# ASW Whitepaper — Reopening School

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## ASW Reopening in August 2020

The American School of Warsaw reopened on 18 August 2020, ready to welcome students and prepared with a three-layer plan, STOP-PROTECT-REACT (Figure 1). We started the year by testing all students and staff. We were pleased to see no positive cases in that initial round of testing, and we started the year without delay. At the time of opening, 93% of parents chose to send their children back to in-person school and only 7% stayed in the offered hybrid mode. Over the first four weeks of school, this increased to 97% with roughly 3% in hybrid mode by the date of this publication. As previously shared, our STOP layer of the plan includes weekly surveillance testing, temperature checking at entrances, and daily attestation.

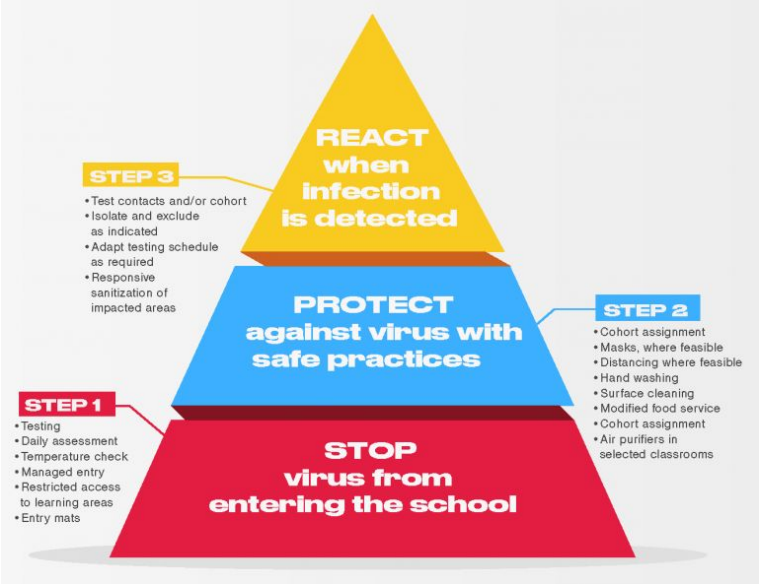


Figure 1

Shortly after opening, we were challenged with the first COVID-19 case in week 2. Outside testing identified one individual and our testing protocol detected altogether 4 pupils (out of 1000) and after implementing the crisis procedure (5-day hybrid model for three grade levels most affected by the outbreak and one-day hybrid for another grade level impacted by a single asymptomatic sibling) and moving to twice-weekly testing for tangential cohorts, the outbreak was stopped. On 10 September 2020, one additional case was identified in the upper school cohort and identified through pooled testing.

As of 15 September 2020, no further infections have been detected. These episodes increased confidence in our protocol and in the crisis response procedures developed to catch further infections and isolate them from the cohort and general population.

Below are details of the testing protocol we have deployed. We believe other schools worldwide can benefit from our learning as they struggle with reopening and maintaining classroom learning in a safe environment.

## Reopening schools and universities

Over the summer, a group of faculty members and students from the California Institute of Technology and elsewhere analyzed reopening plans from about 500 colleges and universities. They reported on Aug. 11 that 27 percent of schools were planning to test undergraduates as they enter the campus. About 20 percent planned "to test their communities regularly to some extent." The vast majority, in other words, did not.

Lior Pachter, a professor of computational biology at Caltech who participated in the analysis, called those findings "very troubling." He said the data suggested many colleges were clinging to "an unrealistic belief, a kind of fiction, that people would come back to campus and not get sick."

In late June, the Centers for Disease Control and Prevention said it did not recommend that colleges test all students, faculty, and staff for the virus upon entry to campus because there were no systematic studies to show the effectiveness of that policy. However, the CDC added that colleges in areas with "moderate to substantial community transmission" of the virus might consider testing some or all asymptomatic students to identify outbreaks.

Oberlin College recently announced its reopening plans and weekly testing using a pooled sampling approach as one of the key measures taken to ensure safety in the College. Similar measures are being introduced by Syracuse University, which recently announced pooled testing will be used to regularly test all of its 20,000 students.

