

MI Safe Schools COVID-19 Antigen Testing Program: Worksheet

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Introduction

What: The MI Safe Schools testing program is a voluntary program offered by MDHHS for Michigan Pre-K–12 schools who wish to offer weekly testing to educators and staff in order to reduce risk associated with in-person school operations. MDHHS will provide training, guidance, and rapid antigen testing materials to schools who sign up and agree to the program requirements. Testing is not a requirement for schools to return to in-person learning.

Purpose: To enable rapid detection of COVID-19 cases among staff to reduce or prevent COVID-19 outbreaks in Michigan schools. Testing to diagnose COVID-19 is part of a comprehensive strategy and should be used in conjunction with promoting behaviors that reduce spread (e.g., mask use, social distancing, hand hygiene); maintaining healthy environments (e.g., cleaning and disinfection, ventilation); managing school operations (e.g., class sizes); and preparing for when someone gets sick. Testing is not a requirement for schools to return to in-person learning. However, testing and early detection of cases are tools that may help reduce risk for in-person instruction.

Requirements: Schools must agree to the following requirements before beginning any school-based testing:

- Engage stakeholders, including participating educators, and school administrators
 - Stakeholders must be enthusiastic and willing to meet participation criteria
- One individual (testing point of contact) must be identified per school, and contact information supplied
- Participants exhibiting COVID-19 symptoms must self-isolate at home

- Participants must cooperate with contact tracing, social distancing, and other COVID-19 safety precautions
- Schools must report negative and positive test results on the day of testing
- Plans to obtain consent
- Physical space, equipment, and staff to conduct testing safely and privately
- Ability to maintain confidentiality of results and protect privacy

Partners: The Michigan Department of Health and Human Services, Michigan’s intermediate and local school districts, and Michigan’s local health departments.

Testing Overview

Who: Pre-K through grade 12 teachers, administrators, paraprofessionals, teaching aides, and non-instructional staff who are working in-person and have daily student interactions are all eligible to participate in this program, through their participating school or district.

Testing Cadence:

- Testing must be done once weekly
- Testing should be conducted before the start of the school day
- Negative and positive test results must be reported daily using [this online reporting form](#)

Who may attend in-person classes?

- Those without symptoms of COVID-19, and without known exposure to COVID-19
- Those who are participating in testing may attend so long as their antigen tests are negative

When should staff be excluded from in-person classes?

Figure 1. Testing Scenarios

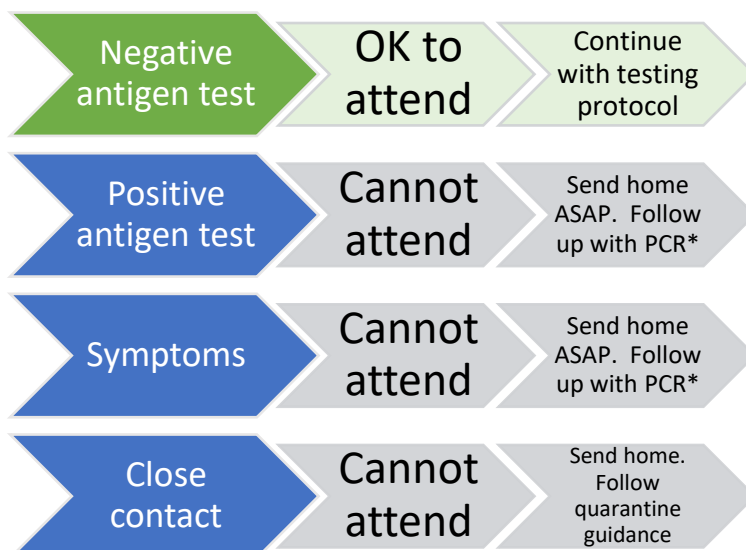


Table 1. Students and staff should be excluded if they meet any of the following:

| Exclude staff who meet the following criteria | Exclude until at least |
|---|--|
| Asymptomatic close contacts* of a person with COVID-19 | May resume attendance once local health department quarantine requirements have been met (usually 10-14 days) |
| Symptoms including fever, cough, other respiratory symptoms, or those symptoms outlined by the CDC | May resume attendance once symptoms have resolved for more than 24 hours, and if the individual has a negative molecular (not antigen) test |
| Asymptomatic with Positive Antigen test | May resume classes if they have a negative molecular (PCR) test within 48 hours of the first test. If molecular test is positive, or not conducted in this timeframe see below |
| Asymptomatic with Positive Molecular (PCR) test | Isolate for 10 days from date of first positive test, or as per CDC guidelines |

If PCR testing necessary, you may use this tool to locate local testing sites: [MDHHS Test Site Locator Tool](#)

* “Close contact” is defined as being within 6 feet of the COVID-19 positive person for a 15-minute time frame cumulative over a 24-hour period. You can find the most up-to-date CDC definition of close contact for COVID-19 [on the CDC’s website](#).

