



DEPARTMENT OF HEALTH
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STATE DEPARTMENT OF EDUCATION
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K-12 COVID-19 Testing Program Guidebook

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K-12 COVID-19 Testing Program Guidebook

Introduction

Governor Larry Hogan and State Superintendent of Schools Dr. Karen Salmon are committed to supporting Maryland schools returning safely to in-class instruction statewide. The COVID-19 Testing Task Force, Maryland Department of Health (MDH), and the Maryland State Department of Education (MSDE) have developed a K-12 COVID-19 Testing Program to provide free COVID-19 tests for school systems and non-public schools as an additional resource to support schools that are open, or plan to reopen, in March 2021 and remain open for the remainder of the 2020-2021 school year.

The state will **provide both rapid antigen point-of-care (POC) tests and polymerase chain reaction (PCR) specimen collection supplies** proportional to the number of students and staff returning for in-person learning, based on the anticipated number of students and staff that may need diagnostic testing based on guidance from MDH. **This is a voluntary program.**

MDH and MSDE are pleased you have chosen to participate in this important program to support your school and to partner with you in the fight against COVID-19. Please send any questions at MDH.K12Testing@Maryland.gov or contact one of the specific resources provided in Section H.

Overview

The program provides schools with the necessary information and resources to implement both rapid POC tests and PCR specimen collection processes in schools to **test symptomatic students and staff, as well as asymptomatic students and staff who are determined to be a close contact of a person with confirmed COVID-19.**

Schools can use the allocated program testing resources to implement a testing program based on the program design listed below or to supplement other testing efforts. The allocations provided to schools are intended to support diagnostic testing rather than COVID-19 screening. Schools may use tests to supplement existing screening efforts, but will be supplied based on a

diagnostic based testing model. Schools may request additional supplies to support diagnostic testing efforts (see reorder process in Sections B.e. and D.e.). Requests for additional supplies will not be provided for uses beyond this program.

The amount of testing supplies allocated to each school will be based on the following testing program design:

a. Rapid POC tests will be provided for the testing of:

- Symptomatic students and staff and
- Asymptomatic students and staff who are close contacts of a COVID-19 case

b. PCR specimen collection supplies will be provided for confirmatory testing of:

- Asymptomatic students and staff who are close contacts of a COVID-19 case with a positive rapid POC antigen test result.

The Diagnostic Testing Program will no longer require a confirmatory PCR after a negative rapid antigen test in all symptomatic individuals. Schools should determine the most appropriate testing strategy based on the level of risk. An antigen-negative may not need confirmatory testing if the person has a low likelihood of SARS-CoV-2 infection (e.g., the person has had no known or suspected exposure to a person with COVID-19 within the last 14 days or is fully vaccinated or has had a SARS-CoV-2 infection in the last 3 months). Schools may continue to conduct the confirmatory PCR at their own discretion, based on their current environment and overall assessment of risk

If you are interested in enrolling in the Diagnostic Testing Program, please [submit this interest form](#) and a member of the K-12 testing team will get in touch.

A. Program Requirements

Please take note that you must have the following paperwork on file and procedures in place prior to the administration of any tests. *(Schools awaiting final approval for program participation should review and take steps to ensure that these critical measures are in place.)*

a. Your school is required to hold an active CLIA certification and Maryland Laboratory License and keep these on file in accordance with state and federal regulations.

- If you **DO** already hold both:
 - You still need to fully complete a [Laboratory Licensing Change Form](#), and fax to the number listed on the form. Please be sure to indicate that you wish to conduct COVID-19 rapid antigen testing, and list the BinaxNow Covid-19 Ag Card.
 - Once you fax in the form, as long as your CLIA Certificate is not expired, you can start testing immediately and the state will mail out an amended laboratory license with the relevant test category you have added.
 - **Any additional questions can be directed to paul.celli@maryland.gov.**
- If you **DO NOT** already hold both a CLIA certificate and Maryland Laboratory License on file:
 - You need to fully complete a [State Compliance Application](#) for a Maryland Laboratory License, as well as a federal [CLIA Certification Application](#) (\$180 fee every two years) and **also** indicate the BinaxNow Covid-19 Ag Card for COVID-19 rapid testing.
- Application instructions:
 - Both individual applications are to be filled out and signed by the chosen Lab Director and emailed to paul.celli@maryland.gov. (For CLIA waived testing, the director at minimum must have a BS degree in a physical science, Biology, Nursing, etc.)
 - Upon your application approval, there is a roughly a two-day processing period, after which the lab will be invoiced \$180 by CMS for a CLIA waiver. There are no longer

fees for state licensure or renewal; the state license does not expire.