The Massachusetts Institute of Technology also announced that all students, faculty, and staff will be tested when they arrive on campus. MIT will also be conducting frequent testing and screening. Community members will have to file a daily health attestation to help identify those who may have COVID-19 symptoms. Wearing masks on campus will continue to be a requirement. Compliance with these protocols will be a critical part of campus life.

The Broad Institute has launched a screening program for universities and colleges in Massachusetts. The college and university screening program has been developed for institutions in Massachusetts and surrounding regions, including the rest of New England and eastern New York state, with support from the Association of Independent Colleges and Universities in Massachusetts (AICUM). In the fall of 2020, Broad is providing COVID-19 screening support for more than 100 public and private colleges and universities. The program is designed to support these institutions of higher education, while allowing Broad to continue to serve critical public health needs in the Commonwealth of Massachusetts, especially for at-risk communities. Participating colleges and universities, working with their healthcare providers, determine the scope of the screening effort: who is eligible to be tested (such as students, faculty, and/or staff, with physician approval) and how often (twice weekly, weekly, or once every two weeks).

The University of Illinois at Urbana Champaign has been touted as a role model with respect to testing - they developed their own test kit based on saliva samples and set out to test all students and staff twice a week. Hundreds of employees were redeployed to labs and testing centers as UIUC started performing 15-20 thousand tests per day - or 2% of all United States tests.

Closer to home, the University of Cambridge just last week announced that it will offer all students living in college accommodation a weekly test for infection with SARS-CoV-2, the coronavirus that causes COVID-19, even if they show no symptoms. Whilst the testing of asymptomatic students is not national guidance, the University will be launching this program as part of their 'Stay Safe Cambridge Uni' public health initiative.

Harvard University, Babson College, Emerson College, Clark University, Stanford University, University of Maryland are just a few that have implemented a surveillance testing protocol.

### *What about K-12 schools?*

There has been an ongoing debate about whether children are or are not infectious to others. Early evidence from New South Wales in Australia pointed to limited child-child or even child-adult transmission. However, more recent evidence points to children as potentially being important transmission vectors of SARS-CoV-2 infection.

Twelve children infected with the new coronavirus at childcare centers passed the virus on to at least another twelve people between them, according to an analysis of outbreaks in Utah. Among the resulting cases was a woman who had to be hospitalized after presumptive infection by her child. Cuc Tran at the US Centers for Disease Control and Prevention in Atlanta, Georgia, and her colleagues investigated outbreaks at three childcare centers in Salt Lake County (Morb. Mortal. Wkly Rept. https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e3.htm?s_cid=mm6937e3_w; 2020). At all three centers, the first known case was a staff member. Two had gone to work even though a person in their household had shown COVID-19 symptoms. All 12 infected children, whose ages ranged from 8 months to 10 years, had either mild or no symptoms. Among the children's close contacts who tested positive were six mothers and three siblings; one eight-month-old baby infected both parents. Not all close contacts were tested, meaning that infections associated with the childcare centers might have been missed, the authors say.

A study from Ann & Robert H. Lurie Children's Hospital of Chicago discovered that children younger than 5 years with mild to moderate COVID-19 have much higher levels of genetic material for the virus in the nose compared to older children and adults. Findings, published in JAMA Pediatrics, point to the possibility that the youngest children transmit the virus as much as other age groups. The ability of younger children to spread COVID-19 may have been under-recognized given the rapid and sustained closure of schools and daycare during the pandemic.

# Test Types

During the COVID-19 pandemic, the public became acutely aware of the plethora of laboratory tests available to diagnose viral disease in humans. We all became specialists in the types of tests, which are more or less accurate, and how to interpret results.

So let's go further than the superficial layer and just one level deeper. There are three types of tests currently used in diagnosis and screening for infectious disease (irrespective whether it's SARS-CoV-2 or other):

- Antibody tests
- Antigen tests
- Nucleic Acid Tests (NAT) - PCR and LAMP Genetic/molecular tests

### *Antibody Tests*

Antibody tests are an indirect test of viral infection as they detect — qualitatively or quantitatively — the presence or concentration of antibodies against a given virus (or to be precise, against a given part of the outer protein shell of the virus) in our blood (or serum, to be precise — serum is the liquid part of the blood, so everything other than red blood cells — hence another name for antibody tests are "serology tests"). Antibodies are part of the body's natural defense mechanism — the humoral defense system. There is also the cellular defense system, which is unspecific to a given virus but it is fast and effective. Our body (or to be precise the B Lymphocytes) produce specific antibodies to this given protein (also known as "antigen").

