

Abbott

Project: ACE-IT Implementation Guide

January 3, 2021

COVID-19 Ag

Project: ACE-IT Assisting Childhood Education through Increased Testing

Acknowledgements

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Project: ACE-IT Assisting Childhood Education through Increased Testing

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Project: ACE-IT, Goal & Overview

Goal

Keep schools in the 5-county Southeastern Pennsylvania region safe and open for on-campus instruction by strategically deploying rapid COVID testing resources.

Overview

Project: ACE IT, serving staff and students in school districts across the 5-county southeastern Pennsylvania region, takes a dual-pronged approach in detecting high COVID-19 viral load in school district populations by testing: 1) newly symptomatic students and staff during the school day; and 2) asymptomatic staff in a routine sentinel surveillance program. The program aims to achieve viral suppression through rigorous detection, isolation, and quarantine of identified individuals—and their contacts—while building confidence in the safety of in-person instruction. In particular, Project ACE IT prioritizes testing for the most vulnerable among populations in the region's school districts, such as students with special needs who are unable to wear PPE effectively and staff members who provide them with high-touch support. Test results are transmitted securely to subjects' email addresses, as well as to the PA Department of Health's NEDSS data repository.

Project: ACE IT strives to provide the safest possible working and learning environment. The approaches to testing described on the next page reflect the latest recommended practices by infectious disease and epidemiological experts. Importantly, the program contributes to an emotionally healthy environment for students and staff by minimizing unhealthy suspicions about the health status of colleagues and students.

Project: ACE-IT, Background

As part of the Nation's Coronavirus Testing Strategy, the United States Health and Human Services Department has distributed 150 million of the <u>Abbott BinaxNowTM COVID-19 Ag Card</u> rapid test kits and considerably smaller number of <u>Cue Health</u> kits, which gained attention for its use last spring in the <u>NBA</u> "bubble." Dr. David Rubin, Director of PolicyLab at Children's Hospital of Philadelphia (CHOP), was able to procure an allotment sufficient to create a school-based COVID testing program across 5 counties in Southeastern Pennsylvania. The primary benefit of using these tests is that they are ideal for use in settings that need rapid, low-tech testing. Considerably more accurate than previous generations of antigen tests, not only are BinaxNow tests useful for symptomatic testing; but also, they are <u>increasingly recommended</u> for surveillance or "assurance" testing. These tools were specifically intended to support our critical infrastructure and surveillance screening in congregate settings, such as a school environment.

CHOP, in coordination with local health departments and county intermediate units, has been directed to ensure the effective distribution of these tests to local schools systems to further this national effort. Within several weeks of outreach and planning with collaborators, Project: ACE-IT was born, permitting implementation of a regional school-based testing program.

As a part of this project, school systems are provided with delivery of the tests, product training, and support. Local health departments and school systems may utilize these tools to enhance or supplement local policy related to schools' operations. These rapid test kits are for the exclusive use and control of the school system upon receipt. This program's only mandate is required state and federal reporting when the actual test kit is used.

Our goal is to ensure that the distribution and use of the tests are consistent and safe. The proper use, health authority recommendations, and training of these rapid kits are managed under the Clinical Laboratory Improvement Amendment (CLIA) certificate of waivers held by local departments of health, with support from CHOP. Each local health department has identified a physician to serve as the provider of record for all tests conducted. The policy and use of these tests are at the discretion of school system administration.

Project: ACE-IT, Background, continued

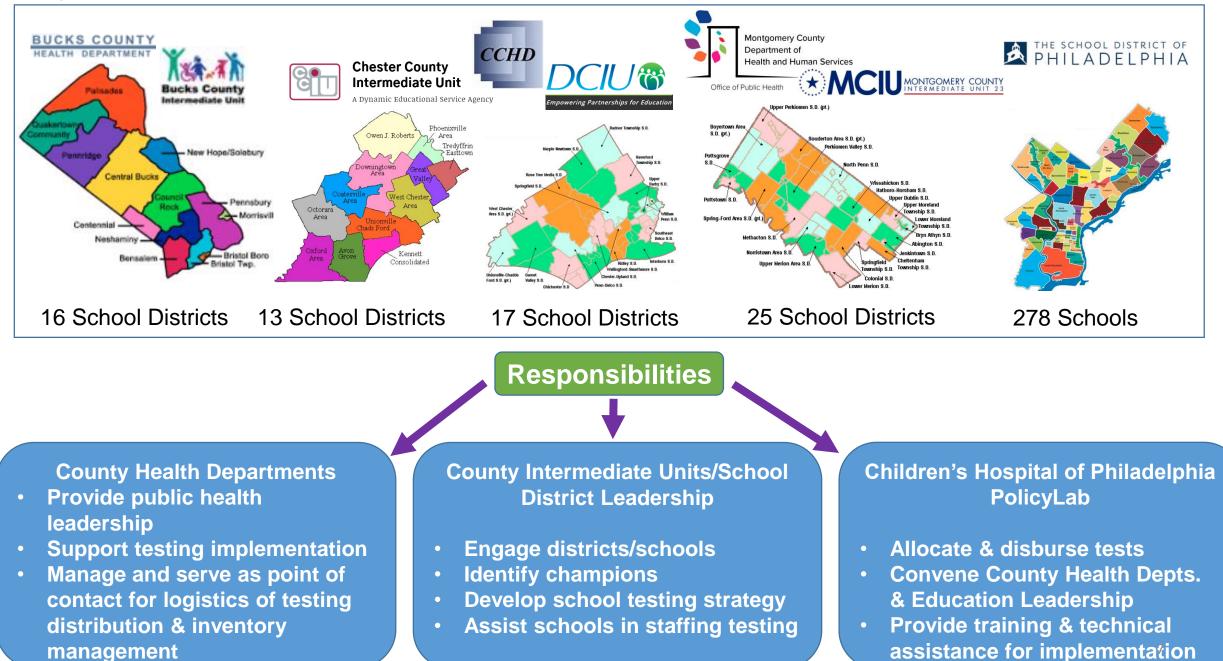
In this packet, you will have access to the Project: ACE-IT COVID-19 School-Based Testing Support Distribution and Implementation Plan, access to certified training, and required legal reporting processes.

We have done out best to estimate the volume of tests required to accommodate our vision of large-scale school-based testing. Please coordinate with your local health department and county intermediate unit to discuss resupply procedures.

Please feel free to contact Maggie Eisen: <u>eisenm@email.chop.edu</u> for operational support and technical assistance.

Keep schools and communities safe in the time of COVID by making operational adjustments

Project: ACE-IT Scope



Project: ACE-IT, Visuals & Talking Points (FAQ for wide distribution)

Your School's/District's/County's/Organization's Logo Here

Project: ACE-IT

School districts and health organizations across southeast Pennsylvania are committed to keeping staff and students healthy and safe during the COVID-19 pandemic. That's the basis of Project: ACE-IT (Assisting Childhood Education through Increased Testing), a collaborative regional effort offering in-school, rapid COVID-19



testing for children and staff who become sick during the school day and weekly testing for staff and high-risk students, voluntarily and free of charge.

This document offers information on the tests and testing program. If you have additional

questions, you may contact ______ at xxx@yyzz.org.

What COVID-19 tests are being used in this program and why?

This program primarily uses <u>BinaxNOWTM tests</u>, which provide results in 15 minutes and are administered using a nasal swab in the *front area* of the nostril. These <u>antigen</u> tests are highly accurate, detecting 97%-98% of symptomatic individuals. If the person tested receives an unexpected result—meaning they are symptomatic but receive a negative result, or they are asymptomatic and receive a positive result—they may be referred for another more sensitive test, such as the <u>Cue Health</u>, or a molecular test, such as a PCR. Referrals for additional testing



will be communicated promptly to staff members or parents/guardians of students who have tested positive. For more information on different types of COVID-19 tests, click <u>here</u>. Who will be tested and when?

Each school district will determine the testing model works best —including who administers

Your School's/District's/County's/Organization's Logo Here

the tests—for their students and staff, using the strongest public health guidance available. Local health departments will be instrumental in supporting this process. Project: ACE-IT's current <u>allotment of tests</u> provide for: 1) symptomatic testing of students and staff, and 2) weekly asymptomatic or



assurance testing of staff and limited groups of students between January and April 2021. All testing will be limited to students and staff who are participating in in-person education.

If I (or my student) feel sick, can I (they) come to the school to be tested?

No staff or students are allowed to enter a school building if they have been exposed to COVID-19 or have <u>symptoms consistent with COVID-19</u>. Instead, a referral to another testing location may be offered. This safety protocol is critical to the safety of the school community. In-school testing will only be available to staff and students who come to school feeling healthy, but begin to feel symptomatic during the school day.



How will I learn about my (my child's) test results, and how will this information be used?

Each school will decide how best to communicate with parents/guardians about their student if they become symptomatic and are tested—with a guardian's consent—during the school day. Staff and families of students tested will receive results via text

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or email shortly after they are known. All test results will be shared with the local health department as required for public health reporting and contact tracing, as well as to determine the stay-at-home period for those testing positive. School staff will also be able to quickly isolate when a student or staff member tests positive. All data will be protected and transferred via a secure server.

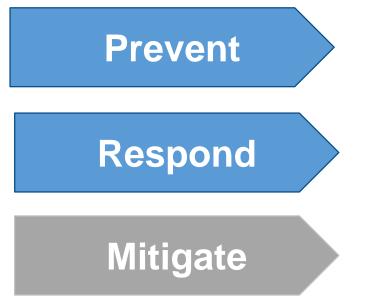
What happens next?

Each participating school will share their testing plans with their student and staff communities, including how to register. Please direct questions about local programming to your school, district, or county health department.

Project: ACE-IT, Visuals & Talking Points

A Public Health Approach to Education aims to provide the maximum benefit for the largest number of people





By conducting tests on campus, school systems can:

- Use tests as an additional screening tool in some cases to prevent the virus from coming on campus
- Provide another source of testing to which the school can quickly <u>respond</u> by removing the individual before they can spread COVID on campus

Source: <u>https://tea.texas.gov/sites/default/files/covid/COVID-Rapid-Testing-Superintendent-Kick-Off.pdf</u> 9

About the Abbott Labs BinaxNOW Test



How long does it take to get test results? 15 Minutes



How is the test administered?

Tests are administered with a nasal swab (to the shallow front of the nostrils only). Adults will be able to self-administer the test with the oversight of a test administrator.



How are the tests packaged?

Tests are the size of a credit card and contain a nasal swab and reagent testing solution (one bottle per testing kit). They are packaged 40 to a shoebox-sized kit.



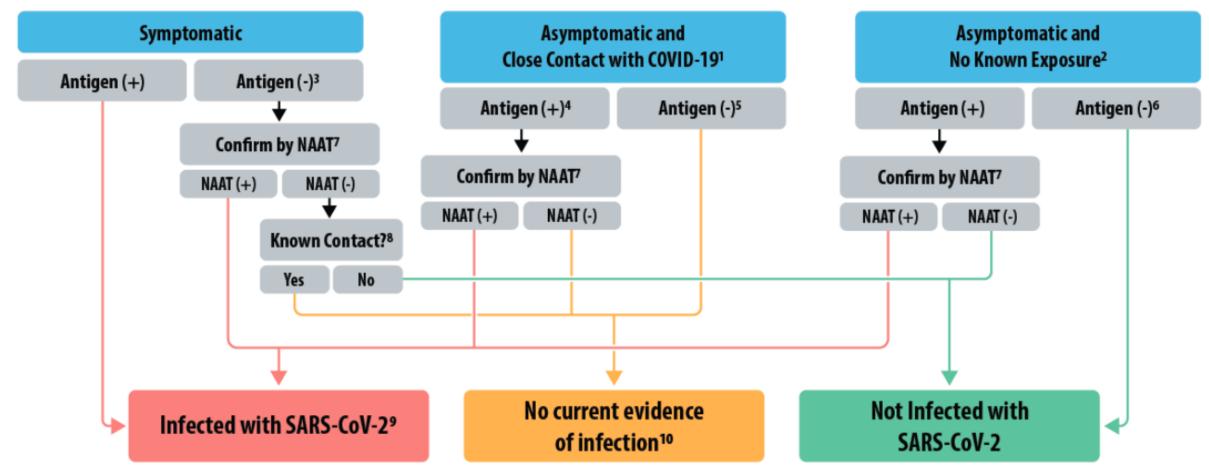


Project: ACE-IT, Testing Strategy

Symptomatic Testing: School-based testing of symptomatic students and staff is paramount for maximizing the student population's educational opportunities in an environment that has grown increasingly stressful during the pandemic. This approach protects the health of fellow students, as well as adults with whom they interact daily, from teachers, to bus drivers, to custodial staff. Trained certified school nurses and other qualified testers will perform prompt testing of symptomatic students during the school day, which facilitates accurate isolation of positive cases and appropriate quarantine of close contacts. This strategy permits non-COVID infected students and staff to return to school as soon as they feel better, optimizing educational activity across the region. Rapid in-school testing allows prompt results reporting to caregivers as well as timely delivery of guidance for appropriate management, isolation, and quarantine guidelines for family members. Real-time results reporting to the Philadelphia Department of Public Health can trigger rapid contact tracing to protect the other close contacts and the school environment.