- Once the invoice is paid, the lab will receive a state license and a CLIA certificate of waiver.

b. It is required to have an authorized prescriber or ordering provider to authorize testing staff to administer tests. Medical review contractors will consider diagnostic test order requirements met if there's a signed order or requisition listing the specific test, an unsigned order or requisition listing the specific test, and an authenticated medical record supporting the physician's intent to order the tests (for example, "order labs", "check blood", "repeat urine. There also needs to be an authenticated medical record supporting intent to order specific tests. [See Appendix for full documentation requirements.]

- For public schools, we recommend that you outreach to your local health department to discuss the possibility of serving this role. You may also establish a new relationship with a community provider (e.g. urgent care or hospital).
- For non-public schools, we recommend that you identify a community provider unless you have an authorized prescriber on your staff. You may also establish a new relationship with a community provider (e.g. urgent care or hospital).

c. It is required that you have an individual with qualifications per the latest [executive order](#) on-site to collect COVID-19 specimens for testing and process the test samples.

d. It is required that you have access to Maryland's Health Information Exchange (CRISP) and have the appropriate personnel to report the rapid POC results into CRISP.

- See [Information on reporting COVID-19 test results](#) and [Training Video](#).

e. It is required that you ensure proper consent or authorization is obtained for students and staff including:

- Consent for a minor to be tested
- Release of information consent
 - An example FERPA consent form can be found [here](#).

f. Please complete testing training, as needed.

- Training by Abbott on their BinaxNOW rapid POC test is required as part of the Emergency Use Authorization (EUA). Further training info will be provided, including a schedule for online Abbott BinaxNOW sessions.

g. While not required, we strongly suggest that you create a Standard Operating Procedure (SOP). Below are factors we would recommend

each school consider when developing protocols:

- **Current estimate for in-person attendance.** Identify how many students/faculty/staff are in-person at your institution, how frequently they are in the institution, and how long they are in the institution per day.
- **Plans for increase in in-person attendance.** Specify the plan in place to increase the number of individuals participating in in-person attendance and how soon those plans go into effect.
- **Current mitigation strategies in effect.** Describe the measures (if any) that have been taken to mitigate the spread of COVID-19 in your institution and what measures you intend to implement.
- **Detail your plan/infrastructure capacity.** Describe your plan regarding what implementation of rapid POC testing and PCR specimen collection would look like at your institution (spacing needs to facilitate rapid POC testing and PCR specimen collection, PPE, storage for test kits, disposal of biomedical waste, etc.).

B. Abbott BinaxNOW™ COVID-19 Rapid Point of Care (POC) Test Information

a. Rapid Point of Care (POC) Distribution:

- **Local School Systems**

- The MDH Office of Preparedness and Response (OP&R) will distribute POC tests to public school system distribution centers.
- Public schools systems will redistribute their supplies to their individual public schools.

- **Non-Public Schools (Non-Public School Systems)**

- OP&R will distribute POC tests to non-public school system distribution centers.
- Non-public school systems will redistribute their supplies to their individual non-public schools.