Antibody tests could potentially be useful in determining whether a given individual had exposure to SARS-CoV-2 although their relatively low specificity limits their widespread use.

There are various methods for determining the presence of antibodies — ranging from rapid diagnostic tests done from a finger prick to laboratory tests done from venous blood puncture.

### *Antigen tests*

These are tests that detect the presence of viral protein (again, also known as "antigen") in upper respiratory tract mucosa. These tests are done using swabs taken from the nose or throat. They can be performed in point of care (read "anywhere") settings as they do not require lab equipment. They are mainly used in screening. They have a relatively high sensitivity at over 95% and essentially a 100% specificity (i.e. false positives). Their limits of detection vary and are usually smaller than Nucleic Acid Tests. There are only a handful of manufacturers producing antigen tests as the technology is actually more challenging and expensive in terms of R&D and manufacturing. But, once developed, the scaling up and production are relatively simple and costs reduce with full production. In addition, the point-of-care setting (i.e. no requirement for lab resources or sophisticated lab equipment) makes them relatively inexpensive to administer.

### *Nucleic Acid Tests (NAT)*

These are laboratory tests that detect the presence of viral genetic material (in the case of SARS-CoV-2 — RNA) in the mucosal secretions of the upper respiratory tract. They are done on material taken from the nose or throat. There are two types of tests most often used — RT-PCR

and RT-LAMP. These are lab-based tests and require trained personnel, sophisticated and expensive equipment, and time for results (which varies). Their limits of detection vary widely between 100 and 100,000 copies/ml. There are hundreds of manufacturers of test kits and many labs make their own test kits from commercially available reagents (which are actually quite inexpensive). However, the actual testing requires trained personnel, sophisticated lab equipment, and infrastructure as well as time - all of which make the testing relatively more expensive.

Table 1 adapted from the CDC provides a simple yet powerful overview of the key differences between antigen and nucleic acid tests.

| | **RT-PCR Tests** | **Antigen Tests** |
|---|---|---|
| **Intended Use** | Detect current infection | Detect current infection |
| **Analyte Detected** | Viral RNA | Viral Antigens |
| **Specimen Type(s)** | Nasal Swab, Sputum, Saliva | Nasal Swab |
| **Sensitivity** | High | Moderate |
| **Specificity** | High | High |
| **Test Complexity** | Varies | Relatively easy to use |
| **Authorized for Use at the Point-of-Care** | Most devices are not, some devices are | Yes |
| **Turnaround Time** | Ranges from 15 minutes to >2 days | Approximately 15 minutes |
| **Cost/Test** | Moderate | Low |

Table 1. Differences between RT-PCR tests and antigen tests

# Testing Strategies

Tests are just tools. It is more important to understand how these tools can be used in a strategy and how different strategies have different protocols and outcomes.

**Clinical diagnostic testing** is the approach used today in managing COVID-19, i.e. utilizing the most sensitive and labor/resource-intensive methodology (lab-based PCR) to diagnose symptomatic individuals. This is accompanied by contact tracing — a very imprecise tool and clearly reactive. Based on various estimations, this approach identifies <5% of infected individuals. This number actually makes sense because:

- PCR is a time tested technology — it has been around for 40 years in laboratory practice and has been known since the early 1970s
- In molecular biology, PCR is by now considered a relatively basic technology and there are many newer technologies (e.g. next-generation sequencing or NGS, whole-genome sequencing or WGS) which are used in clinical genetics
- Tests are done at a single point in time
- Only a few people are actually tested (some symptomatic individuals and some contacts)
- Results can come days later, depending on transport to laboratories and backlog of processing, and false-positive rates, especially in the recovery phase (PCR is positive but the person is no longer infectious)

A 24 July preprint on medRxiv underscored the downsides of slow tests. Shixiong Hu, a researcher with the Hunan Provincial Center for Disease Control and Prevention, and his colleagues followed 1178 people who tested positive for SARS-CoV-2 from January to April and tested their 15,648 contacts, defined as people who had been within 1 meter of a positive person between 2 days before and 14 days after the person's symptoms began. Based on which contacts were infected and when the researchers estimated that people were most likely to spread the virus 1.8 days before the onset of symptoms. The finding suggests that testing people only when they show symptoms and giving them test results days later does little to slow the viral spread.