Assurance Testing: Weekly surveillance or "assurance" testing of asymptomatic staff and select populations of students, including those unable to wear masks, those whose individualized learning plans do not permit six feet of distancing through the school day, athletes in close-contact sports, chorus, and band members, confers multiple benefits to district employees, students, and communities. Weekly testing allows identification of about 50% of positives in a given population. Across the country, teachers have expressed deep concern about returning to the classroom amid the pandemic; and their fears are not unfounded. Assurance testing alleviates some of those fears— both real and perceived. This testing strategy, in combination with close monitoring of staff's health, fosters trust and confidence in the District's commitment to its employees. Similarly, weekly testing of students who require frequent hands-on care and cannot wear masks will ensure early identification of asymptomatic students and bolsters confidence among staff who support them. The capacity to offer weekly assurance testing to students participating in specific high-risk extracurricular activities when they resume, supports critical non-academic development and well-being of students across the region.

Project: ACE-IT, Testing Strategy – CDC Interim Guidance for Antigen Testing for SARS-CoV-2m eff. 12/16/20



NAAT: nucleic acid amplification test, e.g., PCR or Cue Health tests, which are more sensitive than rapid antigen tests. NAATs would typically be used for confirmation of diagnosis in this case.

Source: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

Why BinaxNowTM?

- Primary benefit: Ideal for use in settings needing rapid, low-tech testing
- Abbott Labs—manufacturer—evaluated accuracy and compared results to PCR (molecular) test in 102 patients who had shown COVID-19 symptoms for < 7 days. Analysis revealed:
 - Sensitivity (true positive rate): 97.1%
 - Specificity (true negative rate): 98.5%
- Significantly more accurate than previous generations of rapid antigen tests
- ...but accuracy still depends on viral load & whether or not the individual is symptomatic; and viral load can be high in asymptomatic people

Why BinaxNowTM?

- Data increasingly recommend use of antigen tests in asymptomatic testing; specifically in high-risk congregate settings or schools where the same people gather daily
 - First of its kind out of San Francisco, CA evaluated performance of BinaxNow to detect COVID among people, regardless of symptoms at a public plaza. <u>https://www.medrxiv.org/content/10.1101/2020.11.02.20223891v2</u>
 - *n*=878, including asymptomatic subjects
 - Findings "indicate a clear relationship between relative viral load and test positivity, and provide a
 practical, real-world criterion...suggest[ing] that the Binax-CoV2 test should not be limited to
 symptomatic testing alone but should also incorporate asymptomatic individuals. Limiting use of
 Binax-CoV2 to symptomatic individuals would have missed nearly half of the...infections with
 high viral loads."
- In many real-world contexts, repeat testing of the same cohort of people can quickly identify infected individuals for immediate isolation
 - When used alongside traditional transmission prevention measures, e.g., masking, distancing, and good hand hygiene, it can provide powerful protection for the community
 - Anticipate a ~50% reduction of asymptomatic infectious burden

Best Practices for Schools Using the Abbott BinaxNow[™] Rapid Antigen COVID-19 Test

The purpose of this guidance is to support communities, local leadership, education leadership, and public health in collaborating with schools in creating policies for school re-entry and operations during the coronavirus disease 2019 (COVID-19) pandemic

- It is vitally important that communities take all necessary measures to limit the spread of the SARS-CoV-2.
- School policies should be flexible and nimble in responding to new information, and administrators
 must be willing to refine approaches when specific policies are not working.
- Schools must take a multi-pronged, layered approach to protect students, teachers, and staff. By using different approaches, these layers of protection will make in-person learning safe and possible.
- School systems must be in close communication and coordination with state and local public health authorities, school nurses, local pediatric practitioners, and other medical experts.
- Policymakers and school administrators should acknowledge that COVID- 19 policies are intended to mitigate, not eliminate risk.
- No single action or set of actions will completely eliminate the risk of SARS-CoV-2 transmission; but, the implementation of several coordinated interventions can greatly reduce that risk.
- Virologic testing is an important part of the overall public health strategy to limit the spread of COVID-19.
 Virologic testing detects the viral RNA from a respiratory (usually nasal) swab specimen.

BinaxNowTM Demo

https://youtu.be/rRZLDwEHkgY

Training Checklist

BinaxNOW™ COVID-19 Ag Card Training Checklist

billaxitow covid-15 Ag card fraining checking			the tube and the cap is tightly closed. If greater than 1-hour delay occurs,		
			dispose of sample. A new sample must be collected for testing. DO NOT		
FACILITY/LABORATORY:			RETURN THE SWAB TO ITS ORIGINAL PACKAGING		
			SAMPLE PREPARATION	USER'S	DATE
USER NAME: USER ID: _			TEST PROCEDURE FOR QUALITY CONTROL & PATIENT TESTING	INITIALS	
			The User follows instructions for QC and Patient Testing of BinaxNOW™ COVID-19		
_			Ag Card.		
BinaxNOW™ COVID-19 Ag CARD - KIT OVERVIEW	USER'S	DATE	The User follows instructions for Patient testing as outlined in the package insert		
	INITIALS		and BinaxNOW [™] COVID-19 Ag Card Procedure Card:		
The user acknowledges being shown and understands the following kit			 Bring all materials and patient sample to room temperature 		
components and precautions in the package insert:			 Label test card with appropriate QC or Patient Identification information. 		
Kit Storage temperature			For External QC		
 Lot number and expiration date 			1. Follow instructions for external controls. Hold Extraction Reagent bottle		
 Package Insert including Precautions and Limitations 			vertically. Hovering 1/2 inch above the TOP HOLE, slowly adds 8 DROPS to the		
 BinaxNOW[™] COVID-19 Ag Card Procedure Card 			TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while		
Extraction Reagent			 dispensing. Insert the (+) or (-) control swab into BOTTOM HOLE and firmly push upwards 		
 Swabs provided in the BinaxNOW™ COVID-19 kit 			 Insert the (+) or (-) control swab into BOTTOW HOLE and Immy push upwards so that the swab tip is visible in the TOP HOLE. 		
 Patient samples, controls, and test cards should be handled as though they 			 Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove 		
could transmit disease. Observe established precautions against microbial			swab.		
hazards during use and disposal.			 Peel off adhesive liner from the right edge of the test card. Close and securely 		
 Wear appropriate personal protection equipment and gloves when running 			seal the card.		
each test and handling patient specimens. Change gloves between handling			5. Read result in the window 15 minutes after closing the card. It is important to		
of specimens suspected of COVID-19.			read the result promptly at 15 minutes, and not before. Results should not be		
SPECIMEN COLLECTION, STORAGE AND HANDLING	USER'S	DATE	read after 30 minutes.		
	INITIALS		For Patient Testing		
The user acknowledges being shown; sample collection and storage conditions in			 Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the TOP 		
the package insert:			HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch		
 For use with direct nasal swab specimens with swabs provided in the kit 			the card with the dropper tip while dispensing.		
ONLY			2. Insert sample swab into BOTTOM HOLE and firmly push upwards so that the		
 To collect a nasal swab sample, carefully insert the swab into the nostril 			swab tip is visible in the TOP HOLE.		
exhibiting the most visible drainage, or the nostril that is most congested if			Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove		
drainage is not visible. Using gentle rotation, push the swab until resistance			 swab. Peel off adhesive liner from the right edge of the test card. Close and securely 		
is met at the level of the turbinate (less than one inch into the nostril).			 Peer of adhesive liner from the right edge of the test card. Close and securely seal the card. 		
Rotate the swab 5 times or more against the nasal wall then slowly remove			 Read result in the window 15 minutes after closing the card. It is important to 		
from the nostril. Using the same swab, repeat sample collection in the other			read the result promptly at 15 minutes, and not before. Results should not be		
nostril.			read after 30 minutes.		
• Direct nasal swabs should be tested as soon as possible after collection If				1	<u> </u>
immediate testing is not possible, and to maintain best performance and			USER'S SIGNATURE: DATE:		
avoid possible contamination, it is highly recommended the nasal swab is					
placed in a clean, unused plastic tube labeled with patient information,			TRAINER'S SIGNATURE: DATE:		
preserving sample integrity, and capped tightly at room temperature (15-					
30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within					
	1		Source: City of Philadelphia Public Health Department, 2230 Cottman Avenue Philade	lphia PA 19	149 3

Source: City of Philadelphia Public Health Department, 2230 Cottman Avenue Philadelphia PA 19149 1

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Training Attendance Log, Quiz, & Certification

Binax NOW Training Attendance Log

Location

The lab director's signature on the bottom indicates that training on QC and patient tests as well as any quality assurance documentation has been performed as required. All testers have reviewed and understand all steps outlined in the Binax NOW job-aid, including specimen collection, QC and patient testing. The tester's signature indicates that they have reviewed all training videos and resources on BinaxNOW COVID-19 Ag Card and NAVICA App Set-Up and Training Abbott Point of Care Testing (globalpointofcare abbott) and is confident in the performance of this test. The observer's signature indicates (s)he has observed a control test as well as a patient test being done.

Date Training	Tester Name (PRINT)	Tester Signature	QC Test	Patient	Observer Name (PRINT)	Observer Signature	1
Materials			(✓)	Test		_	
Reviewed				(✓)			
			_				4
			-				
							Certification of Training
			-				1
							This is to verify that personnel responsible for running the BinaxNOW™ COVID-19 Ag Card a
							have been thoroughly in-serviced on the test and the test procedure
							This has included:
							Review of the package insert
			-				Demonstration of the product assay
							 Successful performance of the BinaxNOW™ COVID-19 Ag Card and interpretation

Date:

Lab Director's Signature:

Source: Infectious Disease Diagnostics Laboratory, Children's Hospital of Philadelphia - Rev. 12/7/20

Date:

F

F

Circle T (True) or F (False) for each question:

Name:

- 1. For testing patient direct nasal swabs, hold Extraction Reagent bottle vertically Hovering 1/2 inch above the TOP HOLE, slowly add 8 DROPS to the TOP HOLE of the swab well.
- 2. The BinaxNOW[™] COVID-19 Ag Card device should not be removed т F from the foil pouch until just before use.
- 3. A nasopharyngeal swab is an acceptable sample type for testing on the F BinaxNOW™ COVID-19 Ag Card.
- 4. Direct nasal swab samples may be stored at room temperature for 24 Т F hours.
- It is acceptable to return the nasal swab after patient collection to its 5. original packaging.
- 6. False negative results can occur if the sample swab is not rotated F (twirled) prior to closing the card.
- 7. If no lines are seen, or if just the Sample Line is seen, the assay is F negative.
- 8. Results should be read promptly at 15 minutes, and not before. т F Results should not be read after 30 minutes.
- 9. The appearance of a pink-to-purple Control Line and a pink-to-purple т F Sample Line below it is a positive result.
- 10. Test using only with swabs provided in the kit, and collect direct nasal Т swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Notes:

DATE

Source: City of Philadelphia Public Health Department, 500 South Broad Street Philadelphia PA 19146

Signature of Laboratory Director(s) responsible for personnel and testing:

of results

responsible for reporting patient results:

PRINT NAME

Names of the personnel who have been trained with the BinaxNOW™ COVID-19 Ag Card and are

SIGNATURE

SIGNATURE

DATE

MEDICAL DIRECTOR SIGNATURE

DATE

DATE

TRAINER

BinaxNow Job Aid

Effective Date: 12/11/20

Job Aid: BinaxNow™ COVID-19 Ag CARD Procedure



Please confirm with site administrator/proctor that quality control (QC) has been

performed on the lot of the box this test came from. If not, please wait until QC has been performed.



 When you first open the BinaxNow card (step #5), please check that the blue Control Line is present. If it is not, discard the test

and start over with a new one.

 Make sure you are both registered and familiar with the registration and results reporting app if you have any data entry responsibilities.

Collecting Anterior Nares Specimen

- Make sure you are wearing PPE as directed. Perform hand hygiene and put on new gloves.
- 2. Gently insert swab at least 1 cm inside the nostril with more drainage, or that is



more congested.

3. Rotate swab > 5 times gently against nasal membrane for 10-15 seconds; then

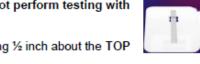
gently remove the swab. Repeat with same swab in other nostril.

4. Test swab with specimen immediately after collection and do not return the

swab to its original packaging.