- **Non-Public Schools (All Other Non-Public Schools)**

- OP&R or the TTF will either distribute directly to independent non-public schools or distribute supplies for pick-up at a location in their county. Information regarding distribution to these schools will be provided as soon as it has been determined.

b. BinaxNow™ COVID-19 Ag Card and Navica™ app set up and test information:

- <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>

c. Abbott BinaxNOW™ Training & Information Contact:

- Barbara Mervin, barbara.mervin@abbott.com, 410-409-3082
- Abbott Technical Services Team at 1-800-257-9525 between 8 a.m and 8 p.m. EST Monday-Friday or email ts.scr@abbott.com.

d. Rapid Point of Care (POC) Supply Reordering Process:

- To request more Rapid Point of Care (POC) tests from the Maryland K-12 COVID-19 Testing Program, please submit an official request [here](#). Please note: Supply reorders will be evaluated based on your school's allocation and you will be notified if your request can be filled.

e. Abbott BinaxNOW™ COVID-19 Ag Card Test Information & Training:

- **Abbott Online Training Information and Support.** Staff administering tests are required to attend at least one training for rapid POC tests or watch the recording of the training modules. The **Abbott BinaxNOW™** training modules recording can be found [here](#).

C. Rapid POC Result Reporting

a. Organizations performing COVID-19 rapid POC testing are required to report results to MDH (see below process flow diagram). At this

time, this may be accomplished by one of two methods:

- Providers can manually enter the results into the portal established by CRISP (The Maryland Health Information Exchange). For additional details, visit <https://crisphealth.org/guidance/providers>.
- Providers can utilize a bulk submission process (for use by entities that are conducting at least 20 rapid POC tests per day and have sufficient infrastructure in place). Please contact Tom Fitzgerald at Tom.Fitzgerald@crisphealth.org for more information.

b. Questions concerning CRISP and reporting can be directed to:

- Tom Fitzgerald at Tom.Fitzgerald@crisphealth.org

c. First-time and existing CRISP users are encouraged to review the following resources:

- [Point of Care Result Entry Process Flow](#)
- [Training video](#)
- [Information on reporting COVID-19 test results](#)

D. Mako Medical Polymerase Chain Reaction (PCR) Test Information

a. PCR Supply Distribution Process

- **Local School Systems (LSS):**

- Mako will send PCR specimen collection kits (each kit includes specimen bags, transport tube with viral transport media, 2 nasal swabs, QR code labels and instructions) to a central receiving point designated by the LSS.
- LSS will distribute the PCR specimen collection kits to their schools.
- Completed specimen collection kits must be returned (ready for testing) directly to Mako Medical with supplied FedEx shipping labels.

- **Non-Public Schools:**

- Mako will send PCR specimen collection kits (each kit includes specimen bags, transport tube with viral transport media, 2 nasal swabs, QR code labels and instructions) to each school.
- Completed specimen collection kits must be returned (ready for testing) directly to Mako Medical with supplied FedEx shipping labels.

b. Mako Medical PCR Test Information:

- **K-12 Local School System Information:**

<https://www.dropbox.com/sh/ux67jj0wsnyxps1/AAC-zJ-Y9hqLWm7Q4a-P7OFXa?dl=0>

- **K-12 All Non-Public School Information:**

https://www.dropbox.com/sh/76dztX0b8ghkfj7/AABVz232us1LqNGM_I8qXweCa?dl=0

c. Mako Medical Contact:

- For additional usernames, if you have been locked out of the portal, or need to reset your password email accounts@makomedical.com.
- Other inquiries, logistics concerns, or collection questions email accounts@makomedical.com or call 704-412-3992 between 9 AM and 5 PM EST.

d. PCR Supply Reordering Process

Be sure to **plan ahead** so that you have enough swab kits and shipping supplies on hand.

- **Local School Systems:**

- Supplies will be ordered at the LSS level. The LSS designated staff member will email accounts@makomedical.com to reorder. If schools are getting low, please let the LSS designated staff member know with 5 days lead time for supplies to be delivered.

- **Non-Public Schools:**

- Supplies will be ordered by the Non-Public School directly. If you are getting low, please email accounts@makomedical.com to request more supplies with a 5 day lead time.

e. **Mako Medical Online Training Information and Support.** Staff collecting specimens are required to attend at least one training for PCR tests or view the recording of the training modules. A recording of the training can be found [here](#).