What MDHHS Will Provide

- Sufficient supply of antigen tests
- Overview of program and the use of antigen testing for the purpose of rapidly detecting COVID-19 cases in staff members
- Guidance on testing cadence and when confirmatory PCR testing may be necessary
- Training materials to understand how to safely administer, read and dispose of antigen tests

School Participation Requirements

1. Schools must provide and adhere to testing plans which include the following:

- Plan for obtaining consent to administer COVID-19 testing (school district responsible for consent forms and obtaining consent, MDHHS can provide examples)
- Train staff to administer antigen tests safely and efficiently, interpret test results, determine accurate next steps based on test results, and fulfill reporting requirements
 - Staff who have completed training videos (available [here](#) and [here](#))

- Plan for specimen collection which includes:
 - Obtaining necessary [Personal Protective Equipment \(PPE\)](#)
 - Identify testing location(s) – Include address of each testing location if this varies
 - Describe how testing will be done to ensure privacy when disclosing test results
 - Describe follow up methods for providing guidance to positive cases regarding isolation and guidelines for returning to school. (phone call, email with guidance, printed letter sent to home address, other method?)
 - [Waste disposal](#) and disinfection of the testing area
 - Defined schedule and identified staff role for reporting test results to [this online reporting form](#)

2. Forming a testing Team is recommended to conduct the Antigen Testing within this pilot

Details of suggested roles and responsibilities are provided below:

| ROLE | KEY TASKS |
|---------------------|---|
| Testing Coordinator | <ul style="list-style-type: none"> ✓ Identify Team members/roles ✓ Coordinate/Document Training ✓ Identify testing site ✓ Secure equipment and supplies ✓ Secure technology for results data entry into MDHHS. ✓ Identify a storage site for test kits until they are needed ✓ Secure biohazard disposal ✓ Verify Consent and contact information |
| Test Administrator | <ul style="list-style-type: none"> ✓ Schedule training ✓ Secure timer for 15-minute test ✓ Provide results to individual |
| Data Entry | <ul style="list-style-type: none"> ✓ Secure training and access to reporting site |

Testing Team Resources

For Antigen testing:

1. How to secure [biohazardous waste disposal](#)
2. Training for administering antigen tests:
 - [MDHHS BinaxNOW Antigen Test Training](#)
 - [Abbot Training](#)

A person who performs the testing must complete both the online training from Abbott and the MDHHS Bureau of Laboratories.

3. Reporting: [Online reporting form](#)

Abbott BinaxNOW – Additional Resources and Details

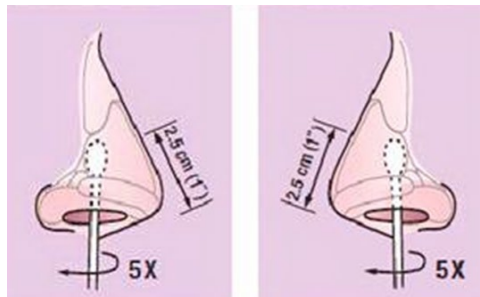
| | |
|--------------------------|---|
| Abbott Website Resources | Product insert BinaxNOW Nasal Swab COVID-19 Tech Tips BinaxNOW Procedure Card |
| Handouts | BinaxNOW COVID-19 Patient Fact Sheet |
| Supplies | <p>Supplies Needed for <u>Antigen test</u>:</p> <ul style="list-style-type: none"> * PPE <ul style="list-style-type: none"> - Surgical masks - Gloves - Eye protection: face shield or goggles - Disposable Coat or Gown * Rapid COVID-19 Antigen Testing Results BinaxNOW Reporting Instruction sheet * Laptop & WiFi * Disinfectant with paper towel/wipes * Hand sanitizer * Pens * Timer. Do not use personal cell phone as a timer, to avoid contamination with COVID-19. * Permanent markers * Biohazard Waste container (follow local and MIOSHA regulations) |

Specimen Self-Collection and Test Administration Instructions

Antigen Testing

1. Participant should first check in at registration desk and provide complete information and consent forms to clerical staff
 - a. Prior to beginning process test administrator puts on PPE (including surgical mask and eye protection), in accordance with [CDC guidance](#)
 - b. Sanitize hands & put on clean gloves
2. Ask whether the participant is on Bactroban or Centany-drugs that interfere with testing (mupirocin)
3. Tear off a paper towel and lay it down on the table to prep for testing
4. Remove the antigen card from foil packet
 - a. Open one per participant at the time of testing
 - b. Check expiration date. DO NOT USE IF EXPIRED
 - c. Keep card flat (horizontal) at all times- do not pick card up off of the testing surface after you lay it on paper towel you prepared for testing
5. Assign a card number and write # on:
 - a. Fact Sheet for participants
 - b. On the front of the antigen test card
 - c. Track form