Running the Test

5. Open the test card just prior to use and lay it flat. Do not perform testing with the card in any other position.



- a. Hold Extraction Reagent bottle vertically, hovering ½ inch about the TOP HOLE.
- b. Slowly add 6 DROPS to the TOP HOLE. While putting drops on the card, hold the swab with specimen in the other hand, taking care not to have it touch anything.
- c. DO NOT touch the card with the dropper tip while dispensing.

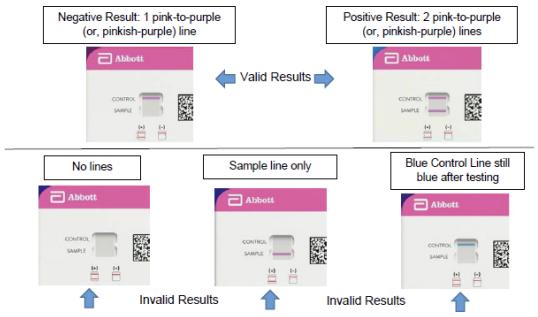
Sources: 1) CHOP OSMO, <u>https://at.chop.edu/osmo/eop/bioresponse/Shared%20Documents1/COVID-19-Swabbing-Instructions.pdf;</u> 2) FDA website: <u>https://www.fda.gov/media/141570/download;</u> 3) Abbott website: <u>https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-</u>training.html

- 6. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.
- Twirl swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.
- 8. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card and set a timer for 15 minutes. The card must

lay flat during the entire 15 minutes of the test-not just when dropping in the reagent.

Reading the Results

9. Read result in the window promptly at 15 minutes after closing the card. Reading before 15 minutes or after 30 minutes reduces assurance of proper test performance. Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.



- 10. If result is invalid, please repeat specimen collection and test with new BinaxNow card.
- 11. Dispose of all items used in biohazard bag provided.
- 12. Report results as directed.

Sources: 1) CHOP OSMO, <u>https://at.chop.edu/osmo/eop/bioresponse/Shared%20Documents1/COVID-19-Swabbing-Instructions.pdf</u> 2) FDA website: <u>https://www.fda.gov/media/141570/download;</u> 3) Abbott website: <u>https://www.elobalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html</u>



BinaxNow Temperature Log, External Quality Control Log, & Downtime Log

BinaxNow[™] COVID-19 Ag Card Temperature Log

SITE LOCATION:						. N	NONTH/	YEAR:								
Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Initials of Recorder																
Room Temperature																
Min-Max (High/low) Temperatures																
Day of Month	•	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Initials of Recorder																
Room Temperature																
Min-Max (High/Iow) Tempera	atures															

Temperature Ranges: Please reset the thermometer's high-low temperatures the day before a weekend or holiday. On the 1st day back after the office/school has been closed for one or more days, the high/low display (actual number range) is written in the space (or spaces) for the closed day or dates. The large single number display is written for the daily temperature on days the office/school is open and the temperature is read.

Room Temperature Acceptable Range: 15° to 30° C / 59° to 77° F

Corrective action for room temperatures that deviate from the acceptable temperature range:

Contact departments responsible to get repair or adjustment information or to determine the service representative to call. Contact CHOP Facilities for unacceptable room temperatures. Call product manufacturer for consultation regarding impact of temperature on lab supplies. Document all corrective action directly on the temperature log. Save copies of any service call paperwork.

Source: Infectious Disease Diagnostics Laboratory, Children's Hospital of Philadelphia, Rev. 12/7/20

Abbott recommends that external positive and negative controls be run:

- Once with each new shipment received
- Once for each untrained operator
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

If the expected external control results are not obtained, do not report patient results. Contact Technical Service at 800-257-9525.

KIT LOT NUMBER:

DATE	BINAXNOW™ COVID-19 Ag CARD KIT LOT/EXP	positive Ctrl Lot/Exp	NEGATIVE CTRL LOT/EXP	POSITIVE RESULT	NEGATIVE RESULT	CONTROL LINE PRESENT: Y/N	TESTER'S INITIALS	CORRECTIVE ACTION / COMMENTS

SUPERVISOR REVIEWED BY:

DATE:

Source: City of Philadelphia Public Health Department, 2230 Cottman Avenue Philadelphia, PA 19149

BinaxNOW™ COVID-19 Ag Card Downtime Internal Controls and Patient Log

LOT NUMBER

EXP. DATE _____ NAME OF FACILITY/SITE: ____

Source: City of Philadelphia Public Health Department, 2230 Cottman Avenue Philadelphia, PA 19149

Record the Date, Patient's Name, Patient Test Result, Internal Control Results and the tester's initials. Positive Internal Control = The pink-to-purple line at the "Control" position can be considered an internal positive procedural control. Negative Internal Control = The background color in the window should be light pink to white within 15 minutes.

DATE	PATIENT NAME	PATIENT ID NUMBER	PATIENT RESULTS	CONTROL LINE PRESENT?		INTERNAL CONTROL RESULTS		COMMENTS	TESTER'S INITIALS
				NO	YES	+	-		
		1							
		-							

SUPERVISOR REVIEWED BY:

STRAC Overview

BinaxNow test results are captured using a web-based application developed by the <u>Southwest Texas Regional Advisory Council</u> (STRAC), a state-chartered, non-profit now under contract to the US Department of Health and Human Services (HHS). STRAC developed its comprehensive data system and reporting mechanism specifically for the State of Texas's school-based testing program for students and staff, <u>K-12</u>, which launched on October 28, 2020. HHS has contracted to deploy the STRAC service outside of Texas. STRAC's system assures the highest quality, integrity, and security of public health data being collected and transmitted to the PA Department of Health's NEDSS data mapping repository.

With the end-user interface for the STRAC system, participants are offered a link to the web-based app for registration including their email address, collection of demographic data, and clinical questions. Test takers' identities are matched to their specimens and results through generation of a QR code that is matched to the specific BinaxNow rapid antigen test 'card' on which the test is run and results are revealed. After the results are entered into the app, they are automatically pushed to the test taker's email address; as well as to the NEDSS repository and any other public health entities as determined appropriate by project leadership and authorities, in the aggregate once per day.

What is the PA Rapid Test and why are we using it?

- This test is an easy to use point of care test for testing school staff and students.
- Proven system currently in use by State of Texas, caught the attention of HHS
- Research and testing prove that this system is ready for implementation in southeastern PA
- Web based app, so no need to worry about app storage on your phone
- Simply scan a driver's license or State ID. No license, no problem! Generate a QR code you can print to store your info. and re-use with each test Answer the diagnostic questions
- Enter your test result, and hit save
- Data are transmitted to PA DOH once/day

Demo: <u>https://youtu.be/AHIJdA_sYK8</u>





PA rapidtest

Test Administrator Email	
Password	
Forgot Password or First Login?	
Help	Login
	22

Account Creation

- When users (e.g., Test Administrators/Proctors) are granted an account from the PA Rapid Test Kit Scanner they receive an email with login information.
- This requires users to set a password for the account attached to their email address, you should use your phone when accessing these links.
- Signing-in from a smartphone (iPhone or Android) or an iPad is required to use the app.

From: <u>ta-welcome@notify.pennrapidtest.org</u> <<u>ta-welcome@notify.pennrapidtest.org</u>> Sent: Tuesday, December 22, 2020 5:12 PM To: Eisen, Magrielle H <<u>EISENM@chop.edu</u>> Subject: [External] Welcome to the Project: ACE-IT Rapid Test Data Reporting System!

Welcome to the Project: ACE-IT Rapid Test Data Reporting System!

You have received this email because your district is participating in a school-based COVID rapid antigen testing program. Education and health department leadership in your county have been engaging in ongoing discussions about how best to implement COVID-19 testing in schools so that staff, students, and communities may stay safe while working and learning in-person.

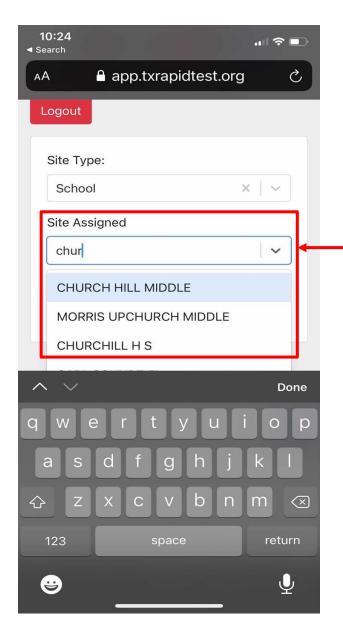
If you do not want to participate in tomorrow's training, that is perfectly fine. There will be other opportunities to train and we will circulate a schedule shortly.

We have partnered with a Texas-based non-profit that has developed an app and has contracted with the PA Dept. of Health for secure COVID results data reporting to governing authorities as required by law. By following the instructions below, you will be able to practice data entry in real-time during the training so that you can become comfortable with the process.

You now have the ability to become a BinaxNOW test administrator; but by setting up an account, you are not necessarily committing to it. To complete this process, you will undergo a brief certification program, which will be discussed during training. Please contact your local health department lead for details.

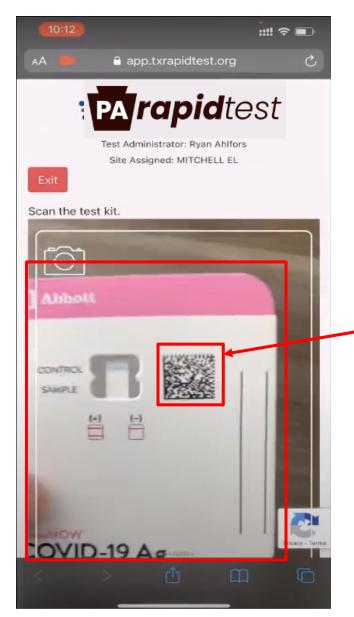
Click here to set your password the first time. Click "Forgot Password or First Login?", submit your email, and then you will receive a password reset email.

App URL: <u>https://app.pennrapidtest.org/</u> Test Administrator Email: <u>EISENM@chop.edu</u> Phone number on file: 267-977-9693



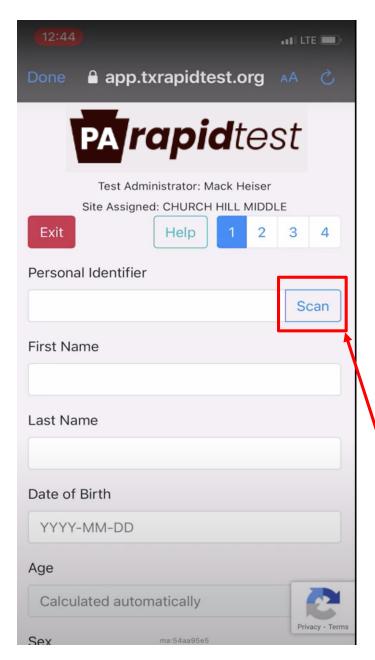
Logging on & Identifying your testing location

- Log-on to: <u>https://staging.txrapidtest.org/chop/</u>
- The first thing a test administrator or proctor must do is select the location where you're conducting the test.
- This will allow proper tracking and reporting on a school's test results.
- We will circulate a list to review to ensure all schools are captured in this list.



Pairing identity with BinaxNow barcode

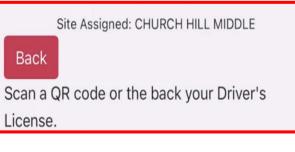
- The app requires use of your device's camera; it uses the camera to scan the BinaxNow test.
- All the user has to do is hover the phone over the barcode in the top right section of the test, and the app will automatically log the unique identifier for the BinaxNOW test.
- This happens very quickly, so don't be shocked! The software within the app is built for this specific purpose and it's good at its job ^(C)!



Adding Demographic Data

We are required to log *who* was tested. There are three ways to enter this data: 1) through a manual e-form, 2) by scanning a driver's license, or 3) by scanning a student's QR code. The code can be created at this site: <u>https://register.pennrapidtest.org</u>.

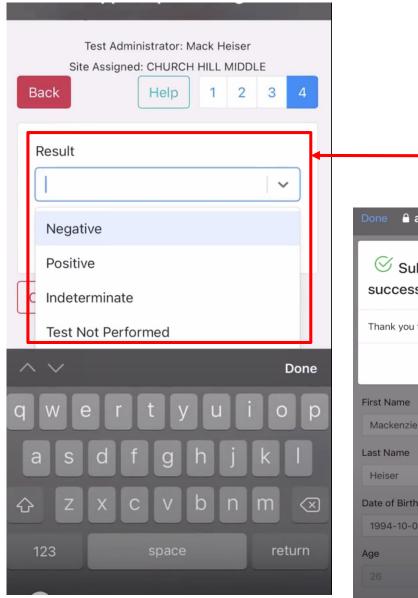
QR codes must be generated online for students either by or with their parents. They can print these out and tape to their binders (or wherever).