E. COVID-19 Test Result Interpretation

a. Interpretation and Management of results

- **Person with Symptoms:**

- **If the rapid POC test result is positive**, treat the individual as having COVID-19. Safely isolate them until they are able to leave the property, do not administer a PCR test, and send them home until they meet criteria for release from isolation.
- **If the rapid POC test result is negative**, safely isolate the individual until they are able to leave the property, administer a PCR test or provide testing resources, and send them home to isolate. If the PCR test is negative, return should be based on existing MDH school guidance. If the PCR test is positive, they should remain at home until they meet criteria for release from isolation.

- **Persons Who Are Asymptomatic and a Close Contact of a Person with COVID-19:**

- **If the rapid POC test result is positive**, safely isolate the individual until they are able to leave the property, administer a PCR test or provide testing resources, and send them home to isolate. If the PCR test is positive, they should remain at home until they meet criteria for release from isolation. If the PCR test is negative, they should remain at home until they complete quarantine according to MDH/MSDE school guidance.
- **If the rapid POC test result is negative**, do not administer a PCR test. Send the individual home to isolate. They should remain at home until they complete quarantine according to MDH/MSDE school guidance.

b. The antigen test algorithm flowchart described above can be found in [Appendix D](#).

F. Contact Tracing

- a. **Schools should communicate to the school community that both the school and the local health department play a role in contact tracing.** Schools should encourage cases and close contacts to cooperate with the processes laid out and to “answer the call” when a health department contact tracer calls.
- Schools should identify the **primary point of contact at the local health department** for contact tracing in schools.
 - The **local health department will have access to a number of materials and resources to assist with contact tracing in schools:**
 - Bulk upload template (Excel) for capturing contacts and instructions for completing the template and uploading the contacts into covidLINK
 - Dashboards and reports in covidLINK that allow local health departments to review and monitor school-associated cases and contacts
 - Schools and school systems are encouraged to **explore executing a data use agreement with CRISP** in order to share student (and potentially staff) rosters. With a student roster:
 - CRISP can provide daily aggregate counts of positive and negative tests for students to the school or school system.
 - With individual permission, CRISP can provide individual test results to the school or school system.
 - CRISP will send a flag to health department contact tracers indicating that the positive individual is a student and the school affiliation. This will greatly facilitate contact tracing efforts as contact tracers will know school affiliation before they call the individual to interview them.
 - If interested, contact Craig Behm, Maryland Executive Director at craig.behm@crisphealth.org.

- **Rapid POC tests and contact tracing**
 - As per the [CDC/CSTE case definition for COVID-19](#), individuals with detection of SARS-CoV-2 by rapid POC test are considered probable cases and contact traced as per [CDC guidance for contact tracing](#).
 - Positive rapid POC results are pushed to the state’s contact tracing data management system, [covidLINK](#).
 - Contact tracers call probable cases to provide guidance for isolation and to elicit close contacts (those within 6 feet of the case for at least 15 minutes).
 - Close contacts are advised to quarantine.
- **Interpretation of rapid POC tests and contact tracing**
 - **Symptomatic individuals with positive rapid POC tests**
 - Interpreted as cases, regardless of PCR results.
 - Contact tracing will be initiated, including elicitation of contacts.
 - **Asymptomatic individuals with positive rapid POC tests and positive PCR results**
 - Interpreted as cases.
 - Contact tracing will be initiated, including elicitation of contacts.
 - **Asymptomatic individuals with positive rapid POC tests and negative PCR results**
 - [Interpreted as “no current evidence of infection” or “not currently infected”](#) and should not be considered cases.
 - **Because of the timeline between rapid POC test results and PCR results being returned, the rapid POC tests will have been pushed to covidLINK and contact tracing will have been initiated, including elicitation of contacts.**
 - **Requires coordination with local health department to manually close the case and elicited contacts**
 - If the asymptomatic individual was tested because they were a close contact of a case, they will be closed as a case but they will need to finish their quarantine period as

determined by their last date of exposure to the case.

