

December 10, 2020

Ulster County Department of Health (UCDOH) COVID-19 Testing Guidance and Plan for County Combined School Districts

Table of Contents

Overview		Page 1
NYS Guidance on Testing		Page 1
Yellow, Orange, and Red Zone Testing of Schools		Page 1
Zone Approach to Testing		Page 1
Scope of Testing		Page 1
Testing Material		Page 1
Testing Options		Page 2
Data and Reporting		Page 2
Failure to Meet these Requirements by Schools in Geographic Areas Designated as a Zone		Page 3
Plan for Testing Ulster County District Schools, Faculty, and Staff		Page 3
Scope of Plan		Page 3
Plan Execution		Page 3
Authority to Conduct Testing		Page 3
Memorandum of Agreement		Page 4
Responsibilities of UCDOH and School Districts		Page 4
Test Site Obligations		Page 4
Training of Testers		Page 5
Training, Execution, Scheduling, and Administration		Page 5
Prior to Using BinaxNOW Tests		Page 6
Ongoing BinaxNOW Testing Program Requirements		Page 6
BinaxNOW Test and Materials		Page 6
Material Provided per Kit: Test cards		Page 6
Material Required, but not Provided per Kit		Page 6
Material Optional, but not Provided per Kit		Page 6
Other Equipment Requirements		Page 7
Obtaining Testing Materials		Page 7
Storage Requirements		Page 7
Quality Control		Page 7
Procedural Controls		Page 7
External Positive and Negative Controls		Page 8
Specimen Collection and Handling		Page 8
Equipment Operation, Storage, and Handling		Page 8

Overview

NYS Guidance on Testing

State guidance on testing is dynamic. It waxes and wanes depending on perception of how best to mitigate the evolving COVID-19 threat. The last guidance promulgated to the Schools is identified as Yellow, Orange, and Red Zone testing. It is not certain that New York State will require the Districts to execute this guidance in the near term, but at a minimum the Ulster County Department of Health (UCDOH) believes that a testing methodology based on zone designation where each zone has a set of criteria specific to the zone will be initiated, so we should plan for such.

Yellow, Orange and Red Zone Testing of District Schools

The specifics of current guidance from the State can be found here:

[Schools Designated in Yellow Zones](#)

[Schools Designated in Orange or Red Zones](#)

Zone Approach to Testing

The zone approach for testing requires that, on receipt of an order from the State indicating the local area is identified in a specific zone, the Districts will have to test a certain percentage of their students, faculty, and staff on a weekly or bi-weekly basis and convey the results of those test to the local Health Department and the State.

Scope of Testing

Testing requirement applies to those that attend in-person classes. Students who are participating in hybrid learning or in all-virtual learning and who are attending an OCFS-licensed/registered or enrolled legally-exempt group child program located within a School during School hours are also subject to testing requirements and must be included in the School's random testing protocols. Additionally, the testing requirement applies to Pre-K classes that take place on a School site. Members of the School community who test positive for COVID-19 must isolate, according to established DOH guidance. Further, Schools must notify health authorities immediately upon being informed of any positive test results by an individual within School facilities or on School grounds, including students, faculty, staff, and contracted employees, pursuant to DOH guidance. Partnerships between Schools and local Health Departments are critical to effective implementation of COVID-19 protocols in this educational setting. Specifically, Schools must support all contact tracing efforts from health authorities, and such tracing must be promptly performed to ensure that contacts to newly identified positive individuals are quarantined, according to established DOH guidance.

Testing Material

New York State is providing Schools, through local Health Departments, with Rapid Test Kits upon request. Schools must provide trained personnel, with necessary laboratory permits, to conduct the Tests. Questions on amending or obtaining a Limited Service Laboratory (LSL) registration and requests for test kits should be sent to covid19rapidtest@health.ny.gov.

The Federal Government has prioritized public and private K-12 Districts/Schools to receive Abbott's BinaxNOW rapid antigen test kits to test accomplish the goal established by the NYS Zone requirements. Ulster County Department of Health (UCDOH) strongly believes that these rapid antigen tests will be instrumental in both opening Schools and keeping Schools open so onsite education can safely be delivered to as many students as possible. The Centers for Disease Control and Prevention (CDC) provides [additional information on antigen testing here](#).

The Abbott BinaxNOW test is a minimally invasive anterior nasal swab test. The test must be administered by a trained health professional (e.g. registered nurse or doctor) and yields results in just 15 minutes without any additional equipment. The BinaxNOW Covid-19 test is a lateral flow test that detects the presence of protein antigens for SARS-CoV-2 in direct nasal swabs in individuals within the first seven days of symptom onset.

