# Statement from Houston Area Public Health Authorities on COVID-19 Rapid Antigen Testing in Schools

November 10, 2020

<u>Public health prevention measures</u> such as wearing masks, hand washing, and maintaining physical distancing are effective tools for reducing the spread of SARS-CoV-2 (the virus that causes COVID-19). <u>Diagnostic</u> testing in congregate settings such as K-12 schools are an additional effective mitigation strategy that schools may consider. Recently, the Texas Education Agency (TEA) and Texas Division of Emergency Management (TDEM) have developed a <u>COVID-19 Rapid Antigen Testing program</u> for schools across the state of Texas at no cost to the schools.

Testing for COVID-19 is only one preventive measure that can help reduce the spread of COVID-19 and does not substitute for non-pharmaceutical interventions such as mask wearing, hand washing, and physical distancing. Parents should be strongly discouraged from sending sick children into school, and should not send kids in for the purpose of getting testing.

#### What is the test?

Schools that participate in the program will be receiving the Abbott BinaxNOW "point-of-care" or "rapid" testing kits, which give results in 15 minutes and no specialized equipment is needed. This rapid antigen BinaxNOW test detects a protein associated with the virus (not genetic material) and is different than the "gold standard" Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) test.

## How accurate is the test?

Test **sensitivity** is the ability to identify an individual **with** the virus as positive (true positive). Test **specificity** is the ability to identify an individual who **does not** have the virus (true negative). Even though Abbott has reported a 97% sensitivity for their test, and a 98.5% specificity, these rates are reported by the manufacturer itself and represent a small sample of patients, all of which were symptomatic. Studies of other rapid antigen tests (not including Abbott BinaxNOW) have showed a lower sensitivity. This generally means that a positive test is considered diagnostic (i.e., can be relied upon as being positive), but a negative test may not be accurate (i.e., it must be followed up with another action such as repeat testing, etc.). More data on the sensitivity and specificity is needed on BinaxNOW tests.

Importantly, rapid antigen tests have lower sensitivity than RT-PCR tests particularly in asymptomatic individuals. RT-PCR tests are still the gold standard for detection of SARS-CoV-2. The research done by Abbott was done on symptomatic individuals only, and this rapid antigen testing is <u>FDA authorized for patients with symptoms only in the first 7 days of illness</u>. Using it to test asymptomatic individuals is considered off-label use. Currently, there are no sensitivity

and specificity data available for asymptomatic individuals for the Abbott BinaxNOW test. Additionally, there are recent reports of false positive results in rapid antigen tests, particularly in areas with lower COVID-19 rates.

#### How many tests will a school get?

For those schools that apply, TEA and TDEM will send a monthly allotment of Abbott BinaxNOW tests according to the guidelines tabled below.

Trauma Service Area COVID-19	Allocation Distribution	
Hospitalization Rate		
7%	On-Campus Staff Count + 5% of Student Enrollment	
7-15%	On-Campus Staff Count x 2 + 5% of Student Enrollment	
>15%	On-Campus Staff Count x 4 + 5% of Student Enrollment	

#### Who can administer the test?

Only a certified test administrator is authorized to conduct the rapid Abbott-BinaxNOW test procedure. A test administrator may be **any** individual identified by the school system who completes <u>the required training</u> and submits all testing results as required by state and federal law. Given the importance of accurate data regarding community transmission, it is critical for schools/school districts to report the results of rapid antigen tests regardless if positive, negative or inconclusive.

## What safety measures should be taken during testing?

Necessary PPE must be worn as follows:

- Per CDC, a gown, N95 equivalent or higher-level respirator (or facemask if a respirator is not available), gloves, and eye protection are needed for staff collecting specimens or working within 6 feet of the person being tested.
- Gloves and facemasks are needed for staff who will not be directly involved in specimen collection or who will be **greater than 6 feet away** from person being tested. (i.e. those that are self-swabbing).

#### How should the tests be used?

Schools should have a plan for testing and are encouraged to consult with their local health departments in the development of that plan. Schools should still recommend that parents avoid sending symptomatic students to school, regardless of the schools' ability to test. Given the fact that schools will receive a limited number of tests, when developing their plans, a tiered testing strategy with groups prioritized as below is recommended. Please note that these

guidelines are based on current community transmission and information available and subject to change as new information evolves. All schools/school districts opting into the TEA-TDEM <u>COVID-19 Rapid Antigen Testing program</u> should make their testing plans available to the local health departments within their jurisdiction. Local health departments are available to provide technical assistance and to help schools/school districts develop a COVID-19 testing plan.

# 1. Priority 1: Testing symptomatic students and staff

Abbott BinaxNOW tests are FDA approved for symptomatic individuals. Therefore, when developing a testing strategy, it is recommended that district employees and students that develop signs and <u>symptoms</u> consistent with COVID-19 during the school day or during an in-school activity be prioritized for testing. Students or district employees that become symptomatic while at home are encouraged to stay home and seek testing at an alternate site. Parents should not send symptomatic children to school for the purposes of testing. Rapid antigen tests perform best when the person is tested in the early stages of infection with SARS-CoV-2 when viral load is generally highest. Therefore, the tests should be used during the period of the first 7 days of symptoms.