- If a letter is needed to allow an individual to return to school, the local health department will provide that.

b. For more information on Maryland's Contact Tracing efforts, please visit [covidLINK](#)

G. School Guidance Documents

Topic	School Guidance Document
Exclusion and isolation of students and staff with COVID-19 or COVID-19 symptoms	COVID-19 Guidance for Maryland Schools (Q13, 14)
	Response to a Confirmed Case of COVID-19 and Persons with COVID-19-like Illness in Schools
	Decision Aid: Exclusion and Return for Laboratory Confirmed COVID-19 Cases and Persons with COVID-19-like Illness in Schools, Child Care Programs and Youth Camps
Quarantine of close contacts of persons with COVID-19	COVID-19 Guidance for Maryland Schools (Q15, 16)
	Decision Aid: Exclusion and Return for Laboratory Confirmed COVID-19 Cases and Persons with COVID-19-like Illness in Schools, Child Care Programs and Youth Camps
Communication and notification procedures	Response to a Confirmed Case of COVID-19 and Persons with COVID-19-like Illness in Schools
Personal protective equipment (PPE) for school health services staff	School Health Services Frequently Asked Questions (Q1, Appendix A)
School Guidance for contact tracing	Response to a Confirmed Case of COVID-19 and Persons with COVID-19-like Illness in Schools

H. Key Program Contacts

a. CLIA Certification and Maryland Laboratory License, Office of Health Care Quality

- Email: paul.celli@maryland.gov

b. CRISP (The Maryland Health Information Exchange)

- Email: Tom.Fitzgerald@crisphealth.org

c. Abbott BinaxNOW™ Training & Information Contact:

- Barbara Mervin, barbara.mervin@abbott.com, (cell) 410-409-3082
- Abbott Technical Services Team at 1-800-257-9525 between 8 a.m and 8 p.m. EST Monday-Friday or email ts.scr@abbott.com.

d. Mako Medical PCR Testing Contact:

- For additional usernames, have been locked out of the portal, or need to reset your password - accounts@makomedical.com
- Other inquiries, logistics concerns, or collection questions - accounts@makomedical.com
- Mako can be reached by phone between 9 AM and 5 PM EST at 704-412-3992.

e. Maryland State Department of Education Contact:

- Contact: Gabriel Rose
- Email: Gabriel.rose1@maryland.gov

f. Maryland Department of Health Contact:

- Email: MDH.K12Testing@Maryland.gov

Appendix

A. K-12 COVID-19 Testing Information Resources

The links below will provide you with frequently asked questions to help inform others about the testing program described in this document. Please feel free to provide these to the relevant parties.

- a. [Frequently Asked Questions for Parents \(FAQs\)](#) - Provides additional information for parents about the K-12 COVID-19 Testing Program
- b. [Testing FAQ](#) - Provides general information about COVID-19 Testing
- c. [Schools Resource Guide](#) - Provides additional information for schools, including teachers and staff, regarding the K-12 COVID-19 Testing Program
- d. [Compliance Documentation to fulfill Laboratory Requirements](#) - Provides useful information about documentation schools will need to order new supplies

B. Glossary

- **Symptomatic Testing** - Testing of individuals with COVID-19 symptoms.
- **Asymptomatic Testing** - Testing of individuals who are not presenting COVID-19 symptoms.
- **PCR Test** - Polymerase chain reaction test; a molecular diagnostic test that is used to determine if you have an active COVID-19 infection by detecting the virus' genetic material. Must be sent to a lab for processing after the test is administered.
- **Rapid Antigen Test/Point-of-Care Test/Rapid POC Test** - An antigen diagnostic test that is used to determine if you have an active COVID-19 infection by detecting specific proteins from the virus. Does not require being sent to a lab for processing, and results are obtained quickly.
- **CLIA Certification** - Clinical Laboratory Improvement Amendment; certification that allows a facility, primarily laboratories, to legally examine a person through waived tests in order to assess health, diagnose, and determine treatment. Necessary to have on file in order to administer any COVID-19 test in a K-12 setting.
- **Maryland Laboratory License** - In effect, Maryland's version of the CLIA Certification. Necessary to have on file in order to administer any COVID-19 test in a K-12 setting.
- **Diagnostic testing model** - The testing protocol employed by this program, which tests symptomatic students and staff, as well as those with close contact to confirmed COVID-19 cases
- **Surveillance or Screening testing model** - Testing protocols which screen all students and staff for potential COVID-19 infection regardless of symptoms or exposure. This is not the model that MDH is using for the K-12 COVID-19 Testing Program, and is not recommended by MDH in schools guidance.
- **Close contact of a person with confirmed COVID-19** - 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. (see additional information [here](#))