Testing Options

To ensure that students, faculty, and staff have been tested for COVID-19, Schools have the following options:

- Schools can accept written test results from healthcare providers;
- Schools can have students, faculty, and/or staff go to a test site run by New York State, Ulster County, or a partner facility to have specimens collected for testing;
- Schools can establish partnerships with other entities who are authorized to perform testing to have their students, faculty, and staff tested;
- Schools that currently have a limited service laboratory (LSL) registration can add COVID-19 antigen testing to their existing LSL registration, request to receive rapid tests from the state, and perform testing on their students, faculty, and staff; or
- Schools can become approved to perform testing by obtaining an LSL registration and once approval is granted, request to receive rapid tests from the state and perform testing on their students, faculty, and staff. For Schools that do not have an LSL, Local Health Departments (LHDs) are required to allow Schools to operate under their LSL for the purposes of conducting weekly testing. If the LHD does not have an operational LSL or is unable to support the School in conducting testing, the LHD must work with the School to identify community partners with an LSL. See Guidance.
- Schools can utilize pooled testing. However, pooled testing must be conducted by a laboratory that is approved to conduct diagnostic pooled testing so that individuals receive their test results and they can be reported to the state.

Data and Reporting

Governor's Executive Order states, "Every licensed professional authorized by the Department of Health Physician Office Laboratory Evaluation Program to administer a test for COVID-19 or influenza, whether alone or in conjunction with any other test, shall report such results immediately (not more than 3 hours) to the NYS Department of Health through the Electronic Clinical Laboratory Reporting System (ECLRS) when a result is received."

Providers can contact eclrs@health.ny.gov or the ECLRS Help Desk at (866) 325-7743 for more information or to set up ECLRS.

Schools will also report results through the School Dashboard survey.

Failure to Meet these Requirements by Schools in Geographic Areas Designated as a Zone

Schools that do not meet the reopening requirements established in the current set forth in [current state guidance](#) must remain in remote/distanced learning until such time as the requirements are met. Reopened Schools that fail to comply with these requirements may be subject to Public Health Law Section 16 orders, or other fines and penalties.

Notwithstanding a School's compliance with the testing requirements, New York State and UCDOH reserve the right to keep any School closed if there is determined to be a threat to public health or extenuating circumstances exist.

Questions about this guidance should be sent to covid19rapidtest@health.ny.gov.

Other resources:

- [New York State Department of Health \(DOH\) COVID-19 Website](#)
- [Centers for Disease Control and Prevention \(CDC\) COVID-19 Website](#)

Plan for Testing Ulster County District Schools Students, Faculty, and Staff

Scope of Plan

The intent of this document is to provide the combined Districts with a plan to conduct screening of at least 20% of each School's students, staff, and faculty on a bi-weekly basis. This plan will identify the testing material and process, training to administer the test by School medical professionals, how to obtain training and testing material, how to set up and conduct training in the School environment, and how to document and convey the results of the testing to local and state Departments of Health.

Plan Execution

Schools should carry out these strategies in a way that protects privacy and confidentiality, consistent with applicable laws and regulations. In addition to state and local laws, regulations, and guidance, School administrators should follow guidance from the Equal Employment Opportunity Commission when offering COVID-19 testing to School personnel. Schools also should follow guidance from the U.S. Department of Education on the Family Educational Rights and Privacy Act (FERPA) and its applicability to students and COVID-19 contact tracing and testing.

Authority to Conduct Testing

The District will conduct testing under the UCDOH CLIA registration/ Health Commissioner's license and will be required to follow the guidelines that direct UCDOH operations. Under NYS Scope of Practice rules, an RN works under the direction of an MD. Therefore, each School District must provide RN staff to perform this POC testing. Once the Memorandum of Agreement (MOU) has been signed and the RN staff doing the testing have been trained, the District will be given the test kits which the NYSDOH has provided to us. A School District may opt to work with another medical provider and do the testing under that provider's Clinical Laboratory Improvement Amendment (CLIA) registration. That is the District's option. Regardless, all test results must be reported to UCDOH and the NYSDOH.

Memorandum of Understanding

Ulster County, in coordination with the Combined School Districts, has generated a Memorandum of Understanding (MOU) to guide the execution of the testing plan. The MOU will be disseminated to the Schools as soon as it is available and will also be viewable as a link from this document.

