Int J Infect Dis 2021;102:299-302.

- 25. Hong K, Cao W, Liu Z, Lin L, Zhou X, Zeng Y, et al. Prolonged presence of viral nucleic acid in clinically recovered COVID-19 patients was not associated with effective infectiousness. Emerg Microbes Infect 2020;9:2315-21.
- 26. Kretzschmar ME, Rozhnova G, Bootsma MCJ, van Boven M, van de Wijgert J, Bonten MJM. Impact of delays on effectiveness of contact tracing strategies for COVID-19: a modelling study. Lancet Public Health 2020;5:e452-9.
- 27. Pilarowski G, Marquez C, Rubio L, Peng J, Martinez J, Black D, et al. Field performance and public health response using the BinaxNOWTM rapid Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen detection Assay during community-based testing. Clin Infect Dis 2021;73:e3098-101.
- 28. La Scola B, Le Bideau M, Andreani J, Hoang VT, Grimaldier C, Colson P, et al. Viral RNA load as determined by cell culture as a management tool for discharge of SARS-CoV-2 patients from infectious disease wards. Eur J Clin Microbiol Infect Dis 2020;39:1059-61.
- Singanayagam A, Patel M, Charlett A, Lopez Bernal J, Saliba V, Ellis J, et al. Duration of infectiousness and correlation with RT-PCR cycle threshold values in cases of COVID-19, England, January to May 2020. Euro Surveill 2020;25:2001483.
- **30.** Pilarowski G, Lebel P, Sunshine S, Liu J, Crawford E, Marquez C, et al. Performance characteristics of a rapid severe acute respiratory syndrome coronavirus 2 antigen detection assay at a public plaza testing site in San Francisco. J Infect Dis 2021;223:1139-44.
- Sood N, Shetgiri R, Rodriguez A, Jimenez D, Treminino S, Daflos A, et al. Evaluation of the Abbott BinaxNOW rapid antigen test for SARS-CoV-2 infection in children: implications for screening in a school setting. PLoS One 2021;16:e0249710.
- 32. Fujita-Rohwerder N, Beckmann L, Zens Y, Verma A. Diagnostic accuracy of rapid point-of-care tests for diagnosis of current SARS-CoV-2 infections in children: a systematic review and meta-analysis. BMJ Evid Based Med 2022;27:274-87.
- 33. McKay SL, Tobolowsky FA, Moritz ED, Hatfield KM, Bhatnagar A, LaVoie SP, et al. Performance evaluation of serial SARS-CoV-2 rapid antigen testing during a nursing home outbreak. Ann Intern Med 2021;174:945-51.
- 34. Hughes DM, Bird SM, Cheyne CP, Ashton M, Campbell MC, García-Fiñana M, et al. Rapid antigen testing in COVID-19 management for

- school-aged children: an observational study in Cheshire and Merseyside, UK. J Public Health (Oxf) 2023;45:e38-47.
- Cooch P, Watson A, Olarte A, Crawford E, Consortium C, DeRisi J, et al. Supervised self-collected SARS-CoV-2 testing in indoor summer camps to inform school reopening. medRxiv 2020. https://doi.org/10.1101/ 2020.10.21.20214338
- **36.** Waggoner JJ, Vos MB, Tyburski EA, Nguyen PV, Ingersoll JM, Miller C, et al. Concordance of SARS-CoV-2 results in self-collected nasal swabs vs swabs collected by health care workers in children and Adolescents. JAMA 2022;328:935-40.
- Waggoner JJ, Vos MB, Tyburski EA, Nguyen P-V, Ingersoll JM, Miller C, et al. Adequacy of nasal self-swabbing for SARS-CoV-2 testing in children. medRxiv 2022. https://doi.org/10.1101/2022.03.07.22270699
- **38.** Altamirano J, Lopez M, Robinson IG, Chun LX, Tam GK, Shaikh NJ, et al. Feasibility of specimen self-collection in young children undergoing SARS-CoV-2 surveillance for in-person learning. JAMA Netw Open 2022;5:e2148988.
- Schrom J, Marquez C, Pilarowski G, Wang G, Mitchell A, Puccinelli R, et al. Direct comparison of SARS-CoV-2 nasal RT-PCR and rapid antigen test (BinaxNOW<sup>TM</sup>) at a community testing site during an Omicron surge. medRxiv 2022. https://doi.org/10.1101/2022.01.08.22268954
- 40. Soni A, Herbert C, Filippaios A, Broach J, Colubri A, Fahey N, et al. Comparison of rapid antigen tests' performance between Delta (B.1.61.7; AY.X) and Omicron (B.1.1.529; BA1) variants of SARS-CoV-2: secondary analysis from a serial home self-testing study. medR-xiv 2022. https://doi.org/10.1101/2022.02.27.22271090
- FDA. SARS-CoV-2 viral mutations: impact on COVID-19 tests. In: Administration USFaD. U.S Food and Drug Administration; 2022. Accessed July 24, 2024. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests
- 42. Cocherie T, Bastide M, Sakhi S, Zafilaza K, Flandre P, Leducq V, et al. Decreased sensitivity of rapid antigen test is associated with a lower viral load of Omicron than Delta SARS-CoV-2 variant. Microbiol Spectr 2022;10:e0192222.
- ELC. ELC reopening schools: support for COVID-19 screening testing to reopen and keep schools operating safely: California: Center for Disease control, Division of Preparedness and emerging Infections (DPEI). Accessed August 18, 2022. https://www.cdc.gov/ncezid/dpei/elc/covidresponse/states/california.html