Going back to school

A guide to set up an effective and efficient process for testing in your K-12 institution

To learn more, please visit BDVeritor.com
Table of contents

Section 1  SIMPLE TEST, BIG RESULT
Returning to school >
Point-of-care testing >
Understanding COVID-19 testing approaches >
Choosing the right testing solution >
Understanding antigen testing >
Understanding testing differences >
Antigen testing: The right tool for a confident return >
A smooth testing experience >
It’s already working: Schools and universities >

Section 2  5 STEPS TO ESTABLISH TESTING PROCESS IN YOUR K-12 INSTITUTION
Building your program >
Step #1: Create a plan to reopen >
  Planning for success: The MOT Charter Schools pilot program >
  Handling positive cases >
  Preparing for paperwork >
  Secure supplies >
Step #2: Prepare for a school readiness walkthrough >
Step #3: Conduct the school readiness walkthrough >
Step #4: Prep to open with a pilot test "soft-opening" >
  Best practice: A drive-thru trial run >
Step #5: Implement testing process and report results >

Section 3  ADDITIONAL GUIDANCE
Appendix 1: Making a place for antigen testing >
  Mobile or centralized location >
  Sample testing site layout >
Appendix 2: Testing considerations >
  Managing positive cases >
Appendix 3: Contact information >
The BD Veritor™ Plus System >
References >

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• This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
Section 1
SIMPLE TEST, BIG RESULT
We know returning to school is critical

Making it happen will take a clear plan — that everyone feels confident about

As we begin to emerge from the pandemic, opening schools is a critical step in returning to a sense of normalcy. That’s because school closures result in massive and long-term costs both to society and individuals. In order to return teachers, staff and students to in-person schooling, it will be necessary to do everything possible to instill a sense of confidence that it is safe to return.
Point-of-care testing can help

Educators, parents and students all know how important tests are to the school experience. And testing for COVID-19 is no different. Clear, quick and objective results can help you to:

- **Detect** individuals who are infected so they can get timely access to care
- **Prevent** spread within the community
- **Track** how your school does as a whole over time
- **Report** to the local and state public health agencies

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The Rockefeller Foundation estimates that it will take **300 million tests per month** to reopen public schools safely.¹
Understanding COVID-19 testing approaches

COVID-19 testing in your schools can include two different approaches to containing the spread and helping students, staff and parents return with confidence. Your program can include either or both of these approaches.

**Symptomatic testing**
Testing those who exhibits signs of infection

1. Students or staff exhibit symptoms
2. Symptomatic individuals are tested immediately onsite
3. Rapid results allow for immediate action
   - **Negative** individuals return to class/work
   + **Positive** individuals isolate

**Benefits of symptomatic testing**
- Rapid diagnosis of symptomatic patients (even those who might have previously tested negative)
- Immediate isolation of positive patients
- Ability to quickly trace contact with others
- Implementation of other mitigation practices such as disinfecting classrooms, etc.
Understanding COVID-19 testing approaches (cont’d)

Screening by serial testing
Ongoing serial testing of all, or a subset of, students/staff

1. Students/staff are selected for screening
2. Tests are performed on a recurring schedule
3. Rapid detection of asymptomatic individuals
   - **Negative** individuals return to class/work
   + **Positive** individuals isolate

**Benefits of screening by serial testing**

- Highly proactive approach to risk mitigation
- Potential to rapidly detect asymptomatic individuals
- Ability to limit contact while also quickly tracing contact with others
- Implementation of other mitigation practices such as disinfecting classrooms, etc.

To learn more, please visit BDVeritor.com
Choosing the right testing solution for your school

There are two types of diagnostic tests available for diagnosing people who are suspected of having contracted COVID-19. Both have clinical utility, but rapid antigen testing delivers a combination of simplicity, speed and proven results that make it an ideal choice for use in settings such as schools.

Molecular Tests

Antigen Tests
Understanding antigen testing

ANTIGEN TEST
Detects viral proteins and positive results indicate active infection

1. Obtain specimen using nasal swab.

2. Utilize reagent to prepare sample for testing.

3. Sample is added to cartridge, which contains antibodies that detect viral proteins. Once processed, the cartridge is inserted into an analyzer.