Responsibilities of the UCDOH and School Districts

- Ulster County Department of Health Responsibilities
 - UCDOH will provide each District with enough testing material to test all faculty, students, and staff for each School in the Ulster County Combined School Districts. They will also train and certify District Nurses in the use of the BinaxNOW test kits. Those trained will administer the tests at their Schools. The tests will be administered under the UCDOH Clinical Laboratory Improvement Amendment of 1988 (CLIA).
 - UCDOH agrees to provide training to Registered Nurses employees by the District and, upon completion of the training, allow those nurses who are listed in the [Certification of Training](#) to conduct tests using the Rapid Test Kits provided for the purpose of fulfilling this Agreement.
 - UCDOH will distribute Rapid Test Kits and all necessary information regarding testing protocol and procedures as set forth below.
- District Responsibilities
 - The District agrees to accept Rapid Test Kits to operate with assay kits replenished at a rate limited by the amount the UCDOH is able to acquire from NYSDOH.
 - The District shall conduct tests according to the protocol and procedures as set forth below.
 - The District shall record each rapid test on the Rapid Test Kit Patient Record and Internal Control Tracking Form.
 - The District shall report positive results generated using the Rapid Test Kits to the NYSDOH within 3 hours.
 - The District shall direct every person who receives a positive result to contact his or her Primary Care Provider and follow all isolation and quarantine protocols required by NYSDOH and UCDOH guidelines as promulgated on the date of the positive result.
 - The District shall enter each test result (positive and negative) into the New York State Department of Health Electronic Clinical Laboratory Reporting System (ECLRS).

Test Site Obligations

Public and private K-12 Districts/Schools that wish to receive BinaxNOW tests to administer at School must first complete [the online application](#). The application requests the following information:

- Student enrollment and number of staff members
- Number of tests desired, if less than the maximum allocation
- Primary point of contact
- Testing locations, including building names and addresses
- Health care professionals who will administer the tests and their professional license numbers
- Shipping address for receiving the test kits

- PPE needs
- Affirmation that the District/School meets the requirements for receiving the BinaxNOW test kits

Training of Testers

Testing will be administered by School medical professionals after they have received competency training and certification by the UCDOH. The training is open to all District Registered Nurses. It is the decision of the District as to whether all of their RN staff is trained or whether they would prefer to adopt a Train-the-Trainer approach.

The training will consist of several webinars produced by the Abbott company followed by hands-on testing training conducted by Ulster County Nurses. The training will include a review for the donning and doffing of Personal Protection Equipment (PPE) and will be scheduled once the UCDOH receives a list of medical professionals available for training in each District. Training will be conducted at the BOCES Facility in New Paltz in the first floor conference room. The application for training to administer the Abbott BinaxNOW COVID-19 Ag Card can be obtained [here](#). The form is fillable, so please complete and submit your application for training on line or, if that capability is not present, via email to **Melissa Winfield**: mril@co.ulster.ny.us. UCDOH will notify applicants and District administration when the application is approved. **For questions about the online application process, please email Melissa at the email provided above.**

Training Execution, Scheduling and Administration

Training commences Tuesday December 15, 2020 at BOCES mentioned above. Each nurse that has completed the online sign up form will be provided a date and time to receive the training. Please arrive as scheduled. UCDOH will provide six trained RNs to administer the training. They will set up in the BOCES Conference room to provide online and hands-on instruction. Upon arrival please enter the conference room at your assigned time and identify yourself to the test administrator. If you have already watched the training videos identified in the following link:

<https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html> you will be required to sign a form to attest to that fact. If you have not watched the videos you will be required to watch them in the conference room before receiving the practical training. We recommend that you try to view the videos in advance to speed up the training process. Assuming that applicants have not viewed the 4 training videos in advance of arrival, the entire training session will last an hour. Watching the videos in advance will shave 30 minutes off the time required to receive the instruction. Following the videos, the applicant will receive hands-on instruction on how to administer the test and document the results. UCDOH will be able to provide training to 3 or 4 District nurses at one time. Accordingly, scheduling will be done on hourly intervals from 8 am to 5 PM with 30 minute lunch break. The training effort should allow 32 District nurses to be trained daily.

If your District/School does not have a RN to administer the BinaxNOW test onsite, please contact Dan Proctor, Director of COVID-19 Operations for the UCDOH: dpro@co.ulster.ny.us. Please note that LPNs can administer the test, but only after the MOU has been signed and under the supervision of an RN. Districts/Schools may choose to work with an outside entity, such as a local medical clinic, to administer the BinaxNOW tests for their staff and students, as long as these entities meet requirements (i.e., training, CLIA waiver, reporting, etc.) set forth for BinaxNOW testing.