Diagnostics experts, public health officials, and epidemiologists are calling for a radical shift in testing strategy: away from diagnosing people who have symptoms or were exposed and toward **screening whole populations** using faster, cheaper, sometimes slightly less accurate tests. By making it possible to identify and isolate infected individuals more quickly, proponents say, the shift would slow the virus' spread, the key to safely reopening schools, factories, and offices.

The analogy often used is blood glucose testing in pre-diabetics and diabetics. Before home glucometers were available, diabetics were managed poorly because they had their blood glucose tested every few months. First, there was HbA1c as a proxy to blood glucose. Still, it was only available every 3 months. Then, home glucometers started appearing and despite their inaccuracy, they became the gold standard because tests could be done frequently with immediate results, thus allowing for quick decision making.

### *Rapid antigen tests in asymptomatic screening*

Experts are now touting antigen tests as the future of surveillance testing. They are fast, point of care, relatively inexpensive, and relatively sensitive. What does it mean relatively sensitive? In broad terms, sensitive enough to detect persons who are about to be or are infectious and not

sensitive enough to detect those that are not yet or no longer infectious. What does that mean exactly? Not everyone who is infected is infectious. One needs to have a certain concentration of the virus in their upper respiratory tract mucosa to start shedding. This viral concentration has a typical bell curve over time where at the beginning it is quite steep and then it dies down and levels off (sometimes for months after recovery). Based on various studies, the level at which an infected person becomes infectious is around 100k — 1million copies of the virus/ml. Hence to be effective in diagnosing the infected/infectious, we need a test with at least this Limit of Detection (LoD) — $10^5$–$10^6$ copies/ml. Going below would not make a difference in reducing transmission because those individuals are not yet or no longer infectious. This is supported by the above study, in which increasing test sensitivity by 100 times (from LoD $10^5$ to $10^3$ copies/ml) had little to no impact (5–10%) on reducing transmission, whereas weekly testing frequency reduced transmission by 300–400% vs a single-test and isolation strategy. Increasing frequency from weekly to every three days reduced transmission by a further 60–70% (interestingly, increasing frequency from every three days to every day had only a marginal impact).

These concepts are explained in layman terms in this article:

> Cheap, frequent COVID tests could be 'akin to vaccine,' professor says

…and in more scientific detail here:

> Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance

Just last week, the CDC issued specific guidance on using rapid antigen tests for SARS-CoV-2. One of the key areas in this guidance related to screening and surveillance testing. The guidance states that...

> *When used for screening testing, test results for SARS-CoV-2 should be considered presumptive. Confirmatory nucleic acid testing following a positive antigen test may not be necessary when the pretest probability is high, especially if the person is symptomatic or has a known exposure. When the pretest probability is low, those persons who receive a positive antigen test should isolate until they can be confirmed by RT-PCR.*
>
> *Confirmatory nucleic acid testing following a negative antigen test used for screening testing may not be necessary if the pretest probability is low, the person is asymptomatic, or has no known exposures,* ***or is part of a cohort that will receive rapid antigen tests on a recurring basis****. Nucleic acid testing is also considered presumptive when screening asymptomatic persons, the potential benefits of confirmatory testing should be carefully considered in the context of a person's clinical presentation.*

Additionally, the FDA in its guidelines provided similar recommendations clearly stating that it is not necessary to perform confirmatory high-sensitivity molecular tests on individuals with negative antigen tests or other point-of-care test results if they are obtained during routine screening or surveillance.

In the last days, Polish experts expressed similar opinions that the availability of rapid antigen tests in Poland would be a breakthrough in the management of the pandemic.