Done 🔒 app	o.txrapidtest.o	rg 🗚 🖒						
PA	rapidte	əst						
	dministrator: Mack Hogen and H							
Back	Help 1	2 3 4						
Is this the first te had for COVID-1	est (of any kind) th 9?	e patient has						
N/A	No	Yes						
	Is the patient employed in healthcare with direct patient contact?							
N/A	No	Yes						
Is the patient sy	mpomatic?							
N/A	No	Yes						
Is the patient pregnant?								
N/A	No	Yes						
Clear Form	Progress Saved	Privacy - Terms						
	ma:54aa95e5							

PA Rapid Test Kit Scanner -Medical Questionnaire

User is prompted with a medical questionnaire for information regarding the patient's previous tests and symptoms.



A app.txrapidtest.org ▲A × Submission successful. Thank you for your time. Mackenzie Date of Birth 1994-10-07

Submitting Results

- The test administrator/proctor is then required to input the result.
- The email address and phone number on file are then notified with the result via email and/or text.

Accessing Individual

- In order to access their results from the email, users must validate their identity by entering a correct birthdate for the person who was tested.
- Users will then get a be able to open a pdf with their results.

COVID-19 Test Result > Inbox ×	
results@notify.txrapidtest.org	Γhu, Nov 19, ⁻
Your COVID-19 results in PDF format is ready! Click the following link and enter your birthday to retrieve it: https://results.txrapidtest.org/?key=J2StOyRctvlekfhUUqQ	M
Reply Forward	

PA rapidtest	Ċ
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DOB	Dear
mm/dd/yyyy	You ha 2020-1
Submit	Negativ presum perform basis fo results of clinic



COVID-19 TEST RESULTS

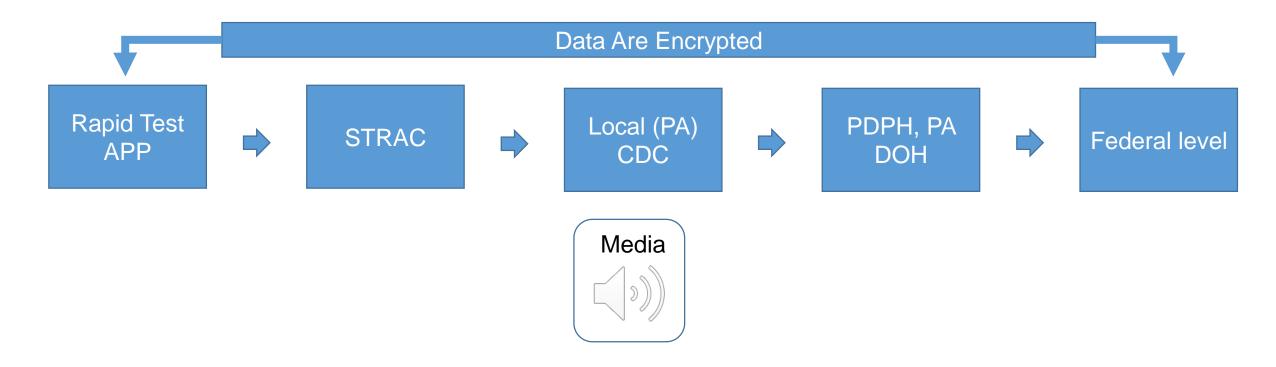
REF #: 28088

Dear Mackenzie Heiser,

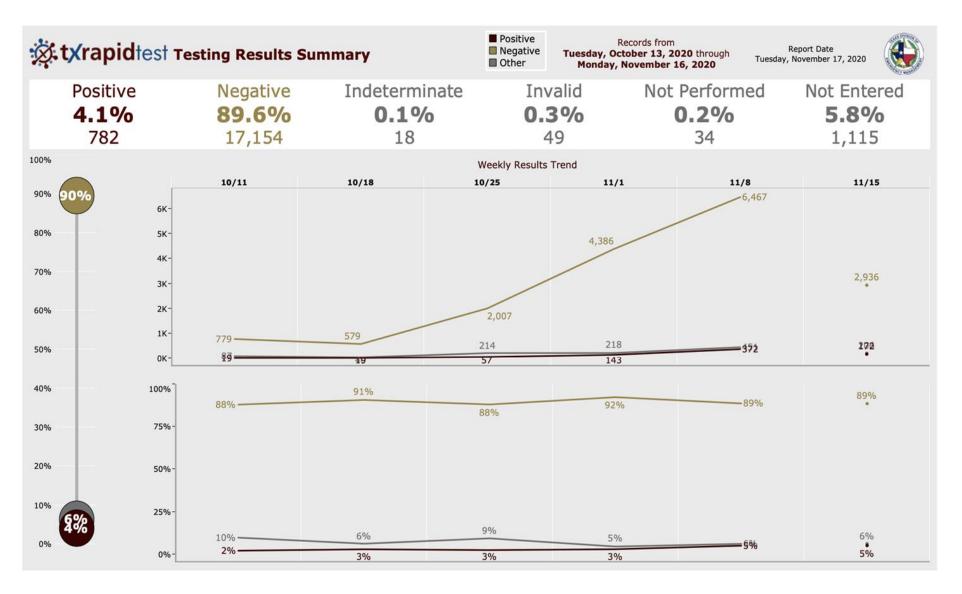
ou had a BinaxNow AG Card test to determine if you were infected with the COVID-19 virus on 020-11-19 11:46:16.587. The test result shows you are **NEGATIVE** for the COVID-19 virus.

Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole pasis for treatment or patient management decisions, including infection control decisions. Negative esults should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

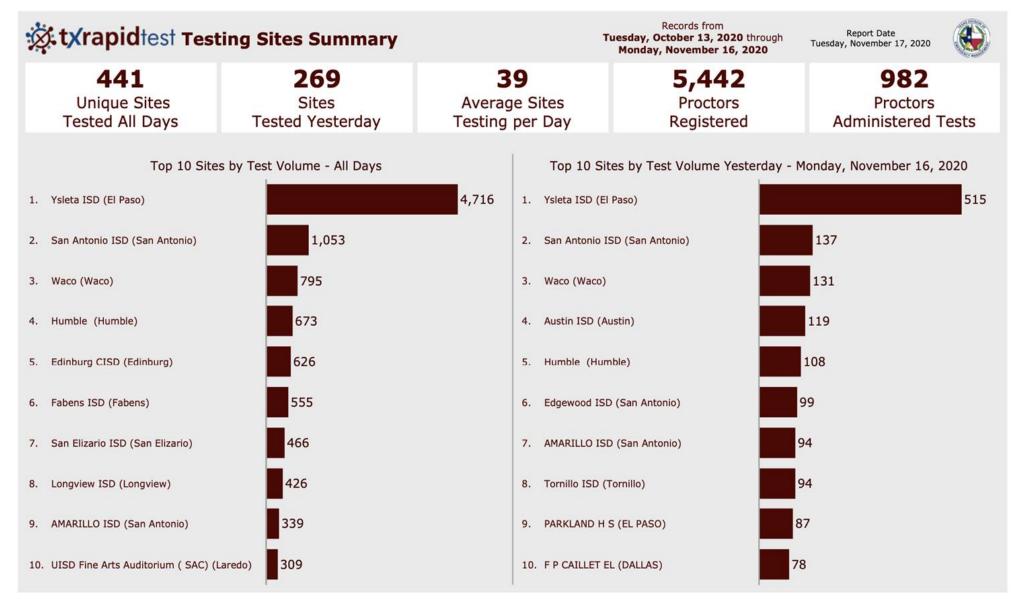
Data Flow Wire Diagram



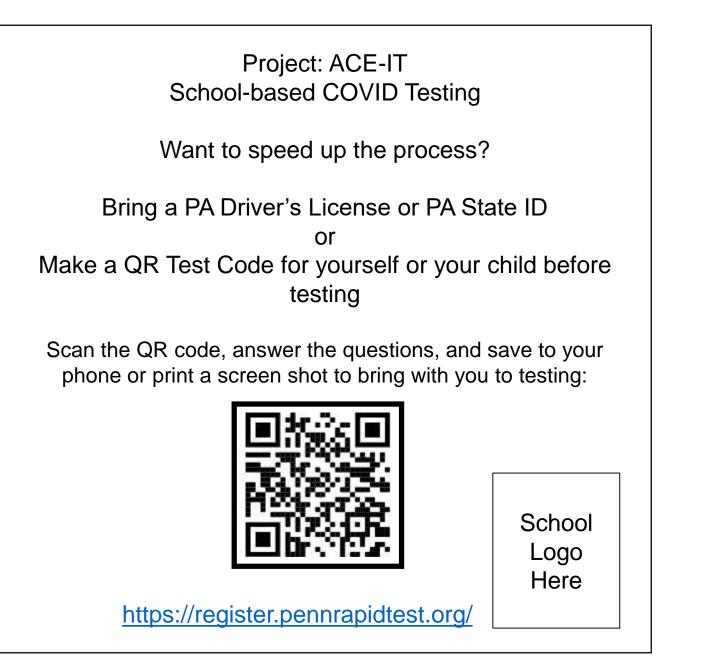
Results: Longitudinal Dashboard (similar output for PA)



Results: Snapshot Dashboard (similar output for PA)



STRAC Start-Up Guidance – Create & Distribute a Pre-Testing Flyer and Attach it to Consent/Permission Forms



Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

Breakdown of School Systems' Key Responsibilities in Testing Process Testing requires school systems to...

- Develop the overall plan of test administration for the school(s), including:
 - Who and when tests are administered
 - Where the tests are administered, and how the test layout, staging, and flow those getting tested will work at the testing location(s)
- Identify Test Administrators
- Train Test Administrators using training materials, videos, and live webinars
- Communicate the testing plan with teachers, staff, parents, students, and the community
- Ensure coordination of internal staff managing and administering the tests
- Distribute PPE to test administrators on school sites
- Ensure schools follow medical waste protocol
- Build protocol for staff & students who test positive
- Report test results to PA Department of Health via the STRAC app

Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

Key steps for schools before testing:

- 1. Determine testing approach
 - Recommended testing approaches to have the most impact on program objectives of keeping schools <u>safe</u> and <u>open</u> for on-campus instruction include:
 - Screening: Recurring testing of asymptomatic individuals. Suggest limiting to staff and students requiring routine close contact with staff only.
 - Targeted response: Testing of individuals who become symptomatic during the school day
 - Hybrid of screening & targeted testing
 - Schools systems may opt to use other approaches to testing. When considering other approaches it
 is *not* recommended to use tests:
 - Immediately prior to exposure to another group that has not been tested (e.g. testing a volleyball team prior to a game)
 - In lieu of implementing other safety protocols (e.g., allowing first grade students who have tested negative to not wear masks)
 - End a close contact stay-at-home before the incubation period has completed (e.g., allowing a teacher who was identified as a close contact to come back after 2 days with a negative test)

Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

Key steps for schools before testing, continued:

2. Communicate with stakeholders

Possible practices for communicating with school system stakeholders about Project: ACE-IT are below. School systems should feel free to communicate in any way that makes sense in their local context.