4. The analyzer “reads” the cartridge as either a positive or negative result. Antigen tests generally provide results in 15 minutes.
**Understanding testing differences**

<table>
<thead>
<tr>
<th>FACTOR</th>
<th>PCR</th>
<th>ANTIGEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAMPLE TYPE</td>
<td>Test dependent: e.g. nasal, nasopharyngeal, saliva</td>
<td>Nasal swab</td>
</tr>
<tr>
<td>ACCURACY</td>
<td>High - results can vary by test*</td>
<td>Less capable than PCR of detecting low viral loads*</td>
</tr>
<tr>
<td>PERSONNEL NEEDED</td>
<td>Moderate if administrator collected; fewer if self-collected</td>
<td>Moderate if administrator collected. Additional may be needed to load instruments and read and report results.</td>
</tr>
<tr>
<td>COSTS</td>
<td>$25 to $100+ *** per person (lab fee), plus $15 to $20 per person for test administration</td>
<td>$5 to $25 per person (test cost), plus $15 to $20 per person for test administration. Some tests require purchase of an instrument. Confirmatory tests for positive results, if needed, are additional cost.</td>
</tr>
<tr>
<td>TIME TO RESULT</td>
<td>24 to 48 hours** plus transport time</td>
<td>15 to 30 minutes</td>
</tr>
<tr>
<td>CONFIRMATORY TEST</td>
<td>Not needed</td>
<td>Confirmatory test recommended in some cases****</td>
</tr>
</tbody>
</table>

* Ask to see real-world performance data for the specific test being used
** Turnaround time could be subject to change based upon demand and capacity. Schools should be aware of this and monitor accordingly. Prices vary and will change as the market evolves.
*** Cost estimates based on input from experts at Health Catalyst
**** For more guidance on confirmatory testing see the CDC Interim Guidance for Antigen Testing for SARS-CoV-2

**Considering pooled testing?**

Pooled testing might seem like a viable solution for your school, but it is important to understand the limitations. With pooled testing, individual samples are pooled before being tested. Depending on the type of pooled testing, when a positive sample is detected, schools may be required to consider **all** subjects in a pool to be:

- **Considered positive**
- **Isolated and contact-traced**
- **Re-tested to identify the positive individual(s)**
Rapid antigen testing + testing frequency is a formula to limit transmission

The rapid results, lower cost and point-of-care efficiency of rapid antigen testing make it an ideal choice for serial testing. This combination of speed + frequency is perfectly suited for a testing protocol focused on limiting the spread of disease.

Example of school based testing: Entrance-screening

100% Sensitivity
48-hour turnaround

80% Sensitivity
15-minute turnaround

* Most antigen tests exceed 80% and approach 95% for high viral loads

Michael Mina, MD PhD, Harvard T.H. Chan School of Public Health/Medical School

*To learn more, please visit BDVeritor.com*
Antigen testing

Why it’s the right tool for a confident return

Research conducted by the Rockefeller Foundation shows that these are the top three current needs for schools.

Safety

“I need a mitigation strategy that minimizes the risk of SARS-CoV-2 transmission within my school.”

– School administrator

Confidence

“Teachers, staff and parents all need to feel confident that the school environment is safe before we reopen for everyone.”

– School principal

Ease of use

“We are a school, not a hospital. We need testing tools that can be easily used and deployed by anyone throughout the school.”

– Teacher
Safety + Confidence + Ease of use = A smooth testing experience

Rapid antigen testing with solutions like the BD Veritor™ Plus System meets the needs of schools who are implementing both symptomatic testing and/or screening programs.

Safety

Rapid: Results in 15 minutes means students and classes can be informed immediately, not days after, a potential exposure.

Confidence

Performance: Antigen testing has been used in non-traditional settings— including schools, airports, nursing homes and events.

Ease of use

Portable and convenient: Deploy testing in convenient locations. Optional connectivity tools can simplify reporting and documentation workflows.

Flexibility

Support all testing needs: Antigen testing with the BD™ Veritor System supports both symptomatic and comprehensive screening programs.
It’s already working

Schools and universities across the country have already begun to develop processes that use testing to help bring their students and staff safely back to school. Their efforts are validating the value of testing and can serve as a blueprint for success.
Section 2

5 STEPS TO ESTABLISH TESTING PROCESS IN YOUR K-12 INSTITUTION
Building your program

This guide consolidates the lessons and strategies adopted by schools across the U.S. that have already implemented testing programs as well as best practices and recommendations from the CDC and thought leaders across the country. It breaks the process down into five critical steps to help you build out a workable, cohesive plan to implement testing at your school. These steps include:

1. CREATE a plan to reopen
2. PREPARE for a school readiness walkthrough
3. CONDUCT the school readiness walkthrough
4. PREP to open with a pilot test “soft-opening”
5. IMPLEMENT testing process and report your results

For additional information on building your plan, consult the CDC School Mitigation Toolkit, here.
Step #1: Create a plan to reopen

Your plan should include a number of milestones, including:

- **Build a core team**
  (including parents, staff and teachers)
  - Identify a responsible physician
  - You will need buy-in and support from your entire school ecosystem to build your plan

- **Apply for a CLIA Certificate of Waiver**
  - To perform testing at your locations you will need a CLIA Certificate

- **Planning and coordination**
  - Identify antigen testing strategy: Select schools, testing program/cadence, processes and plan
  - Identify personnel to conduct testing
  - Identify location and process of testing
    - Collection
    - Processing
    - Disposal
Planning for success—a case study

The MOT Charter Schools pilot program

MOT Charter Schools recently launched a testing program across two campuses (K–12). They developed a successful testing process that provides a model for success.

**K–3**

1. Check consent
2. Staff brings testing cart with all equipment to the classroom
3. Select students come into hall one at a time and are swabbed (total time for student is 30 seconds)
4. Students return to classroom
5. Test is run – results are recorded

**4–12**

1. Select students walk to centralized testing location in the school 4 to 5 at a time
2. Check consent
3. Students are swabbed
4. Swabs are placed in baggie for later testing
5. Students return to classroom
6. Test is run – results are recorded

Testing process takes 20-30 minutes per classroom
Handling positive cases

Student immediately isolated

Class takes recess while room is cleaned

Picked up by parents

Close contacts are tested

Reflex testing via PCR is encouraged

Student must test negative before returning to class
Preparing for paperwork

There are a number of documents that will need to be prepared prior to implementing the testing program, including:

- A letter to parents/guardians informing them of the testing program
- A testing consent form
- Testing supply order forms for use by testing staff

Examples of these documents are available through various state departments of education websites.
Secure supplies

Before launching your program, ensure that you have proper testing supplies and PPE to conduct an ongoing program without interruption.

- Antigen testing supplies
- Masks, sanitizers, soap, PPE, other hygiene tools
- Enclosures, partitions, tables, etc. to conduct testing
- Staff for testing, mitigation education and morale building
Step #2: Prepare for a school readiness walkthrough

Your plan is in place, but how will this plan actually work on the ground? The best way to pressure test your plan is by conducting a school readiness walkthrough. First get prepared:

- Planning and coordination

- Develop a meeting agenda to familiarize staff with the plan
  - Discuss the purpose of the walkthrough to assess the testing plan and discuss any concerns
  - Discuss roles and responsibilities of the testing plan
    - Assign a lead facilitator from the school staff
    - Assign two people to take notes
  - Review parent/guardian information and consent forms

For more information on planning for a school readiness walkthrough, download the CDC guide: How to plan and execute a COVID-19 mitigation walkthrough
Step #3: Conduct the school readiness walkthrough

The final step before beginning testing is to conduct the school readiness walkthrough to make sure your school facility, staff and processes are ready.

☐ Check your testing technology
☐ Ensure proper connectivity throughout the facility
☐ Evaluate the readiness of your test site
☐ Consider hygiene and other protocols that work in concert with testing
☐ Evaluate staff training

For more information on planning for a school readiness walkthrough, download the CDC guide: How to plan and execute a COVID-19 mitigation walkthrough
Step #4: **Prep** to open with a pilot test “soft-opening”

Before launching the permanent testing program, consider creating a brief pilot test “soft-opening”

- Helps to evaluate gaps in staff training, performance, throughput
- Helps to build familiarity, comfort and confidence among staff and students
- Actively promote the launch of testing to your students, parents and school community
- Encourage sharing of testing experience on social media

To learn more, please visit BDVeritor.com
Best practice: A drive-through trial run

Prior to launching their in-school testing program, the MOT Charter Schools first held a “drive-through” clinic for all students and staff to familiarize everyone with the swabbing process for when it may be potentially required.

1. Student/staff drives up
2. Administrator brings: 1 consent form, 2 swabs in package
3. Consent is signed
4. Swab is returned for testing. Results are emailed to student/staff within 2 hours.

This drive-through kickoff period demonstrated the ease, simplicity and value of the testing program to students and staff while social media posts by parents helped drive buy-in from the school community.
Step #5: Implement testing process and report your results

Now it’s time to implement your process and help your students, teachers and staff get back to school. It is important to understand that once the testing program is ongoing, results must be reported to the appropriate state or local public health departments.