C. Point of Care Result Entry Process Flow

Version: 12/3/20

Process Flow Chart for Provider entry of Rapid Point of Care (POC) Test Data into CRISP



1: Patient Tested



Provider Portal

2: Provider enters result into CRISP Portal or via bulk submission

- Requires CRISP log-in credentials
- To register for CRISP visit
https://crisphealth.force.com/crisp2_login



NEDSS

3: CRISP system sends test result to NEDSS

- Sent to NEDSS as an HL7 Message, using the same means and methods as all other lab sources submitting to NEDSS



NEDSS

CRISP
Reporting

4: NEDSS sends the records to CRISP reporting

- NEDSS sends messages to CRISP as an HL7 messages, through the same means and methods as other COVID-19 tests sent from NEDSS to CRISP



NEDSS

CRISP
Reporting

5: NEDSS sends data to the CDC

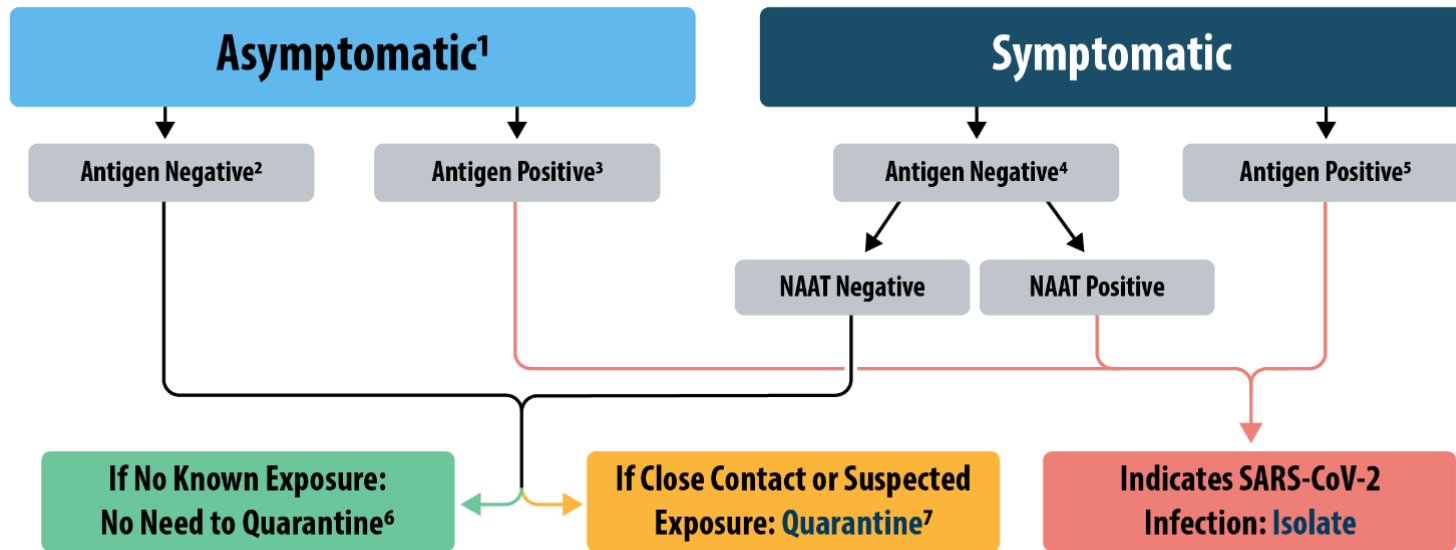
- NEDSS sends this data to the CDC, using same business rules that apply to COVID-19 data, regardless of source



6: Other business processes

- Rapid point of care tests flow into other business process(es) in the same way as a result submitted by a lab
- Note: Since there are different types of rapid point of care tests (e.g., PCR, antigen, etc.) different business rules may be applied – those rules will apply regardless of whether the data are entered in CRISP, or through some other means / method

D. Antigen Test Algorithm



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