- Introduce testing program to school principals prior to broader announcement
- Announce testing program to all school staff via a (possibly virtual) all-staff meeting
- Send a mass email (see slides #61-63 for samples) or phone message recording to parents introducing the program
- Provide informational handouts and FAQ documents (see slide #8) about the testing program to all staff and parents of students
- Post all documents prominently on district/school websites
- 3. Identify testing team
 - Identify District Test Coordinator who will:
 - Oversee inventory processes in partnership with local health department and within the school system
 - Support school leaders with test program implementation
 - Report testing needs and other issues through designated channels
 - Be available to answer specific campus questions and concerns

Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

Key steps for schools before testing, continued:

- 3. Identify testing team, continued
 - Identify **Test Administrators** who will:
 - Be trained to administer the BinaxNow test and enter data into the STRAC app
 - Administer tests to staff/students (if not self-administered) and run the assays
 - Implement safety protocols
 - Report test results via the STRAC app
 - Work in collaboration with labor identified through partnership with local health department
- 4. Prepare testing locations

Prior to testing, the COVID-19 district Testing Coordinator or their designee should do the following to prepare:

- A. Plan for test distribution and storage:
 - Develop plan for receiving, storing, and distributing tests and supplies. Ensure test kits are stored in locations with temperatures between 15 and 30 degrees Celsius; or 59 and 77 degrees Fahrenheit
 - Allocate and facilitate delivery of tests and supplies to campuses, ensuring that campuses have enough tests & PPE at any given time to meet planned and emergency testing needs

Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

Key steps for schools before testing, continued:

4. Prepare testing locations, continued

Prior to testing, the COVID-19 district testing coordinator or their designee should do the following to prepare:

- B. Plan test-day logistics:
 - Identify a testing location, following guidance provided during training
 - Create a testing process flow
 - Ensure PPE and critical equipment for testing (e.g., tables, chairs) and other supplies (see slide #44) are on site
- C. Prepare COVID-19 test administrators:
 - Ensure staff are appropriately trained to conduct testing using training video and materials
- D. Perform a Dry Run:
 - Do a walk-through of each campus prior to the actual day of testing, preferably 2-3 days in advance
- 5. Prepare staff & students

Prior to testing, the campus principal or their designee should do the following to prepare

- A. School systems **must** obtain consent/permission forms
 - Depending on the district approach, this may require sending the slip in advance, on a case by case basis, to all or a subset. Obtain appropriate consent forms from all individuals tested, prior to testing, including staff members, students (with parental consent if under the age of 18)

Project: ACE-IT, Recommended Schools Systems' Responsibilities in Testing Program Implementation

- 5. Prepare staff & students, continued
 - School systems may consider including a QR code on the form to facilitate data entry
 - Prior to testing, the campus principal or their designee should do the following to prepare
 - B. Build a testing schedule and share with school stakeholders
 - C. Practice protocol for individuals that test positive
- 6. During Testing: Test Day Management

During testing, the COVID-19 school system Testing Coordinator or their designee should:

- A. Be on call to help troubleshoot and answer questions
- B. Visit campuses throughout testing to provide additional support, observe, and document lessons learned during testing, the COVID-19 campus testing administrators should:
- C. Follow all the guidance they learned in training webinar, videos, and materials
- D. Call help number or COVID-19 district Testing Coordinator or local health department contact for questions

Testing Event Start-Up Guide: Supplies

PPE:

Surgical/medical facemasks

Gloves

Physical barriers (e.g., plexiglass)

Cloth face coverings or facemasks for people being tested

Eye protection (goggles or disposable face shields that cover the front and sides of the face)¹

Gowns¹

¹Recommended for symptomatic testing only

Registration and interview materials²:

Folding chairs & tables

Several light-weight trays to lay BinaxNow cards

Chux pads or heavy paper towels

Clipboards

Pens & Markers

Sticky labels

Sanitation and hygiene:

<u>Cleaning and disinfection</u> supplies

Regular trash bags and cans

Touchless dispensers with hand sanitizer²

Handwashing station with potable water

Supplies for cleaning a spill of transport media or biological specimens

Soap and paper towels

Cleaning and disinfection supplies

Other Supplies:

Non-contact digital thermometers + extra batteries

Paper forms

Smartphones or iPads

Access to power outlets, WiFi and/or strong cell service

³ Alcohol-based hand rub with 60%-95% alcohol.

²Use items made of materials that can be cleaned between individuals.

Testing Event Start-Up Guide: Planning

PPE requirements vary based on the staff's role in specimen collection and whether they will be 6 feet away from the person being tested:

Consider whether you can minimize the number of staff needed and the amount of PPE used by having individuals <u>collect their own specimens</u> while being supervised by healthcare providers who are at least 6 feet away or outdoors

Ensure that all staff involved in specimen collection are appropriately trained and wear PPE as appropriate to their role

- Training includes proper use of PPE, including donning and doffing; symptom screening procedure; and proper technique for specimen collection
- For staff having direct contact with participants or specimens, gloves should be changed and hands sanitized after every participant. Staff not having regular direct contact with participants or specimens should change their gloves and sanitize their hands after contacting individuals or potentially contaminated surfaces, or as specified below
- Staff should change or clean and sanitize eye protection when it is soiled (e.g., after a patient sneezes or coughs onto it) or whenever they touch it or take it off
- Staff should change facemasks whenever they are soiled; become we; whenever they touch them or take them off
- Staff should change their gown when it becomes soiled or when they have more than minimal contact with the person being swabbed. They may wear the same gown to swab more than

Testing Event Start-Up Guide: Planning

- Consider the physical space where the testing will be performed
- Clearly communicate to potential participants who is eligible for testing and any limits on your capacity for testing
- Consider coordinating with your local health department on reporting information on positive test results
- Anticipate how to address individuals' mobility issues and language barriers
- Develop a plan for isolating individuals who are symptomatic or whose test results are returned positive
- Develop a risk communication plan for addressing individuals' concerns about confidentiality, potential stigma
 or undesirable outcomes based on test results (being moved to a new location, separated from family, etc.),
 and any distrust. Plan a response to situations when individuals refuse to be tested
- Develop a plan for coordinating with local EMS and healthcare providers in case individuals need medical attention
- Notify all individuals who are scheduled to be tested that they should pre- register all of their information at: [
 to generate a QR Code which may be scanned by test administrators in lieu of a driver's license or manually
 entering the information. Individuals to be tested should take a picture of the QR code generated or print a
 copy of the QR code to bring to the testing location.
- Develop a plan for disposing of biohazard waste (used specimen collection materials; soiled gloves, masks, etc.)

Testing Event Start-Up Guide: Physical Space

- In general, an outdoor location for mass testing events is preferred because it has better ventilation and more room for social distancing. Provide climate- controlled or climate-protected rest areas (large enough for social distancing) for staff
- If an outdoor location is not feasible, large indoor spaces (e.g., gymnasiums) are best, where sufficient space can be maintained between stations (i.e., periphery greater than 6 feet apart)
- For indoor specimen collection activities, designate separate spaces for each specimen collection testing station, either rooms with doors that close fully or protected spaces removed from other stations by distance and physical barriers, such as privacy curtains and plexiglass
 - To prevent inducing coughing/sneezing in an environment where multiple people are present and could be exposed, avoid collecting specimens in open-style housing spaces with current residents or in multi-use areas where other activities are occurring

Do not keep testing and other supplies in the immediate specimen collection area to avoid the possibility of contamination test materials. Consider having each person carry BinaxNow test card and swab from the check-in area to the specimen collection area

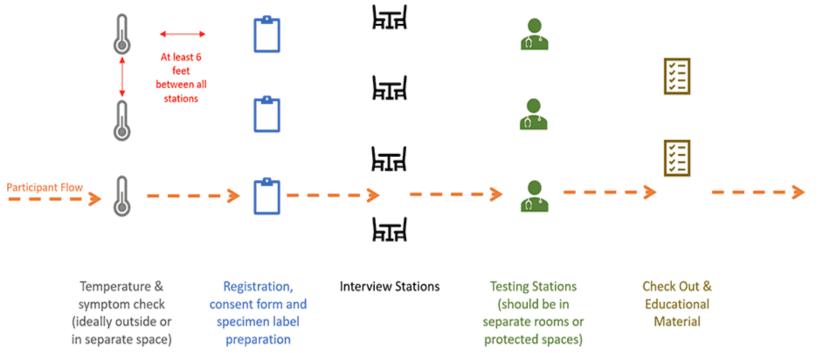
- <u>Clean and disinfect</u> all surfaces often using an Environmental Protection Agency-registered disinfectant from <u>List Nexternal icon</u>:
 - At least hourly for surfaces within 6 feet of where specimen collection was performed;
 - Anytime the surface is visibly soiled or within 6 feet of an uncovered cough or sneeze;
 - $\circ~$ At the end of shift for all surfaces and equipment in the specimen collection area

Testing Event Start-Up Guide: Flow for Testing Multiple People in Succession

- Have all staff involved in the testing conduct a test on themselves to verify all registration/reporting functions are working and the testing process is appropriate.
- Provide surgical masks or <u>cloth face coverings</u> for those undergoing testing in the area being used for the testing event. Cloth face coverings should <u>not be used</u> by:
 - \circ Children under age two (2), or
 - Anyone who has trouble breathing or is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
- As able, all participants undergoing testing should wear a surgical mask or <u>cloth face covering</u> throughout the process, only removing it during swabbing.
- Develop a plan of how individuals will flow through functional stations, in one direction (see example in Figure below)
- Designate stations with clear functional roles, define responsibilities for staff in each station, and provide PPE guidance to staff as appropriate to them. To prevent contamination, testing staff in full PPE should not leave the testing area
- Pilot the processes and flow before the actual testing event. The staff could be tested at this time
- Place touchless hand sanitizers between each station and at the facility's entrance
- Coordinate so that the flow of individuals is steady, moves in one direction, and does not lead to crowding
- Minimize the amount of time an individual spends in the testing area.
- Individuals awaiting swabbing should not wait within 6 feet of where swabbing is being done or downstream from the area if the indoor space has directional airflow

Testing Event Start-Up Guide: Flow for Testing Multiple People in Succession

- Have the person being swabbed face away from others so that if they cough or sneeze, the respiratory droplets will
 not be directed toward another person or space where others will walk
- Maintain at least 6 feet of distance between individuals and use physical barriers where appropriate. In situations
 where people will form lines, encourage people to stay 6 feet apart by providing signs or other visual cues, such as
 tape or chalk marks
- If participants are already cohorted (e.g., by class or workgroup), consider testing them together to limit their exposures to people in other groups.
- Consider processing classes together and consider extra space that might be needed to accommodate multiple people being tested.



Testing Event Start-Up Guide: Test Administrator (TA) Responsibilities Before Testing Event

1. Login and register at: <u>https://pennrapidtest.org/</u> in the space for "Agency," enter[/select] the name of your school [district]. The registration process may take up to twelve (12) hours before it is active. You will need this web-based app. to report results from each test.

Complete BinaxNow training and certification – for more information, email Maggie Eisen: <u>eisenm@chop.edu</u>

- 2. The Lead Test Administrator (TA) will be integral to planning:
 - Test event location(s), assuring that test stations are set-up to prevent testing subjects' potential of contaminating the testing area(s).
 - Confirming that there is cellular and/or WiFi service wherever the STRAC app will be used.
 - Flow of individuals to be tested, while ensuring maintenance of proper social distancing (6 feet minimum)
 - Acquisition of materials required to conduct testing, including desks/tables, chairs, electrical outlet availability to charge iPhones, Androids, or iPads, and waste disposal cans and liners.
- 3. The Lead TA will be responsible for assuring that every test kit that is used for quality control testing or training and documented in the STRAC app.

For these kits, rather than reporting positive or negative results, the TA should choose the option for "Test not Performed." The TA conducting the quality control test or training should use their own personal information to enter into the system.

Testing Event Start-Up Guide: Test Administrator (TA) Responsibilities During Testing Events

- 4. Test Administrator (TA) Safety Personal Protective Equipment (PPE) on hand will include Gloves, Surgical Masks, Face Shields, and Disposable Gowns.
- 5. When the TA supervises the test subject in collecting their own samples and inserting the swab in the test instrument, they will maintain social distancing (6 feet). They will need a face mask and gloves as the minimum level of PPE.
- 6. When the TA collects the test sample from a test subject, they will be in close contact. Therefore, minimum PPE requirements will include gloves and a surgical mask. A face shield and a disposable gown and not required but recommended.
- 7. CDC recommends changing of gloves only if having direct contact with test subject or specimen. Face shield, face mask and gown should be changed if they become soiled. All PPE should be changed after interaction with a test subject with a positive result.
- 8. Suggested Testing Methodologies Voluntary Targeted testing may be conducted, as needed, on staff and students who present COVID-19 symptoms while on campus and those individuals who have been in close contact (within 6 feet for more than 15 minutes) to individuals who test positive for COVID-19 in the two (2) days before the positive test. Voluntary Screening Testing may be conducted weekly on staff, or Staff may be tested on a single day or spread throughout a week of testing.

Testing Event Start-Up Guide: Test Administrator (TA) Responsibilities During Testing Events

BinaxNow Testing Process – Registration, Collecting Sample, and Running the Test

- 1. Enter the require<u>d information into the portal on each individual who is tested:</u>
 - Scan the QR code on the BinaxNow Ag test card
 - Scan the individual's driver's license if available, or manually enter the informatio
- 2. Ensure that every student under the age of 18 who comes for testing has a signed parental authorization form to conduct COVID-19 testing.
- 3 Follow training provided by CHOP, your local health department, or designated certified trainer and refer to the **BinaxNow Test Job Aid**

Conduct the testing by:

- Allowing the individual to use the swab to collect their own sample, or using the swab to collect the sample from the individual directly.
- Once the reagent is dropped onto card, card must remain flat at all times until the result is determined.
- Insert the swab into the test card by:
 - Allowing the individual to insert the swab appropriate into the test card, or
 - Inserting the swab directly into the test card.
- Leaving card on the flat surface, remove the strip covering the adhesive and fold the card closed; press firmly on the card to seal.
- Wait 15 minutes for the test to reveal the result.



Testing Event Start-Up Guide: Test Administrator (TA) Responsibilities During Testing Events BinaxNow Testing Process – Results & Post-Test Responsibilities

4. Results

Enter the result into the STRAC app and submit the results.

Notify the individual if they are present of the outcome.