# 2. Priority 2: Testing of <u>asymptomatic close contacts</u>

Testing individuals following close contact is recommended regardless of the setting of the close contact (e.g. school or home).<sup>1</sup> Students and staff that are close contacts should NOT return to the classroom after a negative test and should not be removed from the 14-day quarantine period after exposure regardless of the test result. The goal of testing close contacts is to rapidly identify and isolate additional positive cases and their contacts. *[See recommendations on how to interpret the test below.]* 

# 3. Priority 3: Surveillance/Serial Testing

The purpose of surveillance testing is to monitor the status of the pandemic in our communities. Surveillance testing does not mean that everybody needs to get tested. According to models, surveillance testing is most effective when the same individuals are tested repeatedly over time (e.g. twice per week). Given the number of tests being provided by TEA/TDEM, Houston Area Public Health Authorities recommend prioritization of high-risk groups if a surveillance testing strategy is to be implemented. Examples of high-risk groups include (in no particular order):

- Staff and teachers with frequent in-person contact.
- Students, teachers, and staff in special education programs and classrooms
- Students in classrooms where distancing guidelines are not possible. Athletes and others in high-risk sports.

<sup>&</sup>lt;sup>1</sup> Someone who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period\* starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated. This is irrespective of whether the individuals were wearing a mask or other PPE.

#### How do I interpret the test results?

A positive antigen test is diagnostic for COVID-19 and should be considered a true positive<sup>2</sup>. Negative test results should be interpreted as follows:

		Did they have	
		a known	
BinaxNOW	Is the person	COVID-19	
Test Result	symptomatic?	exposure?	Interpretation
restricsuit	Symptomatic.	слрозите.	Recommend PCR testing within 48 hours for
			contact tracing purposes. If both tests are
Nevel	N	Maria	negative, individuals should still quarantine for
Negative	Yes	Yes	14 days due to known exposure.
			Recommend PCR testing within 48 hours.
			Individuals can return to school if fever free
			for 24 hours and there is a negative PCR test,
Negative	Yes	No	with medical documentation.*
			Recommend PCR testing for COVID-19 and
			recommend quarantine for 14 days to monitor
Negative	No	Yes	for symptoms due to known exposure.
			Likely negative for COVID-19.
Negative	No	No	No further testing is recommended.

\*For students with known underlying illnesses such as seasonal allergies and asthma, school officials should determine if symptoms are consistent with their previous illnesses. School nurses can then enact the appropriate intervention for the symptoms of the condition. If these symptoms then improve, it is reasonable for the student or staff member to return to the classroom.

#### How do you report cases?

- Each school must report test results from the rapid antigen testing program through an online portal (<u>app.txrapidtest.org</u>).
- All test results including positive, negative, and inconclusive results should also be reported to the local health department immediately.
- Additionally, all cases must be reported to the Texas Department of State Health Services (DSHS) via the pre-existing DSHS COVID-19 Case Reporting Form.

<sup>&</sup>lt;sup>2</sup> There is some emerging evidence that false positives may be increasing and this guidance may change in the future.

The above guidance is being provided by the Greater Houston Area Public Health Authorities in an effort to assist area school officials in their ability to understand the optimal use of these kinds of testing modalities and how best to interpret the results based on what is currently known now for these types of tests. Specific case-by-case situations should be considered in light of these general recommendations and should be interpreted along with the latest science and evidence with such information in mind.

Sincerely,

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Sources: www.tea.texas.gov/sites/default/files/covid/k-12 covid-19 testing project faq.pdf www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#table1 https://www.dallascounty.org/Assets/uploads/docs/covid-19/public-health/DCHHS-COVID-ScreeningTool-K12-Schools-081120.pdf San Antonio Metropolitan Health District, "GUIDANCE FOR SCHOOLS ON RAPID ANTIGEN TESTING", Oct. 20, 2020. Gregory Hebert MD, Harris County Public Health, "Binax Points"

#### **APPENDIX: Other Frequently Asked Questions**

#### Should a student or staff go back to the classroom after testing positive?

If the student or staff member has a positive antigen test they should immediately go home and follow school pick up protocols. This is considered a true positive. If a student then follows up with a negative PCR test, typically it is still recommended that the earlier positive test be considered accurate (especially if the student is symptomatic or has a known contact). Individual cases should be discussed with your local health department.

#### Should a student or staff member go back to the classroom after testing negative?

Given the known chance of false negatives in rapid antigen tests, an individual that is symptomatic or has had a close contact with someone with COVID-19 (for example, another student in the classroom), should not go back to the classroom with a negative antigen test. (See "How do I interpret the results" above for recommendations on what should be done in each situation). If the individual is just being tested for surveillance, and does not have symptoms or a close contact, they are ok to go back to the classroom.

#### Does each school or school district need a CLIA certificate of waiver?

The Texas Division of Emergency Management (TDEM) has obtained a CLIA waiver (#45D2193699) which allows for testing at multiple locations including school systems across the state. TDEM's CLIA information, along with the provider of record will automatically populate in the test registration system and should not have to be manually entered by test administrators.

#### Do schools or school districts need to have a physician ordering the tests?

Dr. Alex Lazar (<u>https://faculty.mdanderson.org/profiles/alexander\_lazar.html</u>) has agreed to serve as the provider of record for the BinaxNOW tests in K-12. This information will be included in the data reported to DSHS on each individual's information and test results that are entered into the <u>https://app.txrapidtest.org/</u> portal by test administrators.

# Do those staff members that are trained to do the testing need to be fit tested for N95 masks?

TDEM will be providing the school PPE including foldable N-95 masks. Even though some types of N95 mask have to be specifically fit to an individual and fit tested, the foldable N-95 masks provided do not need to be fit tested.

#### How do you dispose of the tests?

The tests and PPE are considered biohazardous material for disposal. Test administrators should place all BinaxNOW test cards, swabs, and PPE in a biohazard bag and appropriately dispose of the biohazard material.