To participate in testing, Schools must agree to meet the following conditions:

Prior to Using BinaxNOW Tests:

- The District/School have appropriate medical personnel available to administer the tests.
- Testing personnel will complete the required training and training documentation as outlined in this guidance document prior to administering any BinaxNOW tests.
- The District/School is able to receive the tests in one central location and potentially store the maximum number of tests requested.
- The District/School will complete the electronic reporting on-boarding process.
- The District/School will agree to use the tests only for screening of individuals (students or School personnel).
- The District/School has a process in-place for disposal of infectious waste created through the testing process.

Ongoing BinaxNOW Testing Program Requirements:

Testing personnel will adhere to the written Instructions for Use (IFU) provided by the manufacturer in the test package insert.

- The District/School will ensure UCDOH has up-to-date information on test administrators and testing locations.
- The District/School will abide by the infectious waste disposal criteria.
- The District/School will have all individuals being tested, or their parent/guardian, [sign an authorization for testing](#).
- Test sites must submit all required data elements to NYSDOH within 3 hours.
- Test sites must retain documentation related to this testing program for a minimum of two years.

BinaxNOW Test and Material

The BinaxNOW COVID19 Ag Card test has demonstrated a 97.1 sensitivity rate and a 98.5% specificity rate, according to recent clinical studies.

Material Provided Per Kit: Test Cards

- Test Cards (40): A cardboard, book-shaped, hinged test card containing the test strip
- Extraction Reagent (1): Bottle containing 10mL of extraction reagent
- Nasal swabs (40): Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card Test
- Positive Control Swab (1): Non-infectious recombinant SARS-CoV –2 nucleocapsid antigen dried onto a swab
- Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained
- Product Insert (1)
- Procedure Card (1)

Material Required but not Provided per Kit:

- Clock, timer, or stopwatch

Material Optional but not Provided Per Kit:

- Swab Transport Tube Accessory Pack
- BinaxNOW™ COVID-19 Ag Card Control Kit (10 positive swabs)

Other Equipment Required

Each District must procure the equipment and supplies they feel is needed to accomplish each testing. Recommendations for setting up and administering the test will be provided during the hands-on training provided by the UCDOH.

Obtaining Testing Material

UCDOH received the BinaxNow tests and will allocate the tests to the Districts once each District identifies a single point of contact for receipt. Please convey the contact information for your point of contact to Ms. Melissa Winfield at mril@co.ulster.ny.us. The tests will be allocated based on the number of personnel in each District [as identified here](#) . If these numbers are incorrect please inform Melissa ASAP.

Delivery of testing material will be accomplished during the training session. The School representative that participates in the training will be provided enough testing material to test their School personnel.

District Schools will have to develop forms specific to School needs. Recommendations for the development of those forms can be found [here](#).

Storage Requirements

Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

Part Number	195000
DESCRIPTION	BINAX COVID-19 ANTIGEN CARD KIT
# Tests per Kit	40
#Kits per Shipper	16
Kit Box Dimension US	10 x 7.52 x 5 inches
Weight per Kit	1.87 lbs.
Temperature Requirements	Ambient (2-30° C)

Quality Control

Abbott BinaxNOW COVID-19 Ag Card has built-in procedural controls. Abbott recommends external positive and negative controls be run:

- Once with each new shipment received
- Once for each untrained operator
- When required by the LSL Quality Control procedures

Procedural Controls:

A. The pink-to-purple line at the “Control” position is an internal procedural control. If the test flows and the reagents work, this line will always appear.

B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. Abbott BinaxNOW COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator.

Record quality control runs on the Abbott BinaxNOW COVID-19 Ag Card External Quality Control Log (Attachment 3)

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Abbott Technical Support (during normal business hours) and DBCH 8 before testing patient specimens.

Specimen Collection and Handling

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/ transport may yield erroneous results. Refer to the [CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 \(COVID-19\)](#)

Nasal Swab -only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinate's (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril. Refer to the COLLECTION OF NASAL SWAB FOR THE ID NOWTM COVID-19 ASSAY tip sheet.

Abbott BinaxNOW COVID-19 Ag Card is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.

Do not return the nasal swab to the original paper packaging. For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

Equipment Operation, Storage, and Handling

Follow the Abbott BinaxNOW COVID-19 Ag Card Product Insert or Manual for all Quality Control test and specimen test procedures. Conduct all required performance checks.

The District will record temperature of storage area once daily on Abbott Temperature Log form found [here](#).

Any questions please contact Dan Proctor, UCDOH Director of COVID-19 Operations. Email: dpro@co.ulster.ny.us; Phone: 845.340.8065 or cell: 917.796.5390