If the test is positive, handle as directed by district personnel.

5. Post-Test Responsibilities

Test administrators will ensure that all test kits are disposed of as biohazardous material.

Ensure that the results of all testing are reported through the data portal.

Notify school system test coordinator of any shortages of testing materials or PPE immediately.

6. Contacts:

Tests: Abbott Labs Technical Support for BinaxNOW Test Kits – 1 (800) 257-9525 Anything else: Maggie Eisen: <u>eisenm@email.chop.edu</u>; (267) 977-9693

Testing Event Start-Up Guide: Test Coordinator (TC) Responsibilities

1. Login and register at: <u>https://pennrapidtest.org/</u> in the space for "Agency," enter[/select] the name of your school [district]. The registration process may take up to twelve (12) hours before it is active. You will need this web-based app. to report results from each test.

Complete BinaxNow training and certification – for more information, email Maggie Eisen: <u>eisenm@chop.edu</u>

- 2. Each school will notify their contact at the local IU or health department (TBD by each local collaboration) of the Name and Phone number of the school's Test Coordinator (TC).
- 3. The TC will serve as a single primary point of contact with Project: ACE IT related to training and test supplies and will serve as a conduit for testing information coming from health department to the school.
 - Access to the next allocation of BinaxNow Test Kits will be coordinated by Maggie Eisen: <u>eisenm@chop.edu</u> with the TC.
- 4. School/on-site coordination
 - Serve as Point of Contact (POC) for Administrators at the various campuses participating in the testing program (or considering participation)
 - Serve as a resource for Test Administrators to troubleshoot problems encountered with the testing
 - Identify and see to the training of an Alternate Test Coordinator that can serve in the event the primary person in this position is unable to do so
 - Advise Administrators in the district as to the various testing strategies
 - Coordinate with schools within the District participating in the testing program to identify TAs

Testing Event Start-Up Guide: Test Coordinator (TC) Responsibilities

- 4. School/on-site coordination, continued...
 - Ensure Test Administrators are trained and understand the use of the data portal.
 - Ensure all persons identified as Test Administrators at each campus have completed the proper training before receiving testing materials.
- 5. Other Considerations
 - Identify and provide for any necessary set up of any designated testing locations on the individual campuses
 - Ensure that the testing location has all of the equipment necessary for the test administrators to conduct testing
 - Provide testing materials and PPE to test administrators before the initiation of testing activities
- 6. Duties of TC
 - Ensure quality control of the testing materials conducted within the District
 - In the event the data portal is not accessible, serve as a resource for the download and entry of the data on the Department of State Health Services excel spreadsheet and upload it to the TDEM data portal. (The address of the data portal and the procedures to use for this process will be sent directly to the test administrators)

Testing Event Start-Up Guide: Test Coordinator (TC) Responsibilities

- 6. Duties of TC, continued...
 - Ensure that every test kit that is used for quality control testing or training is reported through the app.txrapidtest.org application. For these kits, rather than reporting positive or negative results, the test administrator should choose the option for "Test not Performed." The test administrator conducting the quality control test or training should use their own personal information to enter into the system.
 - Serve as the subject matter expert for the District/ Private school regarding testing procedures of this specific program.
 - Ensure resupply of testing materials and PPE to test administrators as needed
 - Ensure Test Administrators are reporting results as required and serve as a resource if they encounter difficulties. Notify TDEM test coordinator of any problems associated with testing
- 7. Duties for Demobilization of Testing
 - Serve as POC for TDEM concerning demobilization of testing activities
 - Provide guidance to Test Administrators regarding demobilization of the test site at their campus
 - Ensure all reporting has been completed as required by PA Department of Health
 - See to the return of test instruments and supplies as directed by the local health department
- 6. Contacts:

Tests: Abbott Labs Technical Support for BinaxNOW Test Kits – 1 (800) 257-9525

Anything else: Maggie Eisen: <u>eisenm@email.chop.edu</u>; (267) 977-9693

Testing Quick Guide

Testing Preparation

- 1. Each District/School will identify a Test Coordinator.
- 2. Each District/School will identify as many Test Administrators as necessary for each school participating in the program.
- 3. Test Coordinators and Test Administrators will create an account on the Penn Rapid Test website: <u>https://app.pennrapidtest.org/</u>.
- After creating an account on the Penn Rapid Test website, Test Coordinators and Test Administrators will be asked to complete a training with the Project: ACE-IT implementation team. Contact Maggie Eisen: <u>eisenm@email.chop.edu</u> for details.
- 5. BinaxNOW Ag tests will be delivered to the Test Coordinator based on predetermined criteria.

Testing Day

1. Test subject registration begins when the Test Administrator opens the Penn Rapid Test app: <u>https://app.pennrapidtest.org/</u> and enters their login credentials.

To initiate data input, the Test Administrator will open a new BinaxNOW Ag Card and scan the QR code. Personal information for the test subject can be acquired by scanning that person's state ID/license, scanning the individual's unique QR Code, or manually entering the information if the test subject doesn't have a driver's license/ID or printed QR code. The Test Administrator will also enter the COVID screening information required by the app when prompted.

- 2. QR Codes for individuals may be created at: <u>https://register.pennrapidtest.org/</u>.
- Once the test subject is registered, the Test Administrator will either supervise the collection of a test sample or collect the sample from the test subject as demonstrated during training. For questions regarding the actual BinaxNow test kit, contact Abbott Labs Technical Support for BinaxNow Test Kits – 1 (800) 257-9525.
- 4. Once the test is complete, the Test Administrator will add the result to the Penn Rapid Test session opened for that test subject. The Test Administrator will then submit the results.

Testing Quick Guide, continued

After Testing

The Test Administrator will gather all used tests and place them in a biohazard bag. Once full, the Test Administrator will coordinate with the District/School Test Coordinator who will organize for the proper disposal.

Test Resupply

Test Coordinators should be in regular contact with their local health department to help anticipate and coordinate resupply of testing materials.

Any questions about testing or program implementation should be directed to Maggie Eisen, Project: ACE-IT Implementation Lead: <u>eisenm@email.chop.edu</u>

Sample Correspondence about School-based Testing, Letter to Staff

School District Logo Here Healthy Valley School District Logo Here Healthy Valley School District Lev Vygotsky, Ed.D., Superintendent 1234 School House Land Healthy Valley, PA 56789 Phone: (610) 123-4567 Email:

supersuper@healthyvalley.org

Dear Healthy Valley Staff,

In Healthy Valley School District (HVSD), we are committed to doing all we can to keep staff and students healthy and safe. With this goal in mind, we are pleased to share that we will be taking part Project: ACE-IT, a program offering rapid COVID tests for use in schools. This program will allow HVSD to test both symptomatic and asymptomatic individuals— including staff and students, with permission from parents—and reduce the risk to our community. This email offers further information on the tests and the testing program. If you have additional questions, you can view an FAQ here <LINK> or contact xxx@healthyvalley.org.

What COVID-19 tests are used in this program?

This program primarily uses <u>BinaxNOW[™] tests</u>, which provide results in 15 minutes and are administered using a nasal swab in the *front area* of the nostril. These <u>antigen</u> tests are highly accurate, detecting 97%-98% of symptomatic individuals. If the person tested receives an unexpected result—meaning they are symptomatic but receive a negative result, or they are asymptomatic and receive a positive result—they may be referred for another more sensitive test, such as the <u>Cue Health</u>, or a molecular test, such as a PCR. Referrals for additional testing will be communicated promptly to staff members or parents/guardians of students who have tested positive. For more information on different types of COVID-19 tests, click <u>here</u>.

Who will be tested and when?

Our current <u>allotment of tests</u> provide for: 1) symptomatic testing of students and staff, and 2) weekly asymptomatic or *assurance* testing of staff and limited groups of students between January and April 2021. If supplies permit and our program shows success, we will consider opening up asymptomatic testing to additional groups of students.

All testing will be limited to students and staff who are participating in in-person education. These tests are optional but we strongly encourage all staff who work on-site to participate in our "assurance" testing program.

If I feel sick, can I come to the school to be tested?

No staff or students are allowed to enter a school building if they have been exposed to COVID-19 or have <u>symptoms consistent with COVID-19</u>. Instead, a referral to another testing location may be offered. This safety protocol is critical to the safety of the school community. In-school testing will only be available to staff and students who come to school feeling healthy, but begin to feel symptomatic during the school day.

How will I learn about my test results, and how will this information be used?

Staff and families of students tested will receive results via text or email shortly after they are known. All test results will be shared with the local health department as required for public health reporting and contact tracing, as well as to determine the stay-at-home period for those testing positive. School staff will also be able to quickly isolate when a student or staff member tests positive. All data will be protected and transferred via a secure server.

What steps are required to participate in the program?

Tests are available to all staff who work on campus. To participate, staff must complete the form attached [or this e-form <url>]. The first date testing will be available is January ____, 2021.

In order to achieve the mission of our assurance testing program, participating staff are expected to be tested weekly as long as they are not experiencing symptoms consistent with COVID-19. You will be asked to adhere to a weekly testing schedule; and if you need to miss a scheduled test, you will be expected to reschedule and come for a test within ____ hours of your originally scheduled test.

You may use your driver's license or State ID to register at the testing site or create a personalized QR code to print and bring to each test here: <u>https://register.pennrapidtest.org</u>.

Thank you for your support,

Lev Vygotsky, Ed.D., Superintendent Healthy Valley School District

Sample Correspondence about School-based Testing, Letter to Families

School DistrictLev Vygotsky, Ed.D., SuperintendentLogo HereHealthy Valley School District1234 School House LaneHealthy Valley School DistrictHealthy Valley, PA 56789	All testing will be limited to students and staff who are participating in in-person education. These tests are optional but we strongly encourage all staff who work on-site to participate in our "assurance" testing program.				
Phone: (610) 123-4567 Email: supersuper@healthyvalley.org	If my student feels sick, can they come to the school to be tested?				
Dear Healthy Valley Families, In Healthy Valley School District (HVSD), we are committed to doing all we can to keep staff and students healthy and safe. With this goal in mind, we are pleased to share	No staff or students are allowed to enter a school building if they have been exposed to COVID-19 or have symptoms consistent with COVID-19. Instead, a referral to another testing location may be offered. This safety protocol is critical to the safety of the school community. In-school testing will only be available to staff and students who come to school feeling healthy, but begin to feel symptomatic during the school day.				
that we will be taking part Project: ACE-IT, a program offering rapid COVID tests for use in schools. This program will allow HVSD to test both symptomatic and asymptomatic individuals—including staff and students, with permission from parents—	How will I learn about my child's test results, and how will this information be used?				
and reduce the risk to our community. This email offers further information on the tests and the testing program. If you have additional questions, you can view an FAQ here <link/> or contact xxx@healthyvalley.org.	If you give permission for HVSD to administer the BinaxNow test to your student, the school will call to let you know that your student is experiencing symptoms and that we will be administering a BinaxNow test. The test administrator will also call to share the results after the test has been administered. Families of students tested will receive results via text or email shortly after they are known. All test results will be shared with the local health department as required for public health reporting and contact tracing, as well as to determine the stay-at-home period for those testing positive. School staff will also be able to quickly isolate when a student tests positive. All data will be protected and transferred via a secure server.				
What COVID-19 tests are used in this program?					
This program primarily uses <u>BinaxNowTM tests</u> , which provide results in 15 minutes and are administered using a nasal swab in the <i>front area</i> of the nostril. These <u>antigen</u> tests are highly accurate, detecting 97%-98% of symptomatic individuals. If the person tested receives an unexpected result—meaning they are symptomatic but receive a negative result, or they are asymptomatic and receive a positive result—they may be					
referred for another more sensitive test, such as the Cue Health, or a molecular test,	What happens next?				
such as a PCR. Referrals for additional testing will be communicated promptly to staff members or parents/guardians of students who have tested positive. For more information on different types of COVID-19 tests, click here.	To participate, parents must complete the form attached [or this e-form <url>]. The first date testing will be available is January, 2021.</url>				
Who will be tested and when?	You may pre-register your student and create a personalized QR code to print and bring for testing at this site: <u>https://register.pennrapidtest.org</u> .				
Our current <u>allotment of tests</u> provide for: 1) symptomatic testing of students and staff, and 2) weekly asymptomatic or <i>assurance</i> testing of staff and limited groups of	For questions, please contact Dr. Anthony Fauci, MD, Director of School Health Services at (610) 234-5678, or hero@healthyvalley.org .				
students between January and April 2021. If supplies permit and our program shows success, we will consider opening up asymptomatic testing to additional groups of students.	Thank you for your support,Lev Vygotsky, Ed.D., SuperintendentHealthy Valley School District56				

Sample Correspondence re: School-based Testing, Letter to Families of Student Participants in High-contact Extracurriculars