For complete guidance on the reporting requirements for your facility, visit cdc.gov
Section 3

ADDITIONAL GUIDANCE
Appendix 1: Making a place for antigen testing

One of the most important parts of your testing plan is determining where and how your team will perform testing. Once this is decided, prep your testing location or plan with the proper setup and equipment. Every school will be different and you should develop a location plan that works best for your facility.

Mandatories

In addition to considerations on handling testing volume and procedures, your testing location should include and support the materials and equipment needed for testing.

- Test kits and technology
- Instructions for swabbing and processing tests
- Guidance and templates for consent, privacy and communications
- PPE: disposable gloves, aprons, type 11R surgical masks, eye protection
- Waste disposal bags
- Tables/chairs/carts
- Hand sanitizer
- Disinfectant wipes
- Mop and bucket
- Tissues
- General waste bin
- Computers for test registrations
- Clocks/timers
- Mirrors
- First aid supplies
- Stationery supplies: markers, pens, printers
Mobile or centralized

You may choose to take your testing to the students by creating mobile testing carts or you may choose a centralized testing location in the school. If you choose to setup a centralized location, there are some best practices and considerations for both selecting the location and designing the testing flow/process.

1. Test site flooring must be non-porous
2. Test site must be well-lit, and free of air drafts or breezes
3. Registration desk at the point of entry to test location
4. One-way direction of traffic
5. Test subject chairs must be a minimum of 6’ apart
6. Clear division between swabbing and test processing areas
7. Testing requires a level surface
Sample testing site layout

1. REGISTRATION DESK
2. SWABBING DESKS
3. PROCESSING DESKS
4. RECORDING DESK
Appendix 2: Testing considerations

Performing rapid antigen testing
Details will vary depending on your specific testing technology, but generally, point-of-care rapid antigen testing is a simple and efficient 3-step process.

1. Sample collection
2. Sample preparation
3. Sample testing
Managing positive cases

Performing rapid antigen testing
What to do if a student tests positive for COVID-19

1. **Record details:** Ensure any details of the pupil/student are recorded securely to protect their privacy

2. **Contact parent/legal guardian:** Call their parent or legal guardian and arrange for the pupil/student to be collected if needed. They will need to isolate in school – there is more advice on process to follow
   - Isolate per current local or national guidance and talk with the pupil or student, being mindful of the need for social distancing/PPE

3. **Provide reassurance:** They may be anxious about their health and the impact on their family. This is a chance to reassure them:
   - There is support available while learning from home and support for their parents with work and benefits

4. **Offer support:** It is really important that they follow local or national guidance and self-isolate for 10 days. They can take pride that they are doing their bit to protect their friends and family and defeat the virus.
   - Take steps to ensure that pupils or students can access remote learning at home
   - School also needs to identify close contacts of the case in school so they can also self-isolate
IMPORTANT
If, at any point, a student, pupil or staff member begins displaying symptoms, they must follow local department of health and government guidelines and self-isolate.
Appendix 3: Contact info

Contact information

Additional resources on rapid antigen testing in the school setting:

Click on the thumbnails above to view and/or download these resources.
THE BD VERITOR™ PLUS SYSTEM – NOW EUA AUTHORIZED FOR ASYMPTOMATIC SERIAL TESTING – ENABLING SAFE REOPENING OF SCHOOLS

The BD Veritor™ Plus System moves at the speed of what matters—you and your students and staff. The system offers what your organization needs to conduct rapid diagnostic antigen testing for COVID-19 in your schools.

- Speed
  Results in just 15 minutes

- Reliability
  Results you can count on

- Portability
  For point-of-care testing

- Optimal training
  On-demand and in-person training builds confidence

- Traceability
  Keeps track of key data points

- Scalability
  Grows with demand

- Connectivity
  Adaptable, flexible options available

To learn more about simplifying COVID-19 testing at your facility, please visit BDVeritor.com or contact your local BD distributor representative.

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References:
2. Pekosz A, Parvu V, Li M, et al. Antigen-Based Testing but Not Real-Time Polymerase Chain Reaction Correlates With Severe Acute Respiratory Syndrome Coronavirus
3. CDC: K-12 Schools COVID-19 Mitigation Toolkit
4. CDC: Getting Schools Ready For In-Person Learning: How to Plan and Execute a COVID-19 Mitigation Walkthrough