One might ask why antigen tests are not used more broadly. Among the hurdles facing widespread, repeat screening is the scarcity of such tests. Quidel and Becton Dickinson - two of the manufacturers of rapid antigen tests - together manufacture about 3 million antigen tests per week.

But a national screening strategy would likely require 25 million tests or more, says Jonathan Quick, who heads pandemic response for the Rockefeller Foundation.

Quick says companies are reluctant to ramp up production dramatically if they are unsure of the market for the products. One solution, he adds, could be a promise by the U.S. federal government to buy tens of millions of tests, much as it has done with vaccine doses. In one such effort, the governors of six U.S. states announced this week they are banding together to ask Quidel and BD for a total of 3 million tests.

# ASW Surveillance Screening Protocol

The weekly surveillance testing protocol has been based on all of the above premises. epiXpert is using antigen tests that have a Limit of Detection under the threshold considered as infectious. Their sensitivity and specificity are remarkably high at 96,5% and 99,7%. Such an alignment is well above the minimum threshold considered by the FDA as adequate for EUA.

We settled on a weekly protocol based on discussions and consensus from institutions using this approach. We also built into the protocol an increased frequency of testing after a positive case — to twice per week for a defined period (or until no positive cases detected). Based on a recent outbreak, we can say with some confidence that this protocol did indeed detect asymptomatic cases and by implementing the crisis protocol, ASW managed to limit the outbreak to just 4 individuals with no major long period lockdowns.

## *Asymptomatic Screening*

When the COVID-19 pandemic started, the FDA and many other regulatory agencies around the World approved tests for diagnostic purposes - ie to test symptomatic individuals. This was the priority in the test and trace strategies that were deployed by countries in the immediate aftermath of the dramatic events in China, Italy and Spain. Decisions about testing asymptomatic individuals could be taken by healthcare professionals depending on the specific situations. This is a typical situation in medicine because science usually is faster than regulatory processes and physicians, based on available scientific evidence, may order tests (or even prescribe medicines) in other uses than those specified in the manufacturer's leaflet. The regulatory protocol for approving tests for diagnostic purposes used by the FDA in the Emergency Use Authorization involves using the test in 30 confirmed positive individuals and 30 confirmed negative individuals and comparing the results obtained by the specific test with actuals. If the alignment is 95%, it is considered adequate by the FDA.

In late June, the FDA issued guidelines for test developers who wished to receive specific approval for their tests to be used broadly for asymptomatic screening. In this protocol, a post-authorization study can be performed using 20 positive samples and 100 negative samples, and confirming them with a known method. Again, a 95% alignment is considered adequate.

There is also significant experience that has come from other pandemics — the HIV pandemic is a good case example. It is actually quite similar to COVID-19 in that most people who have HIV don't have AIDS. This would be called asymptomatic disease. Based on this, the CDC recommends everyone between the age of 13 and 64 get tested for HIV at least once, and more often if they are in a risk category. Here is an excerpt from the CDC guidelines related to types of tests:

> ***Antibody/antigen Combination Tests***
> *The CDC recommends these blood tests. They can detect HIV earlier than antibody screening tests. They check for HIV antigen, a protein called p24 that's part of the virus and shows up 2 to 4 weeks after infection. They also check for HIV antibodies.*
> ***SUGGESTED***
> *A rapid antibody/antigen test can give results in 20 minutes.*
> ***Nucleic acid test (NAT)***
> *This is also known as an RNA test. It looks for the virus itself and can diagnose HIV about 10 days after you've been exposed. It's expensive, so it's usually not the first*

*choice. But if you're at high risk and you have flu-like symptoms, your doctor may want to use it.*

After decades of experience with HIV, a consensus protocol is screening everyone with an inexpensive, quick, point of care antigen test. If that approach works for one viral pandemic, why would it not work for another?

### *Swabbing technique*

In the first weeks after the COVID-19 outbreak, the prevailing consensus was to use nasopharyngeal swabs. This is often referred to as the "brain swab" because of the invasive nature of the depth of sample collection. This is uncomfortable for many individuals given the sensitive nature of the area involved. This location was based on initial evidence that the virus attacked the upper respiratory airways. All tests which were initially approved in the emergency authorization protocol used nasopharyngeal as the swabbing methodology and had been approved with that specific methodology. In the meantime, new evidence started emerging which showed that the virus is present in the entire upper respiratory tract, and the FDA more recently approved four sites for swabbing: nasopharyngeal, oropharyngeal, mid-turbinate, anterior nares.