• •		•	–	
School District Logo Here	Healthy Valley School District 1234 School House Lane Healthy Valley, PA 56789	If you or anyone in your household is experiencing any of these symptoms in a way that is not typical, we encourage you to contact your physician. Also, please remember that COVID-19 testing is free of charge for all HVSD students at the County Intermediate Unit; and we encourage you to notify us of any test-confirmed COVID-19 cases in your household by calling your school at (246) 135-7891. Please make sure your student is pre-registered for testing and has printed a personalized QR code to bring for testing from this site: <u>https://register.pennrapidtest.org/</u> . Sincerely,		
members/theater students] will be asked <u>19 Ag Card</u> rapid-result testing. Test res	our students and staff, the following [athletes/choir d to undergo optional weekly <u>BinaxNOW™ COVID</u> - sults are available within minutes and the entire bout minutes. Your student will test at ing will begin on February 2021.			
Students must present a photo ID with e out of a QR code that you or they will cr for instructions on how to make a perso permission slip signed by a parent. Plea On school holidays the student will still I	either a driver's license, or school ID card, or a print- eate and bring to the testing site (see the next page nal QR code). They must also provide the attached ase review the testing schedule on the next page. be expected to come for testing if possible. Make-up	Thank you for your support, Lev Vygotsky, Ed.D., Superintend Healthy Valley School District		3, 2021
o i i i	weekends with advance communication.	Team/Group	Day	Time
	I to prevent further spread of the COVID-19 ported in the EI Paso area. The health and safety of	All bands	Monday	7:00a – 9:00a
students and staff is the #1 priority at th	e HVSD, and we will continue to take precautions in		Monday	3:00a – 5:00p
order to safeguard students and staff in authorities.	accordance with local, state, and federal health	Theater	Tuesday	7:00a – 9:00a
	tly watch for symptoms of COVID-19. Any of the	Cheerleading	Tuesday	3:00a – 5:00p
following symptoms indicate a possible COVID-19 infection:		Wrestling	Wednesday	7:00a – 9:00a
 Feeling feverish/temp. >100 Loss of taste Cough 	Loss of taste • Cough • Difficulty	Boys/Girls Basketball	Wednesday	3:00a – 5:00p
o .		Boys/Girls Ice Hockey	Thursday	7:00a – 9:00a
5 5	Shortness of • Significant • Nausea or	Boys/Girls Indoor Track & Field	Thursday	3:00a – 5:00p
exaggerated or runny breath muscle pain shivering nose or ache	breath muscle pain vomiting or ache	Boys/Girls Squash	Friday	7:00a – 9:00a
			1	

Boys/Girls Swimming & Diving

Friday

3:00a – 5:00p

57

Chills

Headache

Fatigue

Sore throat

• Diarrhea

Recommended Consent Form Content

- Consent form should be no longer than 2 pages, printed front/back
- Attach a flyer encouraging pre-registration and creation of personalized QR code: <u>https://register.pennrapidtest.org/</u>
- Consent form should be translated into various languages represented throughout your school district
- Include information specific to your school or district; for example, you may want to add context if consent is to be filled out once testing has been initiated; or, in advance of the possibility of tests being conducted in the future
- Add logistical details specific to your school or district's policy regarding communication of positive and negative test results, referrals for confirmatory testing, and counseling or instruction on what to do after receiving positive results to protect students' families, other close contacts, and the community
- In describing the type(s) of tests being used, use language that is consistent with each test's manufacturer's descriptions of the test
- In describing symptoms of COVID-19, use language that is consistent with the CDC, World Health Organization, or other recognized public health authority
- For disclaimers addressing general liability, use language approved by your local legal counsel, e.g., your County Solicitor

Sample Consent Form

STUDENT CONSENT FORM FOR [OPTIONAL] COVID-19 TESTING

The <<insert school or district name>> takes the health and safety of our students and their families very seriously. As such, in addition to steps to screen for the virus and prevent its spread on a campus, we are adding a voluntary K-12 COVID-19 testing program for students. This program uses Abbott Laboratories BinaxNOW tests provided by the federal government. We will only test with your consent. If you are willing to provide consent for us to administer this test on your child or yourself (if student age 18 or older), please fill out this form.

What is the test?

If your child is symptomatic or part of a group that is designated for testing, if you consent, your child will receive a free BinaxNOW rapid test for the COVID-19 virus. Collecting a specimen for testing involves using a swab, similar to a Q-Tip, placed inside the tip of the nose. A school staff member who has been trained to use this test will collect the specimen and a trained COVID-19 test administrator will oversee the process. Test results will be made available to the parent/guardian who signs this form below. The results will be sent by text message and email within 24 hours of the test. This program is entirely optional for students, although we hope you choose to have the test to keep our schools as healthy & safe as possible. The tests are being offered in addition to existing safety protocols such as mask-wearing, social distancing, and frequent disinfection of surfaces.

What should I do when I receive my child's test results?

If your child or you (if student age 18 or older) tests positive for the virus, your child will be moved to a room away from other students and staff until you can pick them up. We ask that you keep your child home until the infection period has ended (typically, after symptoms improve and at least 10 days from the date symptoms first appear) and your child is no longer contagious. If your child's test results are negative, the virus was not found in the specimen tested and your child may continue to attend school without interruption. In a small number of cases, tests sometimes produce incorrect results – showing negative results (called "false negatives") in people who have COVID-19 or showing positive results (called "false positives") in people who don't have COVID-19. If your child tests negative but has symptoms of COVID-19, or if you have concerns about your child's exposure to COVID-19, you should call your child's doctor, a licensed medical authority, or your local health department.

Known Symptoms:

People with COVID-19 have had a wide range of symptoms reported – ranging from mild symptoms to severe illness. Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

- Feeling feverish or a measured temperature greater than or equal to 100.0 degrees Fahrenheit
- Feeling feverish or a measured temperature greater than or equal to 100.0 degrees Fahrenheit

Loss of taste or smell

Loss of taste or smell
 Cough

Difficulty breathing

Shortness of breath

- Cough
- Difficulty breathing
- Shortness of breath
- Fatigue
- Headache

- Fatigue
- Headache
- This list does not include all possible symptoms.

Disclaimer: While we realize precautions will be taken for the safety of students, please understand that neither the test administrator nor the <<insert school or district name>>, nor any of its trustees, officers, employees, or organization sponsors are liable for any accident or injuries that may occur to your child or yourself (if student age 18 or older), as a result of agreeing to the test.

TO BE COMPLETED BY PARENT, GUARDIAN OR ADULT STUDENT								
Parent/Guardian Information								
You will be notified with test results either via cell phone or email, or both.								
Parent/G								
	t Name:							
	Parent/Guardian Cell/Mobile #:							
Note: Results will be texted to t								
Parent/G								
Email A	ddress:							
Child/Student Information								
Child/Student Print Name:								
Driver's License #:								
(if applicable)							 	
Street Address:				City:			State:	PA
Zip Code:				County	:			
School:							Grade	
							Level:	
Date of Birth:							Age:	
(MM/DD/YYY)								
Race/Ethnicity:			Native Ameri	an/Indig	enous	Gender:	Female	
	🗆 Black	White	Unknown				Male	
							Non-binary	/
CONSENT								

By signing below, I attest that:

- A. I authorize the school system to conduct collection and testing of my child or me (if student age 18 or older) for COVID-19 by nasal swab.
- B. I acknowledge that a positive test result is an indication that my child or me (if student age 18 or older), must self-isolate and also continue wearing a mask or face covering as directed in an effort to avoid infecting others.
- C. I understand the school system is not acting as my child's medical provider, this testing does not replace treatment by my child's medical provider, and I assume complete and full responsibility to take appropriate action with regards to my child's test results. I agree I will seek medical advice, care and treatment from my child's medical provider if I have questions or concerns, or if their condition worsens.
- D. I understand that, as with any medical test, there is the potential for a false positive or false negative COVID-19 test result.

I, the undersigned, have been informed about the test purpose, procedures, possible benefits and risks, and I have received a copy of this Informed Consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask additional questions at any time. I voluntarily agree to this testing for COVID-19.

Signature of Parent/Guardian:	Date:	
Signature of Student:	Date:	
(If age 18 or over or otherwise authorized to consent)		50

Summary of Testing Program Logistics: At least 880 tested over 3 day/ ~17 hours; testing not mandatory

- Monday, October 12th Kick-off meeting
- Tuesday, October $13^{th} @YISD$ Central Office with 50% of staff
 - Approximately 174 tested.
- Wednesday, October 14th @YISD Central Office with remaining 50% of staff, M&O, Grounds, Warehouse, and Transportation
 - Approximately 182 tested.
- Thursday, October 15th @Del Valle High School Various Student Athletes and district-wide staff.
 - Approximately 524 tested.

Prior to 1st day of Testing

Preparation for testing:

- $\checkmark\,$ Receive and inventory test kits and PPE.
- ✓ Quality control each test lot.
- ✓ Separate bottles of reagent from each box of 40 test kits.

Preparation for using the STRAC app:

- ✓ Provide link for training to administrators/proctors.
- ✓ Request initial administrators/proctors (~10) complete training >48 hours before first opportunity to test.
- ✓ Ensure they can access and login to the app. They must be certified and have their own login in order to submit a test result. The delay to get access to the app can be as long as 48 hrs.
- Add link to "invitation" emails so employees and/or students' parents can create QR code in advance of testing to streamline data entry during event

Identify Personnel to Fulfill Roles and Responsibilities

<u>Coordinator</u> – Ensures area is ready, all PPE is in its proper area, assigns roles and responsibilities to staff, maintains inventory control of PPE and tests, answers questions and assists monitors, ensures area is clean and disinfected upon completion of the testing. PPE needed — N95, Face Shield, and gloves

<u>Monitor/Speaker/Nurse</u>– Explains steps of the test and walks individuals through the testing process. PPE needed — N95, Face Shield, and gloves

<u>Isolation Nurse</u> – Documents positive cases and follows ISD's procedures for positive cases, contact tracing, and ensuring proper leave from work. PPE needed — N95, Face Shield, and gloves

<u>Custodians</u> – Assist with disinfection in between testing and fogging of the area before lunch break and at end of testing session (fog all areas to include restrooms). PPE needed – Surgical Mask and gloves

*<u>Monitor/Demonstrators</u> – Follow along with Speaker and assist large groups with "dud" kits PPE needed — N95, Face Shield, and gloves *<u>Monitors/Readers</u> – Assist Demonstrators with reading test kits from start to finish (Blue line, swab insertion, drops, removal of tape, closure of kit, and initial 3-minute read) PPE needed — N95, Face Shield, and gloves

*<u>Monitors/Registrars</u> – Registers patients by following the app QR procedures. Assists with reading test results as needed. PPE needed — N95, Face Shield, and gloves

*<u>Timekeeper</u> – Monitors the various time intervals and advises when to read kits. Resupplies the swabs at patient areas and keeps track of back up PPE during testing. PPE needed – Surgical Mask

*<u>IT</u> – Develop or work with IT to create QR for district employees and students. Play demonstration video and ensure data network connections PPE needed – Surgical Mask

*Security – crowd control, check students at drop-off area to ensure they have parent permission slip, ask if individual has symptoms, radio ahead for assistance with symptomatic individuals. PPE needed – Surgical Mask (Updated 10/25/2020)

*Optional roles, which depend on the number of patients being tested at once

Plan for Weekly Testing of Campus Personnel

Application:

For teachers and campus personnel to voluntarily self-test bi-weekly on Mondays prior to the start of school. Ideally, the entire process would take no more than 30 minutes. Teachers/staff would arrive 20-30 minutes early and be allowed to leave early on Friday to accommodate the testing schedule.

Physical Setup:

Registration Area: Registration not required. At entry, provide hand sanitizer, surgical masks for staff, QR codes, and TDEM cellular devices, if needed.

Testing Area - "HOT/ RED Zone" : Individual desks to serve as testing stations (no chairs), use TDEM or personal cell phone or watch as timer, appropriate signage, hand sanitizer, two 55 gal. trash cans with cut tops (circle/rectangle with RED "X"), disinfection kits -bleach water sprayer & paper towels.

Isolation room with electrical and data available. Room should have a sink and trash can. "ISOLATION" sign should clearly identify room as it is a restricted area. It should be located within visual site of testing area. Should be "fogged" after each use.

Roles and Responsibilities:

Coordinator –(1)

Isolation Nurse -(1)

Monitor/Reader - (self)

Custodians (1-2)

Plan for Weekly Testing of Campus Personnel, continued

Process:

Assuming staff have completed the training and qualification, are able to access the app, and have participated in at least one group session, provide individual testing stations and ask them to self-administer the test. Have them wait three minutes for test to process. Test Coordinator confirms negative and releases or sends a positive test to isolation.