6. Give the Fact Sheet for participants containing the written card # to the participant
 7. Follow the instructions for Nasal Collection
 - a. Encourage the participant to use hand sanitizer
 - b. Hand the participant the swab in the wrapper- Use only the swab that comes in the BinaxNOW kit
 - c. Instruct the participant to:
 - i. unwrap the swab and **do not touch** the swab tip
 - ii. Start with the nostril with the most drainage, if runny nose is reported
 - iii. Gently insert the swab, 1 inch or less into nostril,
 - iv. Rotate the swab 5X against the nasal wall
 - v. Slowly remove the swab and repeat on the other side with the same swab
 - vi. Slowly remove the swab and hand it to the test personnel to be tested immediately. Do not put the swab back in the wrapper
- *Test administrator should only handle the swab while wearing gloves and PPE
8. Refer to the Procedure Card to perform testing and interpretation



Please Note:

- **DO NOT TOUCH THE BOTTLE TIP** Take off the cap of the white reagent bottle provided in the kit
 - **DO NOT TOUCH BOTTLE TIP TO CARD** Invert bottle, hold ½ inch over the antigen card well (upper hole), and add exactly 6 drops
 - If too many drops are added, discard card and go back to step #4
 - Use a timer or wall clock. Do not use a cell phone. Mark the start time to ensure accuracy of testing
 - Be sure to double check the timer actually starts when you hit the button
9. Use EPA registered disinfectant effective against COVID-19 to clean all surfaces.
 10. Discard all waste in biohazard container following local and MI-OSHA regulations.
 11. Change gloves, use hand sanitizer and put on clean gloves.
 12. Prepare area for next participant.

Interpreting and Providing Test Results

Per the Abbott instructions card and training videos, test results will be interpreted based on the control and sample markings after 15 minutes. Results should be given verbally to the individual tested.

- Anyone with a positive result should be immediately isolated and they should be sent home as soon as possible with instructions on [isolation](#). They should be instructed to obtain a PCR (molecular) test. They should also be instructed to watch for [emergency warning signs \(including trouble breathing\)](#) and get emergency medical care immediately if these symptoms develop.

Isolation Guidelines and Next Steps

If you test POSITIVE: Isolation Guidelines

- Isolate yourself from others immediately. Report your positive results to your school as soon as possible. Also let your healthcare provider know so they are aware
- Be on the lookout for any contact tracing communication
- [Monitor your symptoms](#). Watch for severe symptoms or other health emergencies. If you need to call 9-1-1, let them know you have COVID-19
- Your isolation period does not end until you can meet all 3 criteria:
 - It has been 10 days since onset of symptoms, AND
 - You have been fever-free for >24hrs (without use of fever-reducing medications), AND
 - All other symptoms have improved

If you test NEGATIVE (but have related symptoms): Next Steps.

- Still go home and monitor symptoms. You must still contact your school administration about your negative results and symptom status. Reach out to your medical provider if you are still concerned or want further evaluation for medical diagnoses
- Stay home until you are fever-free for 24 hours (without the use of fever-reducing medications). Contact your health provider if symptoms do not resolve or worsen
- If you are under quarantine from an exposure, you must still adhere to the 14-day quarantine period from your last date of exposure

Reporting

BinaxNOW Antigen reporting: Done by testing site staff through MDHHS website*

MDHHS has [a secure website for reporting BinaxNOW Antigen test results](#). The website is the Michigan Disease Surveillance System (MDSS). *This should be done by testing site staff at the time of testing.

Note: You can wait to add all individual tests until the end (or at the end of every hour/ during down time), as long as results are able to be kept organized and not mixed-up. In this case, once facility information, provider information, and test date are entered, you can enter one individual after another before submitting.



Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:
 US +1 800 257 9525 ts.scr@abbott.com

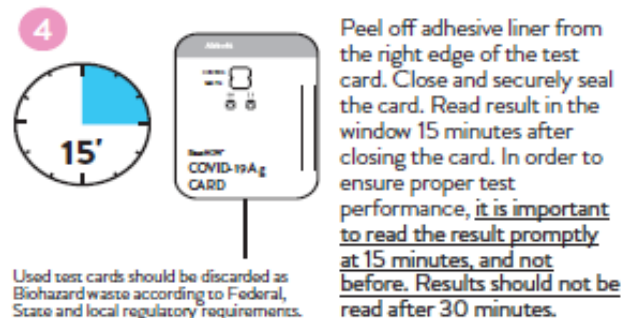
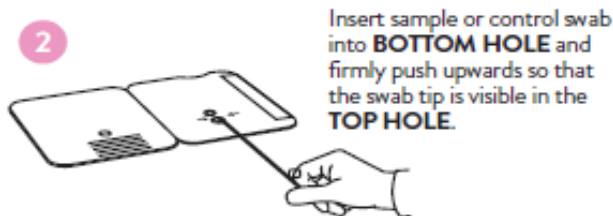
PROCEDURE CARD

For Use Under an Emergency Use Authorization (EUA) Only.

Part 1 - Sample Test Procedure

Open the test card just prior to use. Do not open more than one test card at a time. The card must lay flat during all steps of testing.

Patient Samples require 6 drops of Extraction Reagent.



Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Part 2 - Result Interpretation

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

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 Result



A **positive specimen** will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line positive.

Positive Result



If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result



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In the USA, this test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet 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. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this test 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 the virus that causes 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 authorization is terminated or revoked sooner.