### *Validation of the specific ASW pooled testing technique for asymptomatic screening*

The FDA is the only regulatory agency that issued specific guidelines for test developers wishing to receive Emergency Use Authorization for asymptomatic screening. Based on the FDA protocol, epiXpert has validated the antigen tests in asymptomatic screening using pooled sampling. In July, a sample of 900 asymptomatic individuals was tested using a pooled sampling approach. A total of 180 pools of 5 nasal swabs were tested. Of these, 19 pools and 21 individuals were tested positive. 161 pools and 879 individuals tested negative. A confirmatory PCR test was performed on the 21 individuals who tested positive - all these tests were confirmed positive by PCR for 100% alignment.

Now, we have our own evidence at ASW which further supports these real-world studies. The four individuals diagnosed as having the infection were largely asymptomatic or had very mild symptoms. All their family members were tested with the antigen tests and also by RT-PCR tests and all results were aligned — all negative. This level of evidence is very reassuring as family members are the most exposed and the most at risk when a case emerges.

### *Validation of the Frequency of Testing*

The clinical consensus around COVID-19 provides the first layer of validation - incubation period or the time between exposure to the virus and appearance of first symptoms. This time has been defined for COVID-19 as approximately 5 days (median) with a range of 3 to 12 days. This is a broad range but let's stick to 5 days as the median. The second layer of evidence comes from a study cited above that an individual becomes infectious approximately 1.8 days before becoming symptomatic. This means that between exposure and being infectious, we have about 3 days. So, clearly, the optimal testing frequency would be every 3 days. There are many institutions that implemented a twice-weekly screening frequency (or even three times per week as was done at Harvard University).

Indeed, a twice-weekly frequency of testing reduced viral transmission factor (the famous R0) by up to 95% (not much less than daily which reduces R0 by 99%). So why does everyone, including ASW, use weekly testing instead of every 3 days. In the absence of infections, we actually do not

need to reduce viral transmission factor because there is no virus. It is only when we detect an infection that a twice-weekly protocol should be initiated to stop transmission. This is exactly the protocol we are using at ASW — the twice-weekly frequency of testing is initiated for the cohort in which an infection has been detected. This is exactly how the first outbreak was managed and how within a week, using that approach, the outbreak was stopped with only minimal community transmission (three cases in one grade, one case of a sibling in another grade).

Assessing the horizon of research and development efforts of various tests, it is likely that in the next few months we will have access to at-home tests performed on saliva samples. Before that happens, we believe the weekly screening protocol with twice-weekly pulses whenever an infection is detected provides the best level of protection.

# Reporting and Compliance

In order to provide for clarity in a complicated landscape of legal and health services requirements, a health care advisory company was contracted to provide oversight and advisory services, while implementing the surveillance testing protocols underpinning the entire program. In the context of this, a partnered relationship with an accredited lab under health care oversight provides for the necessary linkage between reporting entities and ASW is, therefore, compliant with emergency regulations and sanitary guidelines.

This relationship between entities can be seen in Figure 2 below.