If a positive test is identified, nurse is notified to confirm. A "Post it" will be placed on the test station to notify others of the positive case and to exercise additional caution when disposing of the testing material and when disinfecting the station. Positive patient should be taken into the ISOLATION room and processed via existing YISD procedures (See <u>Back to School</u> <u>Central</u> for YISD's plan when a positive case is identified). If, for any reason, the school nurse is not available, record the positive result, escort the staff member to their car, and follow the process for positive case notification found in the Back to School Central Plan.

After the 15 minutes have elapsed, Coordinator performs test result verification and enters final result in TDEM app.

For Testing Groups of Fewer Than 50

Application:

To test a group of student athletes (football or volleyball teams) or small group of non-certified administrators.

Physical Setup:

Drop Off Area: Station security guards or non-certified administrators at drop off zone. Ensure students exiting cars have parent permission slip prior to proceeding. PPE needed – N95 mask and face shield

Registration Area: Only necessary for collection of parent permission slips and dissemination of QR codes. PPE needed – N95 mask and face shield

Testing Area - "HOT/RED Zone": a large classroom or space where desks can be socially distanced but grouped in pods of five to create testing stations. One certified coordinator can perform all roles and responsibilities in each pod. This process can take approximately 20 minutes from cradle to grave.

Staff Needed:

Coordinator -(1)

*Custodian -(1) – optional, depending on the number of those being tested at once

For Testing Groups of Fewer Than 50, continued

Process:

Test Coordinator in each small group:

- 1. Emphasizes need for students to follow directions.
- 2. Asks each student to set phone on desk and open stopwatch/timer.
- 3. Directs them to remove personal masks and replace with temporary surgical masks.
- 4. Asks them to remove test kit from packet, check for blue control line on front, lay kit flat on desk. Advises from this step forward not to pick up test from the desk to avoid spilling reagent.
- 5. Directs them to place index finger under nose, huff three times through nose to moisten nostrils.
- 6. Asks each student to remove swab from package and hold. Explains swabbing process emphasizes need to follow instructions.
- 7. Directs them to pull mask down leaving mouth covered but exposing nostrils. Swab each nostril for 15 seconds while coordinator circles room and supplies reagent.
- 8. Explains the process to insert swab in card and to close cards from left to right without picking cards up.
- 9. Advises students to set personal timers for 3 minutes and to replace personal masks.

While tests are processing, coordinator registers students: scans test card, QR code, asks for signs & symptoms, if required, and performs preliminary read during this 3-5 minute window. After completing registration for pod, releases those who are clearly negative, retaining those who are positive.

For Testing Groups of Fewer Than 50, continued

If a custodian will be utilized, Test Coordinator placed a "Post it" on the testing station after testing of the positive case and to emphasize the need for extra caution in the disposal of the testing kit material and station disinfection. Used tests should be discarded in the "red" trash can. Once all the other patients were released, testing stations were disinfected by either the Test Coordinator or custodian and items were properly disposed of. Positive patients were taken into the ISOLATION room and processed via existing YISD procedures (See <u>Back to School Central</u> for YISD's plan when a positive case is identified).

After the 15 minutes had completely elapsed. Tests were read and recorded via TDEM app.

If additional groups were to be tested, custodians follow and sanitize pod while coordinator gathers next group of five from waiting area. With 5-7 coordinators this process can be used for groups exceeding 50 and still move groups through quickly.

For Testing Groups of 50 or More

Application:

To initially qualify and teach many administrators how to perform the test. Intended for use as the first introduction to a large number of teachers/campus staff who will either perform their own self-tests thereafter or help administer tests to small groups. It is important enough personnel are already certified to act as monitors in this setting.

Physical Setup:

Registration Area: Tables, plastic chairs, hand sanitizer, masks for patients, patient QR codes, testing area assignment, cellular/handheld devices. Ensure patients have masks on and that staff have control of who enters. PPE needed – N95 mask and face shield

Testing Area - "HOT/ RED Zone": Student desks (no chairs), microphone, white board, timer/watch, appropriate signage, hand sanitizer, caution tape, two boxes (pos/neg) for QR codes if applicable, blank "Post –its", two 55 gal. Trash cans with cut tops (circle/rectangle with RED "X"), disinfection kits -bleach water sprayer & paper towels, power banks, and fogger (optional).

Demonstration table to hold PPE for immediate use by Speakers and Monitors.

Small tables set up in various locations around the testing area to hold disinfection kits and back up PPE (mask, gloves, and swabs)

Isolation room with electrical and data available. Room should have a sink and trash can. "ISOLATION" sign on the door. This should be a restricted area located within visual site of testing area. Should be "fogged" after each use.

Break Room – A "Clean Room": Staff area for food, water, and personal items. Plastic chairs and tables.

Separate Symptomatic Testing Area – Designate spaces and traffic area for symptomatic people to keep them out of the healthy population (Updated 10/25/2020)

Staffing Needed (Estimated Quantity): *Optional roles, which depend on the number of patients being tested at once

Coordinator (1)	Monitor/Speaker/Nurse (1)	Isolation Nurse (1)	Custodians (1-3)	*Monitor/Demonstrators (3)
*Monitors/Readers (3)	*Monitors/Registrars (3)	*Timekeeper (1)	*IT (2)	*Security (2)

For Testing Groups of 50 or More, continued

Place 50-100 student desks socially distanced in large common area, cafeteria, or gym. Don't use chairs to avoid more spaces to disinfect. Register and stage each round of participants in large entry or hallway.

Monitor/Speaker leads group through instructions for testing:

- 1. Monitor emphasizes need for audience to act together to ensure timekeeping is accurate for all individuals who are being tested.
- 2. Monitor directs subjects:
 - a. To remove personal masks and replace with temporary surgical masks.
 - b. To remove test kit from packet, check for blue control line on front, lay kit flat on desk. Advises from this step forward not to pick up test from the desk to avoid spilling reagent.
 - c. To place index finger under nose, huff three times through nose to moisten nostrils.
 - d. To remove swab from package and hold. Explains swabbing process emphasizes need to follow monitor's instructions.
 - e. To pull mask down leaving mouth covered but exposing nostrils. Swab one nostril (Timekeeper tracks 15 seconds for each nostril. Monitors/Readers/Demonstrators with reagent walk room to apply drops in kits while subjects are swabbing.)
 - f. To insert swab in card. (Monitors/Readers/Demonstrators assist with ensuring swabs are appropriately placed.)
 - g. To close cards from left to right without picking card up. (Timekeeper sets timer for 3 minutes. Monitors/Readers/Demonstrators begin to observe tests and prepare to isolate positives.)
 - h. To replace personal masks and prepare to exit when released.
 - i. To leave everything behind except what they brought with them.

Room monitors read at 3 minutes and release clear negatives, holding positives. After 3 minutes, remove non-biohazard trash from desks. Mark high-risk desks for careful handling. After 12 more minutes, enter final result, dispose of biohazard trash, file QR codes in +/- boxes, respectively. Custodians sanitize. Timekeeper/supply team replace surgical mask, test kit, and swab at each test station.

A "Post it" was placed on testing stations where positive tests were observed to notify the other monitors of the positive case and to exercise caution in the disposal of the testing kit and materials which were placed into the "red" trash can. Once all the other individuals were released, positive patient location was disinfected by the custodian and items were properly disposed of. Positive patients were taken into the ISOLATION room and processed via existing YISD procedures (See <u>Back to School Central</u> for YISD's plan when a positive case is identified).

Goal of Testing: With guidance from the Texas Department of Emergency Management (TDEM), Center for Disease Control (CDC), Texas Education Agency (TEA), Williamson County and Cities Health District (WCCHD) and Baylor Scott and White; Granger ISD will be implementing a phased-in approach to BinaxNOW rapid COVID-19 testing. Rapid antigen based testing will potentially give Granger ISD the ability to quickly identify and isolate positive individuals before they can transmit the virus to others. In turn, this will help reduce the amount of absences for individuals waiting on test results and help to fast track treatment and quarantine for positive individuals and their close contacts. *Participation in BinaxNOW rapid COVID-19 testing is voluntary according to each individual's preference*.

Testing coordinator and testing administrator were chosen from guidelines provided by TEA. These documents are available with Dr. Tara Resla, Erica Moczygemba and Randy Willis.

Testing Program Coordinator (Point of Contact): Dr. Tara Resla Backup: Randy Willis Test Administrators (Overseer of Testing) : TBD

4 Phases to COVID-19 testing:

Phase 1: Rapid COVID-19 testing for symptomatic staff members only.
Phase 2: Rapid COVID-19 testing for symptomatic staff and students. Individuals less than the age of 18 must have parent/guardian permission before testing can be performed.
Phase 3: Rapid COVID-19 testing same as phase 1 and 2 with the addition of asymptomatic and exposure to COVID staff members.

Phase 4: Rapid COVID-19 testing same as phases 1, 2 and 3 but adding <u>asymptomatic and exposure to COVID</u> <u>students</u>. Individuals less than age of 18 must have parent/guardian permission before testing can be performed.

Phase 1 Protocol: Voluntary Symptomatic Staff Members

Phase 1 is voluntary testing for symptomatic staff members at Granger ISD. No one will be required to take a test. They may voluntarily receive the rapid antigen BinaxNOW COVID-19 test after scheduling with the Granger ISD Health Office at a time when a test administrator is available. The symptoms must be consistent with the current guidelines from the <u>CDC</u> and WCCHD.

- 1. Sick at Home: If a staff member is sick at home and they want a test, they may call the Health Office and schedule this test. We will offer a drive up to the back of school (for privacy) and perform the test outside to reduce the risk of exposure to others. Test administrators will be provided PPE to reduce the risk of exposure.
- 2. Sick at School: If a staff member gets sick while at school, they will be asked to immediately go to the isolation room and may volunteer to receive a test. If they choose not to test or wish to go home, they may do so immediately. This must be done quickly to reduce the spread of the virus.
 - If the test is negative, the staff member should still follow-up with their physician to rule out COVID or receive an alternative diagnosis.
 - If the test is positive, the staff member will be required to stay home for 10 days once symptoms begin to improve.
 They will also be encouraged to call their physician to let them know.

Phase 2 Protocol: Voluntary Symptomatic Students

Phase 2 is voluntary testing of symptomatic students at Granger ISD. The symptoms must be consistent with the current guidelines from the CDC and WCCHD. No student will be required to take the test and all students must have parent permission prior to having the test performed. Due to our campus being rural and most parents working all over central Texas, parent permission may be received over the phone by two people. Parent permission slips will be available online, in the health office and will be sent home with information about the test. If the form is filled out in advance, the parents will still be notified prior to any testing.

- If the test is negative, the symptomatic student will be sent home following symptomatic protocol. The student should still follow-up with their physician to rule out COVID or receive an alternative diagnosis.
- If the test is positive, the student will be required to stay home for 10 days once symptoms begin to improve. They will also be encouraged to call their physician to let them know.

Phase 3 Protocol: Voluntary Asymptomatic Staff Members

Phase 3 is voluntary testing of asymptomatic staff members and close contact staff members. Close contact is defined as being within 6 feet of a COVID positive individual for greater than 15 consecutive minutes. The staff members are not required to have symptoms. This is voluntary testing and will be performed as long as testing kits are available. These tests will be scheduled when a test administrator is available.

- If results come back negative, the staff member is not symptomatic and has no history of exposure they can return to work. ٠
- If the results come back negative, the staff member is asymptomatic but has a history of exposure/close contact then that ٠ staff member must still remain on quarantine. A negative test doesn't allow the individual to be removed from quarantine. It may still take up to 14 days to test positive if there was an exposure. 71

Phase 4 Protocol: Voluntary Asymptomatic Students

Phase 4 is voluntary testing of asymptomatic students and close contact students. Close contact is defined as being within 6 feet of a COVID positive individual for greater than 15 consecutive minutes. The students are not required to have symptoms. Parent permission must be provided prior to any testing. Due to our campus being rural and most parents working all over central Texas, parent permission may be received over the phone by two people. Parent permission slips will be available online, in the health office and will be sent home with information about the test. The voluntary testing will be available as long as testing kits are available.

- If results come back negative, the student is asymptomatic and has no history of exposure they can return to school.
- If the results come back negative, the student is asymptomatic, but has a history of exposure/close contact then that student must still remain on quarantine. A negative test doesn't allow the individual to be removed from quarantine. It may still take up to 14 days to test positive if there was an exposure.
- If the results come back positive, the student must follow quarantine protocols. The student will be asked to follow-up with their physician and stay home for 10 days.

Granger ISD plans to implement each phase as deemed appropriate over the course of the next few months. We want to address and educate our staff and community about the type of testing, the science behind it and the recommendations and policies Granger ISD has put in place as directed by WCCHD, CDC and TEA.

All test results will be submitted to the WCCHD, DSHS and TDEM as required.