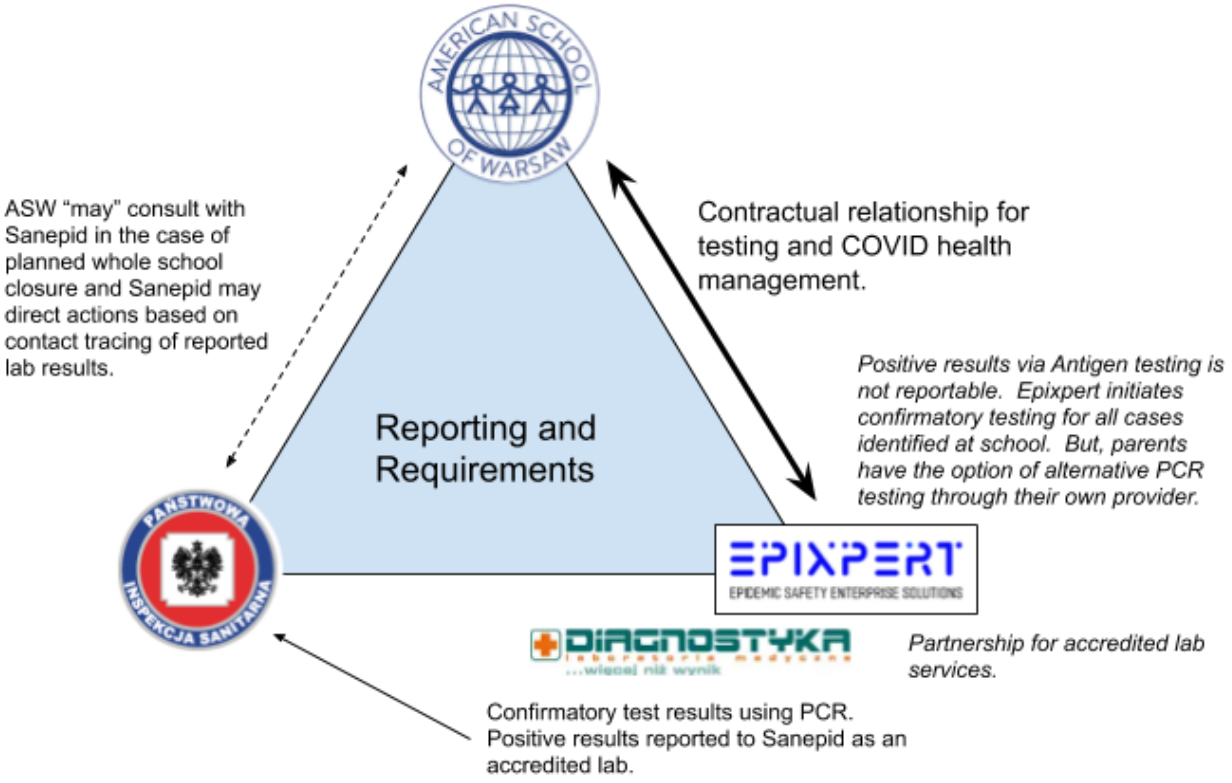


Figure 2

By maintaining these relationships, we comply with all necessary requirements and build necessary lines of communication while relying on our key partner in maintaining health management protocols as needed and adjusted over time.

General guidelines published by the Bureau of Education prescribe a set of general standards that were published in early August 2020. Final planning was delegated to Directors of individual schools and their governing bodies. Our review of our protocol suggests that we meet or exceed all published guidelines available at this time.

## The Future of Managing the Pandemic

As discussed above, COVID-19 has brought unprecedented speed to the science of testing, treatments, and vaccines. Typical multi-year timelines of clinical studies were shortened to weeks or months. So how will we be managing the pandemic going forward?

Without sounding overly simplistic, and in the absence of a safe and fully effective vaccine, the HIV pandemic is a good analogy. We will have three pillars: protection, testing, treatment. The first pillar of protection is paramount because we will never test everyone, nor will we ever vaccinate everyone nor will the vaccine ever be 100% efficacious.

A cautionary tale comes from the University of Illinois at Urbana Champaign which introduced a comprehensive testing program for all students and faculty even more aggressive than the one at ASW. However, it had to go into a two-week lockdown after a surge in infections. In a recent interview for Nature, Prof Martin Burke, the chemist responsible for developing the UIUC testing protocol admitted that the models did not anticipate that students who tested positive would be going to parties. The students have now been suspended but UIUC modified its protocol based on key learning that testing frequently is not sufficient - of equal importance is the fast reaction:

> *It's not just a matter of getting the test done fast; it's a matter of acting on the results as fast as possible. We didn't appreciate how powerful it could be if we were the ones to reach out immediately, as opposed to waiting for the standard process through public-health authorities.*

Thus, the ASW strategic plan encompasses other elements of prevention in the three-layer defense mechanism — STOP, PROTECT, REACT. All these elements protect our community. We encourage everyone to use the same approach at home, at work, and with friends. Remember, we are all accountable to one another in the fight against this virus and need to remember that our practices must be consistent and sustainable.

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